XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
NELI N. PALMA, State Bar No. 203374
KARLI EISENBERG, State Bar No. 281923
STEPHANIE T. YU, State Bar No. 294405
1300 I Street, Suite 125, P.O. Box 944255
Sacramento, CA 94244-2550
Tel: (916) 210-7522; Fax: (916) 322-8288
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

JAMES R. WILLIAMS, State Bar No. 271253
County Counsel
GRETA S. HANSEN, State Bar No. 251471
LAURA S. TRICE, State Bar No. 284837
MARY E. HANNA-WEIR, State Bar No. 320011
SUSAN P. GREENBERG, State Bar No. 318055
H. LUKE EDWARDS, State Bar No. 313756
Office of the County Counsel, Co. of Santa Clara
70 West Hedding Street, East Wing, 9th Fl.
San José, CA 95110-1770
Tel: (408) 299-5900; Fax: (408) 292-7240
Email: mary.hanna-weir@cco.sccgov.org
Attorneys for Plaintiffs County of Santa Clara

DENNIS J. HERRERA, State Bar No. 139669
City Attorney
JESSE C. SMITH, State Bar No. 122517
Chief Assistant City Attorney
RONALD P. FLYNN, State Bar No. 184186
Chief Deputy City Attorney
YVONNE R. MERÉ, State Bar No. 173594
SARA J. EISENBERG, State Bar No. 269303
JAIME M. HULING DELAYE, State Bar No. 270784
Deputy City Attorneys
City Hall, Rm 234, 1 Dr. Carlton B. Goodlett Pl.
San Francisco, CA 94102-4602
Tel: (415) 554-4633, Fax: (415) 554-4715
E-Mail: Sara.Eisenberg@sfcityatty.org
Attorneys for Plaintiff City and County of San Francisco

LEE H. RUBIN, State Bar No. 141331
Mayer Brown LLP
3000 El Camino Real, Suite 300,
Palo Alto, CA 94306-2112
Tel: (650) 331-2000, Fax: (650) 331-2060
Email: lrubin@mayerbrown.com
Attorneys for Plaintiffs County of Santa Clara, et al.

**Additional Counsel Listed on Signature Pages*

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO,
Plaintiff,
vs.
ALEX M. AZAR II, et al.,
Defendants.

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA,
Plaintiff,
vs.
ALEX M. AZAR, et al.,
Defendants.

COUNTY OF SANTA CLARA, et al.
Plaintiffs,
vs.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,
Defendants.

No. C 19-02405 WHA
No. C 19-02769 WHA
No. C 19-02916 WHA

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT, WITH MEMORANDUM OF POINTS AND AUTHORITIES; AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

Date: October 30, 2019
Time: 8:00 AM
Courtroom: 12
Judge: Hon. William H. Alsup
Action Filed: 5/2/2019

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NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that on October 30, 2019 at 8:00 a.m. in Courtroom 12 located at 450 Golden Gate Avenue, San Francisco, CA, 94102, Plaintiffs in above-referenced cases will and hereby do move this Court for summary judgment on each of the causes of action set forth in their complaints because the final rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 84 Fed. Reg. 23,170 (May 21, 2019), violates the Administrative Procedure Act and the United States Constitution. Alternatively, Plaintiffs request the Court enter judgment as to those claims the Court sees as fit for resolution at this time.

MEMORANDUM OF POINTS AND AUTHORITIES

INTRODUCTION

Plaintiffs—the State of California (State), the City and County of San Francisco (City), the County of Santa Clara (County), and providers and medical associations hailing from all over the country—share a common commitment to ensuring patient access to high-quality comprehensive healthcare. Congress, similarly, has enacted increasingly stronger federal laws to protect patients' access to care, ensure the free flow of accurate information, and prohibit discrimination in the provision of healthcare services. In this landscape also exist decades-old, context-specific statutes and appropriations policy riders that govern conscience objections in healthcare. Under the guise of an "anti-discrimination" framework, the Rule now seeks to completely upend the existing regime by vastly expanding the scope of these federal conscience statutes and riders, allowing virtually anyone involved in the provision of healthcare to refuse to provide vital services and information to patients, including women and lesbian, gay, bisexual, and transgender (LGBT) individuals. The Rule does not require any justification, notice, or referral be given to the patient who is denied care or to an employer who must navigate how to accommodate these refusals. There are no exceptions for emergencies. Far from preventing discrimination, the Rule perpetuates widespread discrimination against populations that have historically faced obstacles to obtaining care—interfering with Plaintiffs' missions to offer quality care to patients, to protect the public health and welfare, and to ensure continued access for vulnerable populations.

The Rule exemplifies arbitrary and capricious rulemaking. It conflicts with federal laws that

already prohibit discrimination in healthcare and protect access to care and information, far exceeding the scope of the statutes on which it is purportedly based. The Rule is unconstitutional because it favors religion over non-religion and certain religious beliefs over others; jeopardizes access to reproductive and transition-related healthcare; fosters unlawful discrimination; chills protected expression; and exceeds Congress's Spending Clause authority, threatening billions of dollars in federal funding to the State, local governments, and providers across the country.

STATEMENT OF FACTS

I. THE ASSERTED STATUTORY BASES FOR THE RULE

The Rule purports to implement certain federal statutes concerning refusals to provide healthcare services due to religious or moral objections, including the Church Amendments (42 U.S.C. § 300a-7) (Church), the Weldon Amendment (*see, e.g.*, 132 Stat. 2981, 3118 (2018)) (Weldon), and the Coats-Snowe Amendment (42 U.S.C. § 238n) (Coats-Snowe). *See* 84 Fed. Reg. at 23,170-23,173 (statutory history), and Mot. 3, n.2 (collecting statutes).

Church prohibits government entities from requiring certain funding recipients to "perform or assist in the performance of any sterilization procedure or abortion . . . contrary to [an individual's] religious beliefs or moral convictions" or to make their facilities or personnel available for the objected-to procedures. 42 U.S.C. §§ 300a-7(b)(1), 300a-7(b)(2). It also bars discrimination in employment or extension of staff privileges against "any physician or other health care personnel" on the basis of beliefs about, or willingness to participate in, abortion or sterilization. *Id.* at § 300a-7(c)(1). Finally, it provides that individuals cannot be required to "perform or assist in the performance of any part of a health service program or research activity" funded under a program administered by HHS if the activity would be contrary to religious beliefs or moral convictions. *Id.* § 300a7(d).

Weldon states that no funds in the Labor, Health and Human Services, Education, and Related Agencies Appropriations Act ("Appropriations Act") may be given to governmental entities that discriminate against an "institutional or individual health care entity" because it does not provide, cover, or refer for abortions. *See, e.g.*, 132 Stat. 2981, 3118 (2018).

Coats-Snowe prohibits governments receiving funding from discriminating against any

"health care entity"—narrowly defined as physicians and health profession trainees—that refuses to undergo training to perform abortions, provide referrals for abortions or abortion training, or make arrangements for those activities. 42 U.S.C. § 238n(a).

II. REGULATORY BACKGROUND

In December 2008, HHS issued a rule purportedly authorized by Church and Weldon, allowing it to terminate and/or compel return of certain federal funds from state and local governments that "discriminat[e] on the basis that [a] health entity does not provide, pay for, provide coverage of, or refer for abortion[,]" and requiring recipients of HHS funds to certify compliance with the rule. 73 Fed. Reg. 78,072, 78,074, 78,098-99 (Dec. 19, 2008). In response to comments expressing concerns that the rule would invite discrimination—including against patients with disabilities, patients with HIV, and on the basis of race or sexual preference—Defendants confirmed that discrimination is "outside the scope" of federal conscience laws: "[G]iven the strong national policies embodied in federal civil rights laws that protect individuals from unlawful discrimination . . . and that ensure that federally supported programs are available to all without discrimination, we believe that federal civil rights protections prevail." *Id*. at 78080. The 2008 rule, with the exception of its certification requirement, went into effect in 2009. 76 Fed. Reg. 9968, 9971 (Feb. 23, 2011).

In March 2009, HHS proposed to rescind the 2008 rule, noting that a new round of rulemaking was underway. 74 Fed. Reg. 10,207 (Mar. 10, 2009). Then in 2011, it amended the 2008 rule by removing definitions and prohibitions, among other changes. *See* 73 Fed. Reg. 78,072; 76 Fed. Reg. 9968. It also confirmed that Church, Weldon, and Coats-Snowe do not require "promulgation of regulations for their interpretation or implementation." 76 Fed. Reg. at 9975. The 2011 Rule was not issued pursuant to these Amendments, but rather under 5 U.S.C. § 301, which authorizes the head of an Executive department to issue regulations related to departmental housekeeping. *See* 76 Fed. Reg. at 9975. The 2011 rule designated HHS's Office for Civil Rights (OCR) to receive and coordinate handling of complaints with HHS funding components pursuant to this housekeeping authority. *Id*. at 9977.

Between 2008 and January 2018, OCR received only 44 complaints related to moral- and

religious-based objections. 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018). Yet in January 2018, HHS created a new Conscience and Religious Freedom Division within OCR and issued a Notice of Proposed Rulemaking (NPRM) to vastly expand the reach and scope of two dozen narrowly-drawn federal conscience laws. *Id*. The NPRM proposed to create a new regime broadening prerogatives of religious objectors at the expense of providers, physicians, and patients. It did this by defining (or redefining) key statutory terms more broadly than Congress intended and applying them across-the-board, rather than in the limited contexts Congress had specified.

For example, the NPRM proposed that not only medical providers, but also anyone with an "articulable connection" to provision of a service (including a referral), may opt out of providing certain healthcare services or information on the basis of "conscience, religious beliefs, or moral convictions." 83 Fed. Reg. at 3881, 3923. Services encompassed include abortion, sterilization, euthanasia, certain vaccinations with a connection to use of "aborted fetal tissue," contraception, gender transition/gender dysphoria, tubal ligations, hysterectomies, assisted suicide, and "other health services." *Id*. at 3903. HHS proposed to grant OCR enforcement responsibility, conferring authority to receive complaints, initiate compliance reviews, conduct investigations, supervise and coordinate compliance, and use broad enforcement tools including temporarily or permanently withholding current or future funding. *Id*. at 3931.

HHS received over 242,000 comments on the NPRM. 84 Fed. Reg. at 23,180, n.41. Comments in opposition came from a broad array of individuals, medical associations, public health experts, state and local governments, providers, and patient groups.[1] Despite the volume of comments, HHS issued a largely identical final rule (Rule) in May 2019.

III. THE RULE'S IMMEDIATE AND DETRIMENTAL EFFECT ON PLAINTIFFS

A. Devastation of California's Public Health Programs and Laws

The Rule explicitly targets the State and its laws balancing conscience protections and patient rights, *see* Cal. Compl. ¶¶ 16-40, setting the State up to lose billions of dollars in federal funding should it go into effect. The Rule states that it seeks to resolve "confusion" caused by

[1] *See, e.g.*, Cal. Att'y Gen. Ltr. 2-6, App'x 38; Cty. of Santa Clara Ltr. 4-8, App'x 63; S.F. Dep't of Pub. Health Ltr. 1-3, App'x 162; App'x 402; *see also infra* Section III.B.

OCR's 2016 closing of three Weldon complaints against California, in the State's favor. 84 Fed. Reg. at 23,178-79.[2] HHS previously determined that closing the complaints avoided a "potentially unconstitutional" application of Weldon, given that a violation of Weldon could result in the rescission of all funds appropriated under the Appropriations Act to the State, including funds provided by the Departments of Education and Labor and other agencies. *Id*. (citing *NFIB v. Sebelius*, 567 U.S. 519 (2012)). But the Rule states that HHS no longer agrees with OCR's 2016 interpretation, 84 Fed. Reg. at 23,179, and that despite the previously cited constitutional concerns, HHS remained obligated to not make funding available to entities that, in the agency's view, discriminate in violation of Weldon. 83 Fed. Reg. at 3890.

The Rule also makes clear that an OCR determination of noncompliance will be used to inform HHS's decision whether to approve, renew, or modify federal funding to the recipient and specifically notes that OCR has more recently found the State in noncompliance. 84 Fed. Reg. at 23,177, 23,262.[3] It thus sets the stage for an unavoidable conflict with the State.

The State receives tens of billions of dollars in appropriated and mandatory federal funds for labor, education, and health and human services. These funds support programs run by state agencies and some funds are passed on to local governments and other sub-grantees.[4]

The California Health & Human Services Agency (CHHS), which provides critical services to Californians from all walks of life, expects to receive $77.6 billion in federal funding (almost half of its budget) for fiscal year 2019-2020. Ghaly Dec. ¶¶ 2, 5, 8. Funding at risk includes:

- $63 billion to provide healthcare services for *one-third of Californians* through

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[2] The complaints alleged that the State agency responsible for regulating health plans contacted seven health plans in 2014 to remind them of their obligation to comply with state law, including not discriminating against women who seek to exercise their right to obtain an abortion. App'x 396. The state agency explained that the Knox-Keene Act requires the provision of basic healthcare services and the California Constitution prohibits health plans from discriminating against women who choose to terminate a pregnancy. App'x 398; *see also Missionary Guadalupanas of the Holy Spirit, Inc., v. Rouilllard*, 38 Cal. App. 5th 421 (2019).

[3] In August 2018, OCR informed the State that it had reviewed a September 2017 complaint based on the previously closed complaints and was reopening the investigation alleging violations of Weldon, Coats-Snowe, and Church. Palma Dec. Ex. B. And in January 2019, OCR sent a letter to the State regarding the State's Reproductive FACT Act, concluding that the State had violated Weldon and Coats-Snowe. 84 Fed. Reg. at 23,177; App'x 397.

[4] Ghaly Dec. ¶ 8, Sturges Dec. ¶ 7; Nunes Dec. ¶ 12; Cantwell Dec. ¶ 7.

programs such as Medicaid and the Children's Health Insurance Program. Cantwell Dec. ¶¶ 2, 5, 8; *see also* Ghaly Dec ¶¶ 13-14;

- $1.5 billion for emergency preparedness, chronic and infectious disease prevention, environmental health programs, healthcare facility licensing programs, and other public health programs. Nunes Dec. ¶¶ 5, 9-12, 16; *see also* Ghaly Dec. ¶¶ 17-20;
- $10.8 billion for child welfare and refugee assistance programs and in-home care for seniors and people with disabilities. Ghaly Dec. ¶ 15; Cervinka Dec. ¶¶ 7-16;
- $4.2 million for mental health services. Price Dec. ¶¶ 4-5, 14-15; and
- $89 million to support healthcare for correctional inmates. Toche Dec. ¶¶ 3, 12.

The Rule also places at risk U.S. Department of Labor funding supporting unemployment insurance, apprenticeships, occupational safety, and labor standards (Sturges Dec. ¶¶ 5-9); roughly $8.3 billion in educational funding for state and local programs, including to support instruction for homeless children, special education, vocational education, and childcare and state preschool programs (Palma Dec. Ex. A, 2019-20 Cal. Dep't. Educ. budget, at 11-12) (sum of 2019-20 program expenditures from "Federal Trust Fund"); and hundreds of millions of dollars for public colleges and universities, including the nation's largest system of higher education, and for research (Harris-Caldwell Dec. ¶ 3; Parmelee Dec. ¶¶ 4-9; Buchman Dec. ¶ 11).

B. The Rule's Impact on the City and County of San Francisco

The Rule will cause immediate injury to the City, which must either comply with the Rule in full or risk losing all HHS funds. Either option would cripple the ability of the San Francisco Department of Public Health (SFDPH) to operate as the City's safety-net healthcare provider.

The City has established policies and procedures that protect personnel's religious beliefs while safeguarding SFDPH's obligation to provide high-quality inclusive care to all patients. For example, Zuckerberg San Francisco General (ZSFG) policies allow staff to opt out of providing patient care in conflict with their religious beliefs, but make clear that "the patient's right to receive the necessary patient care will take precedence over the staff member's individual beliefs and rights until other competent personnel can be provided." Chen Dec. Ex. A; *see also* Weigelt Dec. ¶ 4 (discussing conscientious objector provision in City contract with nurses). Because such policies violate the Rule, the City will be required to amend them or forgo HHS funding if the Rule goes into effect. The City would also be required to alter its policies and practices to prohibit involuntary transfers of individuals who have a religious or moral objection to performing critical aspects of their job. This restriction will impede the ability of hospitals and clinics to function

efficiently, adversely affecting individual and public health. *See* Colfax Dec. ¶ 22; Drey Dec. ¶¶ 11-13.

Compliance with the Rule would severely compromise patient care at SFDPH facilities in several other ways as well. Patients in the emergency room at ZSFG will die if nurses can categorically refuse to provide care. Colwell Dec. ¶¶ 6-11. This is neither hyperbole nor hypothetical. Every day, patients present in the ZSFG emergency room with life-threatening conditions. Colwell Dec. ¶ 7. Many times every month, those conditions involve serious complications relating to pregnancy or a sexually transmitted disease or infection. *Id.* For example, a young woman recently presented at the ZSFG emergency room who had bled substantially into her abdomen due to an ectopic pregnancy. *Id.* at ¶ 8. Her condition was critical. *Id.* If any member of the team responsible for her care had opted out of her treatment, the woman would have died before other competent personnel could have been substituted in. *Id.*

Moreover, women seeking abortions will be delayed or denied time-sensitive treatment, increasing medical risks and costs with each passing day. Drey Dec. ¶¶ 9-11. Some transgender people will be deterred from accessing safe transition-related care, and will resort to dangerous self-medication like black market hormones or industrial grade silicone injections, which can have serious—even fatal—effects. *See* Pardo Dec. ¶ 12; Zevin Dec. ¶¶ 6-7. LGBT people and other vulnerable populations will delay or avoid seeking care for fear of discrimination. Colfax Dec. ¶ 22; Pardo Dec. ¶¶ 9-13. These delays will lead to worse individual and public health outcomes, and increased costs to the healthcare system. Colfax Dec. ¶ 22.

But the alternative to compliance—potential loss of all HHS funds—would be devastating. In fiscal year 2017-2018, the City expended approximately $1 billion in HHS funds, representing approximately 10% of the City's total operating budget and one-third of SFDPH's budget. *See* Rosenfield Dec. ¶¶ 4-8; Wagner Dec. ¶ 4. Loss of these funds would be catastrophic, and would compromise SFDPH's mission to protect and promote health and well-being.[5] Beyond SFDPH funds, $58 million in TANF funds, nearly $35 million in Title IV-E Foster Care funds, $10

[5] Colfax Dec. ¶¶ 4, 23; Wagner Dec. ¶¶ 3-5; Colwell Dec. ¶¶ 11-14; Nestor Dec. ¶¶ 9-16; Siador Dec. ¶¶ 3-8.

million in adoption assistance funds, and $8 million in child support enforcement funds also hang in the balance. Rosenfield Dec. ¶ 5. To fully absorb the loss of all HHS funds for even a single year, the City would have to deplete its reserves, suspend capital projects needed to maintain the City's aging infrastructure, and make drastic service cuts in order to maintain a balanced budget, as it is legally required to do. *Id.* All of these actions would result in significant job losses and the abandonment of key safety net services. *Id.* at ¶ 10.

C. Impact on the County of Santa Clara, Providers, and Patients

Plaintiffs in *County of Santa Clara* include the County; private healthcare facilities that provide reproductive-health services and healthcare services for LGBT people; three national associations of medical professionals; organizations that provide services to the LGBT community; and individual physicians and counselors. If the Rule goes into effect, plaintiff healthcare providers will have to forgo federal funding entirely, or immediately reevaluate and rewrite existing religious-objection, staffing, and emergency policies. Either of these sharp changes in course will seriously impair their operations and missions, causing a cascading series of harms for Plaintiffs, their patients, and public health.[6]

The County operates three public hospitals, numerous satellite clinics and pharmacies, a regional public health department covering 15 cities, a behavioral health department, and a public maintenance organization (HMO).[7] It is the only public safety-net health care provider in the County and the second largest such provider in the State, as well as the sole local accreditor of emergency responders. Lorenz Dec. ¶ 5; Miller Dec. ¶ 3. Its hospitals, pharmacies, clinics, and public health department rely on roughly a billion dollars in federal funding for their continued existence and operation. Lorenz Dec. ¶ 22. The Rule puts the County to an impossible choice: forgo that critical federal funding, or implement policies that allow its staff to turn patients away, refuse to help during an emergency, or otherwise stigmatize and harm patients, thereby compromising the County's ability to provide care to the public.

[6] *See, e.g.*, Lorenz Dec. ¶¶ 19-20; Miller Dec. ¶ 7; Halladay Dec. ¶ 5; Singh Dec. ¶ 7; Sproul Dec. ¶¶ 4-6; Tullys Dec. ¶ 9; Burkhart Dec. ¶¶ 19-21, 26-27; Barnes Dec. ¶ 20-23.

[7] Lorenz Dec. ¶¶ 2-6; Singh Dec. ¶¶ 2-3; Cody Dec. ¶ 4; Halladay Dec. ¶ 3.

For example, under the County's current policies, religious objectors must make their managers aware of their objections in advance to permit staffing arrangements that avoid compromising patient care.[8] Workers may raise objections only to the direct provision of care (Lorenz Dec. ¶ 11, Ex. A), subject to the understanding that medical emergencies take precedence (Lorenz Dec. ¶¶ 11, 18; Nguyen Dec. ¶ 4 submitted as Hanna-Weir Dec. Ex. A). Under the Rule, the burden will shift to providers to ask essentially every employee (rather than just medical and nursing staff) about any objections that the employee might have to any job duties. *See* 84 Fed. Reg. at 23,186-88. If the Rule goes into effect, the County will be forced to bear the costs of canvassing thousands of employees and processing responses. *See* Lorenz Dec. ¶ 12. Even then, it may be unable to address religious objections through accommodations and reassignments due to the Rule's scope and restrictions. *See* Nguyen Dec. ¶ 5. And if the County cannot rely on staff to provide care in an emergency, it will not be able to ensure that care is adequately delivered—even with double-staffing or other cost-prohibitive measures. Nguyen Dec. ¶ 6. The barriers to care posed by the Rule will also undermine critical public health initiatives and emergency operations (Cody ¶¶ 4-10; Miller ¶¶ 5-6) and taken together will frustrate the County's ability to budget, plan, and provide care to millions of people (Lorenz Dec. ¶ 19).

Similarly, Plaintiffs specializing in reproductive healthcare and healthcare for LGBT people may be forced to institute costly workarounds and duplicative staffing; to unfairly burden nonobjecting employees; to reduce services; and even to close programs.[9] More patients who fear refusal of care at traditional healthcare facilities will come to them for care, straining their resources.[10] Plaintiffs will need to invest resources to educate the community about the Rule and combat the erosion of community members' confidence in the healthcare system. Shanker Dec. ¶ 14; Valle Dec. ¶ 16. The Rule will also frustrate Plaintiff medical associations' missions of promoting training in abortion care (Backus Dec. ¶ 11) and nondiscriminatory care for LGBT patients (Vargas Dec. ¶¶ 1-2, 6-10; Harker Dec. ¶¶ 1, 6, 9), and will harm their members and

[8] Lorenz Dec. ¶ 11, Ex. A; *see* Tullys Dec. ¶ 9; Halladay Dec. ¶ 5.

[9] Shafi Dec. ¶¶ 12-15; Shanker Dec. ¶¶ 13-15; Valle Dec. ¶¶ 16-23; Cummings Dec. ¶¶ 15-19; Manley Dec. ¶¶ 10-13; Burkhart Dec. ¶¶ 19-21, 27; Barnes Dec. ¶ 22.

[10] Shafi Dec. ¶ 20; Cummings Dec. ¶ 15; Shanker Dec. ¶ 13; Barnes Dec. ¶¶ 30-31.

members' patients (*id*.; Backus Dec. ¶ 11; Vargas Dec. ¶¶ 6-10).

The Rule will also harm the *Santa Clara* Plaintiffs' patients, especially low-income patients (Bolan Dec. ¶ 2; Cummings Dec. ¶¶ 3-4), and interfere with Plaintiffs' adherence to ethical and legal duties (Nguyen Dec. ¶¶ 8-9). The Rule increases the likelihood that patients will be turned away and will incur additional costs and burdens to try to find a willing provider. Lorenz Dec. ¶ 24; McNicholas Dec. ¶ 31; Cummings Dec. ¶ 9. Some patients will not receive or will be delayed in receiving essential care and treatment, suffering serious physical harm.[11] And patients denied complete information will be stripped of the right to informed consent. Nguyen Dec. ¶ 9; McNicholas Dec. ¶ 18. The Rule will further erode trust between patients and providers, causing worse patient outcomes. Carpenter Dec. ¶¶ 8-9; Henn Dec. ¶ 5.

The Rule will deter patients from seeking care for fear of stigma and discrimination and will reduce access to abortion and contraception (Backus Dec. ¶¶ 27-28), exacerbating an increasing national shortage of providers due to restrictive laws and widespread mergers of hospitals with religious facilities. *Id*. ¶¶ 8, 14-17; McNicholas Dec. ¶¶ 19-21. Many patients already travel long distances (and incur associated costs and delays) to obtain care. Phelps Dec. ¶ 18, 30. If the Rule goes into effect, even more institutions will forgo providing and educating providers in abortion and contraception, decimating access to care throughout the country.[12]

The Rule will impose particular burdens on LGBT people, and especially transgender and gender-nonconforming people. The Rule mischaracterizes gender-affirming care for transgender patients as "sterilization," specifically inviting religious and moral objections to providing that care. 84 Fed. Reg. at 23,178, 23,205.[13] LGBT people already face acute health disparities and

[11] Shanker Dec. ¶ 5; Cummings Dec. ¶¶ 11-12; Phelps Dec. ¶ 18. Others will be traumatized or stigmatized. Shafi Dec. ¶ 18; Bolan Dec. ¶¶ 6-9; Henn Dec. ¶ 3; McNicholas Dec. ¶ 44; Ettner Dec. ¶¶ 48, 56.

[12] Phelps Dec. ¶¶ 26-30, 34-35; Backus Dec. ¶¶ 18, 38-39; McNicholas Dec. ¶¶ 26-30.

[13] Equating gender-affirming treatment with "sterilization" is medically inaccurate, contrary to medical and commonsense understandings of the term, and endorses a particular religious view of gender identity. Ettner Dec. ¶ 46. Procedures undertaken for the purpose of sterilization are distinct from procedures undertaken for other purposes that incidentally affect reproductive function. *Id*.; Fountain Dec. ¶ 13. For some transgender people, reproduction may be possible even after completing treatment for gender dysphoria. Ettner Dec. ¶ 47; Fountain Dec. ¶ 13.

barriers to care, problems that will be compounded by the Rule.[14] Many LGBT patients fear going to healthcare providers because of past experiences of hostility, discrimination, and denials of care when they have disclosed to providers their sexual orientation, history of sexual conduct, gender identity, transgender status, or past gender-affirming medical treatment.[15] LGBT patients are disproportionately likely to delay preventive screenings and necessary treatment, causing more acute health problems and more adverse outcomes.[16] The Rule makes it more likely that these patients will be denied care, will remain closeted when seeking care, or will be deterred from seeking care, hurting the patients and the public health. *Id*.

ARGUMENT

I. PLAINTIFFS HAVE STANDING TO RAISE THEIR CLAIMS

Defendants challenge the third party standing of the physician plaintiffs in the *County of Santa Clara* action to bring Free Speech, Equal Protection and Due Process claims on behalf of their patients. Mot. 36. This argument fails. The Supreme Court has unequivocally held that physicians have standing to assert the reproductive rights of patients. *See, e.g*., *Singleton v. Wulff*, 428 U.S. 106, 117 (1976); *Isaacson v. Horne*, 716 F.3d 1213, 1221 (9th Cir. 2013); *Griswold v. Connecticut*, 381 U.S. 479 (1965). The Court recently upheld this unbroken precedent in *Whole Woman's Health v. Hellerstedt*, where physicians vindicated patients' abortion rights. 136 S. Ct. 2299 (2016).[17] If the Rule goes into effect, patients may be denied reproductive care in emergencies and other circumstances in which it is infeasible for them to assert their own rights, and the physician Plaintiffs have standing to vindicate these rights.

This standing extends to LGBT patients seeking to exercise their fundamental right to medical autonomy and bodily integrity on matters central to self-definition under *Skinner v.*

[14] Shanker Dec. ¶¶ 5-10; Ettner Dec. ¶¶ 55-56; Cummings Dec. ¶¶ 8-11.

[15] Henn Dec. ¶¶ 3, 6-8; Bolan Dec. ¶¶ 6-9; Carpenter Dec. ¶ 5; Cummings Dec. ¶ 12; Vargas Dec. ¶¶ 4-5, 13; McNicholas Dec. ¶ 26; Pumphrey Dec. ¶¶ 7-9.

[16] Shanker Dec. ¶¶ 8-12; Henn Dec. ¶¶ 3, 5-6; Bolan Dec. ¶¶ 6-9, 11; Carpenter Dec. ¶ 6; Manley Dec. ¶ 8; Cummings Dec. ¶¶ 9, 11-14.

[17] Provider standing to assert rights of abortion patients was assumed by all members of the Court in *Ayotte v. Planned Parenthood of N. New Eng.*, 546 U.S. 320, 324 (2006); *see also Gonzales v. Carhart*, 550 U.S. 124, 133 (2007); *Stenberg v. Carhart*, 530 U.S. 914, 922 (2000) (same); *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 845 (1992) (same).

Oklahoma, 316 U.S. 535 (1942), and *Eisenstadt v. Baird*, 405 U.S. 438, 453-54 (1972). LGBT patients cannot safely secure healthcare without the aid of physicians and are hindered in vindicating their own rights because of concerns over privacy and stigma and the time-sensitive nature of treatment. *See Singleton*, 428 U.S. at 117-18; *supra* Facts III.B-C; Ettner Dec. ¶¶ 21-22, 48-53. Defendants' own cites confirm that third-party standing exists where "enforcement of the challenged restriction *against the litigant* would result indirectly in the violation of third parties' rights.'" *Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004); *Mills v. U. S.*, 742 F.3d 400, 407-08 (9th Cir. 2014). And physicians have standing to challenge restrictions that chill their patients' speech, interfering with their ability to provide care. *Sec'y of State v. Joseph H. Munson Co*., 467 U.S. 947, 956-58 (1984); *Am. Booksellers Ass'n*, 484 U.S. at 392. Because enforcement of the Rule against Plaintiff providers and physicians will infringe on LGBT and reproductive-healthcare patients' constitutional rights, Plaintiffs' standing is clear. *See infra* Sections VIII-X.

Notably, Defendants do not contest that Plaintiffs have standing to pursue any of the claims they assert on their own behalves. Nor could they. Standing requires (1) "injury in fact," (2) a "causal connection" between the injury and the challenged conduct, and (3) a showing that a favorable ruling will "likely" redress the injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). In an APA action, if a plaintiff is an object of the challenged regulation, "there is little question" that the plaintiff has standing. *Id*. at 561-62.

The Rule inflicts numerous concrete injuries on all Plaintiffs. First, the Rule requires Plaintiffs to establish immediate compliance measures, adversely affecting their policies, hiring practices, and patient care.[18] *See Virginia v. Am. Booksellers Ass'n*, 484 U.S. 383 (1988) (finding standing based on costly compliance measures). Second, Plaintiffs are recipients or sub-recipients of federal funds. *See supra* Facts III.A-C; App'x 399 & 400. A "loss of federal funds promised under federal law[ ] satisfies Article III's standing requirement." *Organized Vill. of Kake v. U.S. Dep't of Agric*., 795 F.3d 956, 965 (9th Cir. 2015) (en banc). Third, the Rule burdens Plaintiffs

[18] Price Dec. ¶¶ 2-14; Cantwell Dec. ¶¶ 4-12; Nunes Dec. ¶¶ 5-19; Toche Dec. ¶¶ 2-12; Harris-Caldwell Dec. ¶¶ 5-16; Hinze Dec. ¶¶ 3-7; Aizuss Dec. ¶¶ 30-35; Parmelee Dec. ¶ 10; Chen Dec. ¶¶ 5-13; Weigelt ¶ 4; Colwell Dec. ¶¶ 5-10; Buchman ¶ 9-10.

with long-term increased costs—for example, for unintended pregnancies and untreated medical conditions.[19] *See California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018).

The public entity plaintiffs also have standing to seek judicial review of governmental action that affects the performance of their duties. *Cent. Delta Water Agency v. U.S.*, 306 F.3d 938, 950 (9th Cir. 2002). The Rule will interfere with the State's enforcement of its consumer protection laws and regulation of its medical professionals.[20] And the Rule will interfere with the duties of the City and County to provide medical care for indigent patients, prevent transmission of communicable disease, and protect health and safety. Cal. Const. art. XI, § 7; Cal. Welf. & Inst. Code § 17000 *et seq*.; Cal. Health & Saf. Code §§ 10100 and 120100 *et seq*.

II. PLAINTIFFS' SPENDING AND ESTABLISHMENT CLAUSE CLAIMS ARE RIPE

Defendants challenge the ripeness of Plaintiffs' Spending and Establishment Clause claims. Mot. 10-12.[21] This argument fails as well. Absent court intervention, the Rule will go into effect on November 22, 2019. Plaintiffs bring these claims now because they must decide—now—whether to forgo federal funding with potentially devastating consequences, or to completely rewrite existing policies, change their operations, incur additional costs and administrative burdens, and, for direct recipients, certify compliance. None of the Plaintiffs can afford to carry the unacceptable risk of an unbudgeted termination of huge swaths of federal funding. And provider Plaintiffs cannot, consistent with their legal and ethical duties and their missions, take a "wait and see" approach to deciding how to handle refusals during medical emergencies. Nor can they wait to set standards ensuring timely, adequate, and compassionate care. Public entity Plaintiffs asserting Spending Clause claims also bear special responsibility to ensure continuity in provision of public health services and care for vulnerable populations and the indigent.

[19] Chavkin Dec. ¶¶ 18-19, 24(q); Lara Dec. ¶¶ 21-22; Cantwell Dec. ¶ 12; Cody Dec. ¶ 10; Colfax Dec. ¶ 22; Pardo Dec. ¶ 12; Zevin Dec. ¶ 6.

[20] Lara Dec. ¶¶ 2-30; Kish Dec. ¶¶ 2-15; Cantwell Dec. ¶¶ 11-12; Morris Dec. ¶¶ 2-11; Pines Dec. ¶¶ 2-14; Hinze Dec. ¶¶ 4-7; Lara Dec. ¶ 4.

[21] Because here the APA provides a single cause of action challenging final agency action, 5 U.S.C. §704, challenges to the Rule under any of the bases enumerated under Section 706(2), including constitutional challenges, are necessarily ripe. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967) (superseded on other grounds by statute as recognized in *Califano v. Sanders*, 430 U.S. 99, 149 (1977)); *see also MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128 n.8 (2007).

Whether a rule violates the Spending and Establishment Clauses of the Constitution is a purely legal question that is ripe for adjudication. *Abbott Labs.*, 387 U.S. at 149. Review is ripe when, as here, (1) delayed review causes hardship to the plaintiff; (2) judicial intervention does not inappropriately interfere with administrative action; and (3) further factual development is unnecessary. *Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998).

First, a judicial challenge to a regulation is ripe when the rule requires parties to comply with new restrictions or risk serious penalties. *Abbott*, 387 U.S. at 152. Delayed review here would result in such a "substantial hardship." *See Pacific Gas and Elec. Co. v. State Energy Res. Conservation and Dev. Comm'n*, 461 U.S. 190, 201 (1983). The Rule's immediate compliance requirements and assurance and certification requirements, 45 C.F.R. § 88.4(a)(1), (2), obligate recipients and sub-recipients to comply throughout the duration of funding and as a condition of continued receipt of funds. 84 Fed. Reg. at 23,269. Thus, Plaintiffs will be forced midway through the fiscal year either to disrupt their budgetary plans to comply with requirements that have an immediate impact on their governance, functioning, business, and patients, or continue to provide services as they always have—believing in good faith that they meet all statutory requirements—but risk losing of funding nonetheless. *See supra* Facts III.A-C. All healthcare provider Plaintiffs will also need to immediately examine and alter their policies, and the Rule targets all Plaintiffs because they are committed to providing reproductive healthcare and LGBT healthcare. *See supra* Facts III.A-C. Thus, the "impact" of the Rule will be "felt immediately" because Plaintiffs will need to alter "their day to day affairs" immediately to comply. Mot. 11-12; *see also Ohio Forestry*, 523 U.S. at 734 (explaining that "agency regulations can sometimes force immediate compliance through fear of future sanctions," which is exactly what the Rule does); *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003) (concluding that requiring plaintiffs to adjust their conduct immediately is the "major exception" to the presumption that a regulation is not ripe).

In *National Family Planning & Reproductive Health Ass'n v. Gonzales*, unlike here, the plaintiffs did not face any immediate regulatory burdens. The expanded definition of the terms "discrimination," "assist in the performance," and "refer" provide precisely the basis for review

lacking in *Gonzales*, as recipients' decision to do something as simple as reassigning an employee could be "transform[ed]" into an act of discrimination subject to enforcement and de-funding, 468 F.3d 826, 828-30 (D.C. Cir. 2006). *California v. United States*, 2008 WL 744840, at *2 (N.D. Cal. Mar. 18, 2008), meanwhile, supports review because Defendants' about-face in their application of Weldon to the State and their re-opened investigation constitute "express statutory language or an express statement from a federal official or agency indicating a present conflict between state and federal law," *id.* at *5. *See also Nat'l Inst. of Family & Life Advocates v. Harris*, 839 F.3d 823, 832 (9th Cir. 2016), *rev'd on other grounds*, 138 S. Ct. 2361 (2018).[22]

Second, judicial action will not inappropriately interfere with administrative action because, as Defendants state, there is "no specific enforcement action against [Plaintiffs] under the Rule." Mot. 10. And even if there were, this case presents purely legal questions regarding HHS's authority to issue the Rule and the propriety of the Rule's expansive reach. *See, e.g.*, *Texas v. United States*, 201 F. Supp. 3d 810, 824 (N.D. Tex. 2016) (rejecting assertion that administrative action should block judicial review where issues were purely legal and defendants asserted non-compliance with their interpretation).

Third, factual development is unnecessary. Defendants have made clear that they are promulgating the Rule to foster "robust" enforcement (84 Fed. Reg. at 2179), and as the Rule itself demonstrates, Defendants consider California's laws to currently be in direct conflict with the Rule. Further, all provider Plaintiffs must immediately make policy and staffing changes to comply with the Rule, with recipients required to make assurances and certifications.

III. THE RULE IS ARBITRARY AND CAPRICIOUS AND THUS INVALID UNDER THE APA

A regulation is arbitrary and capricious if the agency has "entirely failed to consider an important aspect of the problem" or "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983). When an agency has failed to "give adequate reasons for its decisions," to "examine the relevant data," or to offer a "rational connection between the facts

[22] Also telling is the fact that the Rule mentions the State no less than 44 times. *See generally* 84 Fed. Reg. at 23,170. Moreover, there is a current facial conflict between the Rule and the policies of the City and County. *See, e.g.*, Chen Dec. ¶¶ 6-11 & Ex. A; Colwell ¶ 5; Weigelt Dec. ¶ 4.

found and the choice made," the regulation must be set aside. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). The failure to satisfy those threshold requirements makes a regulation procedurally defective and invalid, so it receives no deference under *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837 (1984). *Encino Motorcars*, 136 S. Ct. at 2125.

HHS acted arbitrarily and capriciously in promulgating the Rule. It adopted a one-sided regulation that is not supported by, and is in fact contrary to, the evidence in the record; and it failed to address important issues raised during the notice-and-comment process. And because the Rule is thus "procedurally defective," the Court need not even reach Plaintiffs' other challenges, including whether the agency has exceeded its authority in order to set aside the agency action. *Id*.; *see also Am. Bar Ass'n v. U.S. Dep't of Educ.*, 370 F. Supp. 3d 1, 33-34 (D.D.C. 2019).

A. Defendants Failed to Adequately Consider the Rule's Impact on Patients

HHS received voluminous comments demonstrating that the Rule will harm patients, especially LGBT patients, reproductive-healthcare patients, and patients in rural communities. But HHS brushed those concerns aside. That was arbitrary and capricious.

First, commenters explained that the Rule would make it more likely that patients would be refused care or denied critical information based on religious or moral objections,[23] causing them harm.[24] If the Rule takes effect, more individuals and entities will assert religious objections to a wider variety of care, including reproductive care, care for transgender patients, counseling for same-sex partners, and HIV/AIDS treatment.[25] Commenters also showed that the Rule would result in patients being denied information critical to decisions about their care.

Second, and relatedly, the Rule includes no exceptions for emergencies, so patients will suffer these harms even when they are seeking urgent and potentially lifesaving care. Many commenters pointed out that the absence of an emergency exception created an unacceptable risk

[23] App'x 139 at 137858-60; 77 at 139356; 143 at 139548-49; 85 at 140156; 37 at 139289-90; 177 at 140510-12; 179 at 135453-58; 159 at 66546-47.

[24] App'x 140 at 140484-85; 405 at 58343-44; 87 at 161182-83; 74 at 63129-30.

[25] App'x 95 at 161479-81; 179 at 135454-55; 42 at 135124; 73 at 134958; 77 at 139356; 83 at 139260; 134 at 160481-84; 135 at 149692-95; 120 at 148104-07.

that patients would not obtain the care they need in emergency situations.[26] HHS dismisses this risk by suggesting that it is unaware of an instance where an entire staff of an emergency department refused to provide care, *see* Mot. 24, but Plaintiffs describe such experiences among their own patients. *See* Cummings Dec. ¶ 12; Henn Dec. ¶ 6; *see also infra* Section V.B. And HHS's assertion ignores that the delay caused by a single individual's refusal to provide care in emergent circumstances, such as an ectopic pregnancy, may result in injury or death.

Third, healthcare denials will disproportionately affect certain patients. Commenters explained that the Rule will harm LGBT patients, who already experience discrimination and other obstacles when seeking healthcare.[27] Providers have refused to treat LGBT patients and their children, even in emergencies.[28] Many LGBT people and people living with HIV have reported providers refusing to touch them or using excessive precautions, using harsh or abusive language, being physically abusive, or blaming them for medical conditions.[29] The Rule will make it more likely that these patients will be refused care or be deterred from obtaining care.[30]

Commenters also showed that the Rule will harm patients seeking reproductive healthcare. Religious objections have been asserted to deny rape survivors emergency contraception; to refuse to provide emergency contraception in time to prevent pregnancy; and to deny care to complete miscarriages even when women's lives were in danger.[31] Such incidents will increase under the Rule, which invites denials of care in more circumstances, and seeks to hamstring providers' efforts to accommodate objections safely and compassionately while ensuring adequate and timely care. The Rule creates strong incentives for healthcare entities to curtail or eliminate reproductive healthcare and training, despite national shortages caused by hospital mergers and restrictive laws, compounding logistical and financial hurdles and increasing

[26] App'x 141 at 137583-84; 21 at 139592; 63 at 55809-13; 49 at 160802-05, 160821; 159 at 66547; 16 at 147981-82; 37 at 139292; 133 at 57530; 29 at 147892; 104 at 161036-37.
[27] App'x 63 at 55810-11; 49 at 160804-05; 40 at 57542; 119 at 134731-38; 99 at 135770; 71 at 139246; 180 at 161205-08; 120 at 148096-101.
[28] App'x 63 at 55810-11; 44 at 135828-32; 85 at 140154.
[29] App'x 78 at 160566-67.
[30] App'x 141 at 160566-67; 83 at 139260; 120 at 148099.
[31] App'x 49 at 160802-03; 89 at 140014-015; 154 at 160755.

patients' risks of injury and death.[32] The Rule will also undermine access to healthcare in rural communities,[33] where patients—particularly reproductive healthcare and LGBT patients—often have few if any alternatives if a provider refuses to provide care.[34] Economically disadvantaged patients, who lack resources to seek alternate providers, will also suffer disproportionately.[35]

HHS admitted that these harms will likely occur. It noted that "[d]ifferent types of harm can result from denial of a particular procedure," including that a "patient's health might be harmed if an alternative is not readily found, depending on the condition," 84 Fed. Reg. at 23,251, and cited examples of individuals' objecting to reproductive and LGBT healthcare as evidence of the need for the Rule. *Id.* at 23,176 & n.27. In other words, some patients will be denied critically needed healthcare. HHS also recognized that a patient denied care likely will incur additional costs searching for an alternative; that "the patient may experience distress associated with not receiving a procedure he or she seeks"; and that the patient ultimately may not receive care. *Id.* at 23,251. And HHS conceded that the Rule would adversely affect "rural communities, underprivileged communities, or other communities that are primarily served by religious healthcare providers or facilities," and that "patients in rural areas" will be more likely to "suffer adverse health outcomes as a result." *Id.* at 23,180, 23,253.

HHS failed to address these concerns, concluding instead that patient harm is an acceptable price to pay for furthering the ability of employees to impose their religious views on others. HHS attributes this preference to Congress, dismissing evidence that refusals would cause patients distress by asserting that Congress did not want to "establish balancing tests that weigh such emotional distress against the right to abide by one's conscience." 84 Fed. Reg. at 23,251. And it finalized the Rule "without regard to whether data exists on the competing contentions about its effect on access to services" because, it asserted, Congress deemed religious refusals "worth protecting even if they impact . . . access to a particular service, such as abortion." *Id.* at 23,182.

[32] App'x 49 at 160819-20, 160824-25; 128 at 138106-10; 21 at 139587-93; 133 at 57522-30; 182 at 67867-68; 31 at 71141-43; 140 at 140485-86; 22 at 56915-16.

[33] App'x 115 at 68427-28; 153 at 148143; 31 at 71142; 13 at 66627; 148 at 55627; 143 at 139551-25; 119 at 134733; 94 at 148163; 130 at 139861-63; 163 at 161320-21.

[34] App'x 119 at 134733; 56 at 139926; 178 at 67174.

[35] App'x 49 at 160803-05, 160810, 160825-26; 177 at 140509; 181 at 66040; 163 at 161318-19.

But none of the purported authorizing statutes require—or allow—any of that. Congress established limited protections for religious objectors while also enacting statutes, like EMTALA, to ensure that patients receive all necessary care. *See infra* Section V.B. It is the *Rule* that elevates religious objections over the health of patients, a choice that *HHS* made; Congress did not.

Second, HHS suggested that the Rule would "increase, not decrease, access to care" by attracting providers who otherwise supposedly would not practice medicine because of religious objections. 84 Fed. Reg. at 23,180; *see also id*. at 23,247 (same); Mot. 28. HHS's principal support for this assertion was a small, outdated, and unreliable political poll. *See infra* Section III.C. And HHS ignored the fact that attracting new providers who refuse to provide certain medical treatments or to serve certain classes of patients does nothing to help those patients, who are already especially likely to be underserved, excluded, and shamed. HHS also improperly minimized the overwhelming evidence in the record that an increase in religious refusals would cause substantial—and in some cases fatal—harms to patients.[36] And while HHS suggested that there were "too many confounding variables" and "not enough reliable data" for the agency to quantify "the impact of this rule on access to care" (84 Fed. Reg. at 23,252; Mot. 29), it acknowledged that the harms would result, including harms to "the patient's health" (84 Fed. Reg. at 23,251). The only possible question here concerns the ubiquity of those harms, not the fact (or the seriousness) of them; yet HHS dismissed them.

Finally, HHS offered no adequate response to the many comments pointing out specific ways in which the Rule would undermine the delivery of care to patients. For example, while many commenters explained the need for an emergency exception,[37] all that HHS would say is that it would consider specific emergency scenarios on a case-by-case basis (84 Fed. Reg. at 23,188), an absurd impracticality that would deter healthcare institutions from giving priority to patients in extremis, as medical ethics require (Nguyen Dec. ¶¶ 8-9); and institutions that make

[36] As Dr. Chavkin states in her declaration, HHS misread a paper that she authored to find that there is "insufficient evidence to conclude that conscience protections have negative effects on access to care." 84 Fed. Reg. at 23,251 n. 345; Chavkin Dec. ¶ 15. In fact, the paper demonstrates that religious refusals endanger patients. *Id.* ¶ 16. HHS ignored evidence of patient harms even in the cherry-picked medical-journal articles that it put into the administrative record. *Id.* ¶¶ 23-24.

[37] App'x 16 at 147981-982; 37 at 139292; 133 at 57530; 29 at 147892.

the choice to put patients' lives first do so at their peril. Nor did HHS seriously address the likelihood, arising from the Rule's broad definition of "referral," that patients would be denied information about valid treatment options. The agency merely asserted that providers would be required to obtain informed consent before undertaking particular medical procedures (84 Fed. Reg. at 23,189)—which is not at all the same thing as receiving full and fair information about *other* possible procedures. And HHS made the fatuous suggestion that, rather than being able to trust their doctors and other medical staff to be acting in the patients' best interest based on sound medical judgments, patients could seek out information about undisclosed treatment options using Google (*id.* at 23,253 & n. 354). Finally, HHS ignored the many comments explaining that healthcare institutions' existing religious-accommodation policies are more effective than the Rule in protecting patients while still allowing for religious objections in ways that do not compromise patient care.[38]

B. Defendants Failed to Respond Meaningfully to Comments Detailing Impacts on Providers, Impracticability, and Costs of Compliance

Defendants ignored a multitude of comments from major medical associations, provider groups, academics, and experts who raised concerns that the Rule will be impracticable and exceedingly costly. *See, e.g.*, Cal. Compl. ¶¶ 48-63; App'x 21; S.F. Compl. ¶ 121; S.C. Compl. ¶ 2015; *see also infra* Section V.

First, as to costs, major institutes and governmental entities addressed the burdens that the Rule would impose. The NPRM itself estimated $ 814.3 million for compliance over the first five years. Boston Medical Center explained that this required expenditure conflicts with the "calls to action and efforts being made to bring down the costs of health care throughout the United States." App'x 37; 101 (Mass. Health & Hosp. Ass'n Ltr.). The California Medical Association (CMA) explained that the NPRM failed to consider "the significant time and resources it takes to continuously implement and enforce" the rule. App'x 41. CMA further explained that these proposed "[e]xcessive administrative tasks" "divert time and focus from providing actual care to

[38] *See, e.g.*, App'x 21 at 139591; 63 at 55807; 162 at 134792-793; 37 at 139289; 103 at 64200; 22 at 56917-56918; 29 at 147890; 33 at 68370; 109 at 57601-602.

patients." *Id.*; *see also* App'x 20 (American Hospital Association explaining that the Rule is "burdensome" and "unnecessary" and "create[s] a presumption of noncompliance"); App'x 21 (AMA stating that "it remains unclear why OCR would require physicians to make two separate attestations of compliance to the same requirements, particularly given the administration's emphasis on reducing administrative burden"). Defendants failed to respond to these "significant points raised during the public comment period," and failed to consider these "relevant factors." *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000); Mot. 28 (Defendants admit that this Court must ensure that they "consider[ed]" "the relevant factors" in promulgating their Rule). On this basis alone, the Rule should be set aside.

Second, as to practicability, several entities stated that the increased regulatory burden of the Rule would adversely affect providers' practices. For example, the American Health Care Association and National Center for Assisted Living stated that the Rule's burdens on providers of long-term and post-acute care providers could reduce time to provide high quality patient-centered care. App'x 19. Numerous providers stressed that the Rule ran contrary to codes of ethics and other state and federal laws. App'x 21 (AMA).

Defendants argue that the *data* from the commenters is insufficient and unreliable to quantify these harms. Mot. 28-29. But there is no requirement that commenters provide a certain type of data before the agency must consider it.[39] On the contrary, whether supported by data or not, an agency must respond to "[s]ignificant points . . . which, if true, raise points relevant to the agency's decision." *City of Portland, v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007). The agency is not free to disregard commenters by complaining about "[un]reliable quantification." Mot. 29.[40]

Indeed, this Court recently adopted the D.C. Circuit's rule that "'[t]he mere fact that the . . . effect[ ] [of a rule] is *uncertain* is no justification for *disregarding* the effect entirely.'" *California v. Azar*, 385 F. Supp. 3d 960, 1017 (N.D. Cal. 2019), *stayed on other grounds pending appeal*, 928 F.3d 1153 (9th Cir. 2019). Per HHS's own Guidelines, "[i]f quantification is not possible,

[39] Also, HHS is required independently to assess the impact of its rules. 84 Fed. Reg. at 23,226.

[40] Defendants apply a double standard not permitted by the APA, considering "anecdotal evidence" in support of the Rule (84 Fed. Reg. at 23,247), while disregarding such evidence in comments opposing the Rule (Mot. 28-29).

analysts must determine how to best provide related information" and "[a]t minimum, analysts should list significant nonquantified effects in a table and discuss them qualitatively." RJN Ex. B. Defendants "failed to consider [these] important aspect[s]" of the rulemaking, thus the Rule must be set aside. *State Farm*, 463 U.S. at 43; *supra* Section III.A.

C. The Supposed Benefits of the Rule are Speculative and Unsupported

In articulating the supposed benefits of the Rule, HHS's primary contention is that it will increase the number of healthcare providers. *See* 84 Fed. Reg. at 23,246-47; *see also* Mot. 27. The language that HHS uses to describe this purported benefit makes clear that it is pure conjecture. HHS "expects" the Rule to encourage more people to enter the profession. 84 Fed. Reg. at 23,247. But it acknowledges that it "is not aware of any data enabling it to quantify any effect the Rule may have on increasing the number of health care providers." *Id.* It merely "assumes" that the Rule will result in a greater number of providers. *Id*.

This "assumption" is based primarily on decade-old polling concerning "conscience rights" in healthcare conducted by Kellyanne Conway's company on behalf of the Christian Medical and Dental Associations. App'x 404. The firm conducted two phone surveys of American adults—one in 2009 and one in 2011—and an online survey of members of faith-based medical organizations, including members of the Christian Medical Association. App'x 403 & 404.

HHS cites these results a dozen times in the Rule. *See, e.g.*, 84 Fed. Reg. at 23,246 n.309; *id.* at 23,247 nn.316–18. No other survey is cited more frequently and no other data is more central to HHS's argument. But this data cannot bear the weight that HHS places upon it. The research is outdated, having been conducted before the Catholic Church became one of the largest healthcare providers in the country. *See* Eleanor Barczak, *Ethical Implications of the Conscience Clause on Access to Postpartum Tubal Ligations*, 70 Hastings L.J. 1613, 1621 (2019) (today the Church "operat[es] 649 hospitals and 1614 continuing care facilities across the country, and provid[es] care for one in six patients receiving medical attention every day"). More importantly, the participants in the online survey were "self-selecting." App'x 404. Accordingly, even the pollster herself acknowledged that the poll was "intended to demonstrate the views and opinions [solely] of members surveyed" and was "not intended to be representative of the entire medical

profession [or even] of the entire membership rosters of these organizations." *Id.*[41]

This non-representative poll is the *only* data that HHS cited in support of its assertion that the Rule will increase the number of healthcare providers.[42] And the assertion is belied by other evidence in the record. For example, even though the 2008 rule was largely rescinded in 2011, religious providers did not leave the industry. Instead, religious providers such as Ascension, the "nation's largest religiously affiliated non-profit health care system," are thriving and providing approximately $2 billion in care, equal to Kaiser Permanente. 84 Fed. Reg. at 23,248.

HHS nonetheless asks this Court to defer to the agency even if its evidence is "weak" (Mot. 27), because this is a "difficult policy assessment that should be left" to the agency. Mot. 28. But courts "do not defer to the agency's conclusory or unsupported suppositions." *McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004) (citing *State Farm*, 463 U.S. at 440); *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 342 (D.C. Cir. 1989) (requiring more than "conclusory statement" regarding substantial competitive harm).

In short, the principal benefit that HHS asserted is unsubstantiated by competent evidence and "do[es] not suffice to explain its decision." *Encino Motorcars*, 136 S. Ct. at 2127. The other benefits that HHS identifies fare no better. First, HHS contends (Mot. 27) that the Rule will improve the doctor-patient relationship by "facilitating open communication between providers and their patients." 84 Fed. at Reg. at 23,249; *see also id.* at 23,246. HHS cites a medical journal article for the proposition that it is important for patients to feel confident that their religious beliefs will be honored by their medical providers, *id.* at 23,249 nn. 333-334. But the article in

[41] In the NPRM, by contrast, the polls were cited only once, and only for the limited proposition that 39% of respondents reported pressure or discrimination from administrators or faculty based on their moral, ethical, or religious beliefs. 83 Fed. Reg. at 3887 & n.24. If Plaintiffs had known that HHS would rely on the polls so extensively to support a broad assertion that the Rule will increase access to healthcare, Plaintiffs would have addressed the shortcomings of the survey in their comments on the NPRM. Where "the failure to notify interested persons of the scientific research upon which the agency was relying actually prevented the presentation of relevant comment, the agency may be held not to have considered all 'the relevant factors.'" *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 251 (2d Cir. 1977).

[42] In addition to the study, HHS purports to rely simply on "its own analysis, the comments received in response to the NPRM, [and] anecdotal evidence." Mot. 27. Unidentified and unquantified anecdotes cannot provide adequate basis for HHS's counterintuitive assertion that a rule allowing medical professionals to refuse to provide care will increase access to healthcare.

fact enumerates many barriers to the use of health services among minorities, including discourteous care and stereotypical or discriminatory attitudes from healthcare providers (Chavkin Dec. ¶ 24(h); App'x 383)—all of which will increase as a result of the Rule. Moreover, ensuring that doctors honor a patient's" religious beliefs is altogether different from—and often the opposite of—ensuring that healthcare workers' beliefs are *imposed* on patients.[43]

Finally, HHS contends that the Rule will "eliminat[e] the harm from requiring health care entities to violate their conscience" and will "reduc[e] unlawful discrimination in the health care industry and promot[e] personal freedom." 84 Fed. Reg. at 23,246; Mot. 27. But as explained in Section III.D. below, HHS has received only a small number of complaints alleging violations of conscience rights, showing that existing laws and policies adequately protect healthcare entities from being forced to violate their conscience, and many of those complaints would not be remedied by the Rule. *See Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 50 (D.D.C. 2019) (a regulation is arbitrary and capricious where "the government failed to explain why the [existing] safeguards as a whole would not prevent against the risk" purportedly addressed). The Rule is a solution in search of a problem.

D. The Record Does Not Support the Need for Defendants' Changed Policy

Defendants admit that HHS must "show[]" "'that there are good reasons'" for the new policy. Mot. 26. They argue that there are "good reasons" for their Rule because of an "increasing number of complaints" and because of a need to "provide adequate incentives" to covered entities. Mot. 26; *id*. at 29. The evidence in the record does not support these arguments. And courts "need not" defer to agency analysis "when the agency's decision is without substantial basis in fact." *Earth Island Inst. v. Hogarth*, 494 F.3d 757, 766 (9th Cir. 2007); *Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife*, 273 F.3d 1229, 1244 (9th Cir. 2001) (agency action must be "supported by the record" and not based on "speculation").

OCR received only 44 complaints between 2008 and January 26, 2018, alleging violations

[43] Another article that HHS cites in support of this notion, 84 Fed. Reg. at 23,246 n.310, in fact concludes that "[p]olicies that allow *some* [conscience-based refusals] *while also ensuring patients' access to the requested service* may yield better overall medical quality." App'x 377 at 000537893. In enacting the Rule, HHS ignored the critical qualification.

of conscience rights. 83 Fed. Reg. at 3886. Although Defendants report that they received 343 complaints in fiscal year 2018, the purported "increase" does not justify the Rule. First, 81% of the complaints concern objections to state vaccination mandates which, HHS concedes, the Rule does not preempt. Chance Dec. ¶ 11; 84 Fed. Reg. at 23,212. Second, while seven of the complaints were objections to health insurance companies' covering abortions, including complaints about the State's August 22, 2014, letters to health plans regarding abortion coverage, this State law has been upheld by state and federal courts.[44] And most of the complaints were asserted by individuals who are not covered by the Rule or relate to activities not addressed the supposedly authorizing laws. Chance Dec. ¶ 13; Mot. 27, n.7. Also, the 343 complaints that Defendants rely on amount to less than 2% of the more than 30,000 complaints of discrimination and privacy violations received by OCR.[45] 84 Fed. Reg. at 23,299. These figures demonstrate that rulemaking to enhance enforcement of religious refusal laws is manifestly unwarranted.

Further, even while HHS argues that the Rule is necessary, it is engaging in "robust" enforcement of the federal conscience statutes, Mot. 40, this Court's order delaying implementation notwithstanding.[46] An administration change does not authorize HHS's unreasoned and unsupported reversal of course. *State v. U.S. Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017) (a new administration must give reasoned explanations for regulatory changes and address the factual findings underpinning a prior regulatory scheme).

E. The Religious-Accommodation Framework is Illogical and Unjustified

The Rule creates an unworkable process for accommodating religious and moral objections by requiring that any accommodation be voluntary and by prohibiting any inquiry into whether job applicants may have religious objections to core duties. 45 C.F.R. § 88.2. The Rule substitutes Title VII's established religious-accommodation process with a process that would be

[44] *See Missionary Guadalupanas*, 38 Cal. App. 5th at 421; *Skyline v. Cal. Dep't of Managed Health Care*, 315 F. Supp. 3d 1225 (S.D. Cal. 2018); *Foothill Church v. Rouillard*, 371 F. Supp. 3d 742 (E.D. Cal. 2019).

[45] RJN Exh. A at 147.

[46] *See, e.g.*, Harris Meyer, *HHS accuses Vermont hospital of forcing nurse to assist in abortion*, Modern Healthcare (Aug. 28, 2019), https://www.modernhealthcare.com/law-regulation/hhs-accuses-vermont-hospital-forcing-nurse-assist-abortion.

fundamentally unworkable for health care employers and would jeopardize patient care, rendering the Rule "illogical on its own terms."[47] *See* 42 U.S.C. § 2000e-2(a)(1); *Am. Fed'n of Gov't Employees, Local 2924 v. Fed. Labor Relations Auth.*, 470 F.3d 375, 380 (D.C. Cir. 2006).

The Rule arbitrarily creates a distinct hiring process for regulated entities with regard to religious objections—a process that jeopardizes patient care and impedes providers' efficient management of the workforce.[48] The Rule forbids regulated entities (and possibly sub-recipients and contractors) to inquire in advance as to a prospective employee's objections. An employer "may," after hiring and no more than once per calendar year thereafter except with "persuasive justification," require an employee to inform the employer of any conscience objections. 84 Fed. Reg. at 23,263. Employers will thus be in an untenable position in which they may be hiring individuals who will not perform the core duties of the position. And employers may unknowingly staff an employee in a position that the employee can no longer perform because, unbeknownst to the employer, new objections arose in the course of employment.

The accommodation process is also illogical and unsupported in the administrative record. Under Title VII, employers are required to reasonably accommodate an employee's religion unless doing so would constitute an undue hardship (*e.g.*, "more than a de minimis cost" to the employer). 42 U.S.C. § 2000(e)(j); *Ansonia Bd. of Educ.*, 479 U.S. at 68-69 ("A sufficient religious accommodation need not be the 'most' reasonable one (in the employee's view), it need not be the one the employee suggests or prefers, and it need not be the one that least burdens the employee.").[49] With little explanation, the Rule provides that the employer avoids potential

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[47] Religious accommodations in healthcare have been examined under Title VII. *See Stormans Inc. v. Selecky*, 844 F. Supp. 2d 1172, 1201 (W.D. Wash. 2012); *Shelton v. Univ. of Med. & Dentistry of N.J.*, 223 F.3d 220, 227 (3d Cir. 2000); *Grant v. Fairview Hosp. & Healthcare Servs.*, 2004 WL 326694 (D. Minn. Feb. 18, 2004); *Mereigh v. N.Y. & Presbyterian Hosp.*, 2017 WL 5195236 (S.D. N.Y. Nov. 9, 2017); *Noesen v. Med. Staffing Network*, 232 Fed.App'x 581 (7th Cir. 2007); *Bruff v. N. Miss. Health Servs., Inc.*, 244 F.3d 495, 500 (5th Cir. 2001).

[48] In contrast, for example, under Title VII, "courts have noted that bilateral cooperation is appropriate [and consistent with Congress's goal of flexibility] in the search for an acceptable reconciliation of the needs of the employee's religion and the exigencies of the employer's business." *Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 69 (1986); *Shelton*, 223 F.3d at 227.

[49] Also, "an employer is not liable under Title VII when accommodating the employees' religious beliefs would require the employer to violate federal or state law," or if it would result in discrimination. *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 830-31 (9th Cir. 1999); *Peterson v. Hewlett Packard Co.*, 358 F.3d 599, 607 (9th Cir. 2004).

liability for discrimination only if the employee "voluntarily accepts an effective accommodation." 84 Fed. Reg. at 23,191. If there is no "effective" accommodation or the employee is unwilling to accept any of the options offered, the Rule is silent on what the employer can do without violating the Rule. Presumably, the employer cannot transfer or fire the employee because that would be "discrimination" under the Rule.

Though Congress did not expressly incorporate the framework for religious accommodation from Title VII into the statutes that HHS purports to interpret, that does not release HHS from its obligation to "give adequate reasons for its decisions," *Encino Motorcars*, 136 S. Ct. at 2125, particularly when departing from a long-standing statutory framework that has previously been applied in this context. Defendants cite no authority for their proposition that Congress did not intend for undue-hardship exemptions to apply to federal conscience statutes. Mot. 24-25 (relying on case that finds a "clear conflict" between local restrictions and national banking law). HHS has merely expressed an unlawful preference for certain religious objections, *see infra* Sections VII and IX, and has provided no support for its cursory assertion that Congress intended to impose by means of the supposedly authorizing statutes a regime entirely different from Title VII. Congress clearly never intended for those statutes to put employers and employees in limbo, where objections cannot be resolved and patients are harmed.

The federal conscience laws and Title VII have fact co-existed for decades. Simply put, the Rule supplants Congress's judgments and the courts' settled jurisprudence without demonstrating a genuine need for this radical change. *Cf. Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006) (vacating order where agency "provided no evidence of a real problem").

IV. THE RULE EXCEEDS HHS'S STATUTORY AUTHORITY

It is well settled that "an agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 374 (1986). Accordingly, agency action must be set aside if it is found to be "in excess of statutory jurisdiction [or] authority." 5 U.S.C. § 706(2)(C). Here, the Rule exceeds HHS's statutory authority in three ways: (a) HHS lacks authority to promulgate legislative regulations implementing Church, Coats-Snowe, and Weldon; (b) Congress has not delegated to HHS the

broad enforcement powers that the agency arrogates to itself; and (c) HHS purports to define critical statutory terms in a manner that far exceeds Congress's intent.

A. HHS Lacks Authority to Promulgate Regulations Implementing Church, Coats-Snowe, and Weldon

HHS's power to promulgate legislative regulations "is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). If no statute vests an agency with authority to promulgate a particular rule, the agency's action is "plainly contrary to law and cannot stand." *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) (internal quotation marks omitted). Because federal agencies have no free-standing legislative authority, it is "incumbent upon [the agency] to demonstrate that some statute confers upon it the power it purport[s] to exercise." *Cal. Indep. Sys. Operator Corp. v. FERC*, 372 F.3d 395, 398 (D.C. Cir. 2004); *see also Gonzales v. Oregon*, 546 U.S. 243, 258 (2006). The agency must affirmatively demonstrate this by pointing to specific statutory authority. *Am. Petroleum Inst. v. U.S. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995). There are many examples of such specific grants of rulemaking authority. *See, e.g.*, 29 U.S.C. § 655(b) (authorizing OSHA to issue occupational safety and health standards), 15 U.S.C. § 1392 (directing NHTSA to issue motor vehicle safety standards).

Defendants do not, because they cannot, point to any similar language in Church, Coats-Snowe, or Weldon. Instead, they argue that these Amendments "*implicitly* grant HHS the authority" to issue the Rule. Mot. 12 (emphasis added). Defendants cite *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001), for the proposition that delegated authority may be implicit. But there, Congress had explicitly "charged," *id.* at 227, the agency with "establish[ing] and promulgat[ing] . . . rules and regulations." *Id.* at 222 (quoting 19 U.S.C. § 1502(a)). Given this "generally conferred authority," *id.* at 229, the Court concluded that Congress could have implicitly delegated some interpretive authority to the agency as well, such as authority to "fill a particular gap," *id.* Even with this delegation, the *Mead* court *still* held that the agency's action did not "qualify" for *Chevron* deference. *Id.* at 227 (reversing and remanding for a determination of whether there is some deference under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)). And here, there is no "generally conferred authority" or other evidence of Congressional intent to give

HHS broad authority to promulgate regulations implementing the Amendments.

HHS also relies on its general housekeeping authority under 5 U.S.C. § 301 (1966). Mot. 13. But that statute is "simply a grant of authority to the agency to regulate its own affairs"—not the affairs of Plaintiffs. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). And HHS cites the Federal Property and Administrative Services Act of 1949, which authorizes agencies to "issue orders and directives that the agency head considers necessary to carry out" other specified regulations. 40 U.S.C. § 121(c). But Congress could not have intended these statutes, which long pre-date passage of the conscience statutes, to have granted HHS carte blanche to issue rules and regulations implementing unknown and yet-undrafted laws.[50]

When Congress has not conferred the asserted regulatory authority, courts do not hesitate to "hold unlawful and set aside" agency regulations under APA Section 706(2)(C). *See, e.g.*, *Air Alliance Houston v. EPA*, 906 F.3d 1049, 1060-66 (D.C. Cir. 2018); *Motion Picture Ass'n of Am. v. FCC*, 309 F.3d 796, 807 (D.C. Cir. 2002); *Am. Library Ass'n v. FCC*, 406 F.3d 689, 708 (D.C. Cir. 2005); *Pharm. Research & Mfrs. of Am. v. U. S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 37-45 (D.D.C. 2014). Here, HHS cannot demonstrate that "some statute confers upon it the power it purported to exercise." *Cal. Indep. Sys. Operator Corp.*, 372 F.3d at 398.

B. The Rule Impermissibly Expands HHS's Enforcement Authority

Defendants have improperly conferred broad enforcement powers on OCR without statutory basis. 5 U.S.C. § 706(2)(C); *see* 84 Fed. Reg. at 23,220 (asserting "authority to enforce the Federal Conscience and anti-discrimination laws"). Congress knows how to authorize enforcement authority such as the Rule's funding termination provisions. *See, e.g.*, 42 U.S.C. § 2000d-1 (Title VI), 20 U.S.C. § 1682 (Title IX); 42 U.S.C. § 6104 (Age Discrimination Act); 29 U.S.C. §794 (Rehabilitation Act of 1973), 42 U.S.C. § 18116(a) (Section 1557 of the ACA). The "silen[ce]" of the statutes on which HHS relies "contrasts sharply with the[se] other enforcement provisions." *Omni Capital Int'l, Ltd. v. Rudolf Wolff & Co.*, 484 U.S. 97, 106 (1987).

Although the Rule purports to enforce more than two dozen statutes, only one speaks

[50] Nor can HHS grant itself authority through its own regulations. *See* Mot. 13 (citing UAR (45 C.F.R. § 75.300(a)) and HHSAR (48 C.F.R. § 301.101(b)(1))).

directly to HHS's power to enforce. Section 1553 of the ACA designates OCR "to receive complaints of discrimination based on this section." 42 U.S.C. § 18113(d). The plain text of the statute confers on OCR the power to receive complaints *only under the ACA's prohibition against discrimination based on refusals related to assisted suicide*. There is no direct grant of authority to OCR—under that section or any cited statute—of "robust" enforcement tools that could halt or reverse all federal funding for all the reasons covered by the Rule. 84 Fed. Reg. at 23,254. Nor does the plain language of any of the statutory sources that Defendants have cobbled together grant, either individually or collectively, the enforcement over Plaintiffs that HHS asserts. *See* Mot. 14 (citing 42 U.S.C. § 18023(b)(4) (ACA exchange plans); *id*. at § 18041(a)(1) (ACA exchanges); *id*. at § 1302 (small rural hospitals); *id*. at § 263a(f)(1)(E) (certification of laboratories); *id*. at § 1351a (authorizing the Center for Medicare and Medicaid Innovation).

The cases Defendants cite— *U.S. v. Marion County School District*, 625 F.2d 607 (5th Cir. 1980) and *U. S. v. Mattson*, 600 F.2d 1295 (9th Cir. 1979)—do not support a finding of inherent regulatory enforcement authority. *See* Mot. 13-14. *Marion County* simply held that the attorney general could sue to enforce contractual assurances of compliance with Title VI—it does not support any "inherent" authority to impose such contractual assurances in the first instance. *Marion*, 625 F.2d at 617. When the Ninth Circuit was faced with a similar question, it *rejected* the attorney general's argument that he had inherent authority to bring suit to enforce civil rights laws against a recipient of federal funds, and dismissed the case. *Mattson*, 600 F.2d at 1299 (noting the "repeated failure of Congress to authorize such suits").

C. HHS's Definitions of Statutory Terms Exceed Congress's Intent

Although the Rule purports to do nothing more than implement existing federal law, HHS's definitions of several statutory terms—specifically, "health care entity," "assist in the performance," "referral or refer for," and "discriminate or discrimination" (collectively "Challenged Definitions")[51]— far exceed the substantive bounds of their legislative origins. *See e.g.*, 45 C.F.R. § 88.2-88.3(a)-(c). "Health care entity," "assist in the performance," and "referral" increase the number of prospective objectors from clinical staff to a potentially limitless group of

[51] The Challenged Definitions can be found in full at 45 C.F.R. § 88.2.

workers, while "discrimination" prescribes unworkable limitations on a provider's ability to learn of and address possible objections among this expanded group of workers, undermining providers' ability to provide undisrupted patient care. Defendants contend that these definitions accord with the statutes and are reasonable interpretations entitled to deference under *Chevron*. Defendants are wrong on both counts.

As an initial matter, *Chevron* applies only when Congress delegated authority to an agency to make rules carrying the force of law, and the agency's action involves the exercise of that authority. *See Mead*, 533 U.S. at 229. For the reasons explained above, Congress did not delegate authority to HHS to promulgate legislative rules concerning Church, Coats-Snowe, or Weldon. *See supra* Section IV.A. Accordingly, *Chevron* is inapplicable. Moreover, none of the underlying statutes extends an unqualified religious-objection right to every person employed by a healthcare provider. Even assuming that HHS had authority to issue a rule here, *this* Rule would still deserve no deference because the definitions are contrary to the "unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43. They are thus "in excess of statutory . . . authority" and should be set aside. 5 U.S.C. § 706(2)(A).

Health Care Entity. The term "health care entity" is expressly defined in Coats-Snowe and Weldon. Coats-Snowe defines it to include "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n(c)(2). Weldon defines it to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." 42 U.S.C. § 18113. The Rule ignores this plain language, adding several additional categories of individuals and entities. Citing to *Samantar v. Yousuf*, 560 U.S. 305 (2010), HHS argues that the use of the word "include" in both Coats-Snowe and Weldon indicates that the specific list of "health care entities" contained in those laws is illustrative, not exhaustive. Mot. 18. But *Samantar* does not stand for the proposition that the word "include" should *always* be treated as preceding an illustrative list; merely that it may do so. And certainly, anything added to an "illustrative" list should be similar to the enumerated items. Here Coats-Snowe and Weldon are aimed at

healthcare professionals and organizations. By contrast, the Rule's definition of "health care entity" includes, at a minimum, all members of the workforce of a healthcare entity, which spans almost every kind of actor involved in healthcare, including volunteers, contractors, medical staff and nonmedical staff from pharmacy clerks to medical billing trainees—entities and individuals with very different roles and functions from those included by Congress. This unprecedented body of persons and entities is empowered to refuse care according to the definitions below.

Assist in the Performance. The Rule defines "assist in the performance" to include "tak[ing] an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity," including "counseling, referral, training, or otherwise making arrangements for" a procedure. 45 C.F.R. § 88.2. This sweeps much more broadly than Congress intended. HHS argues that the Rule's definition is consistent with Church, ignoring the context and history of that law. Church was passed in 1973 as a reaction to the Supreme Court's decision in *Roe v. Wade* and a Montana district court decision that imposed a temporary restraining order "compelling a Catholic hospital, contrary to Catholic beliefs, to allow its facilities to be used for a sterilization operation." 119 Cong. Rec. S9595 (Mar. 27, 1973); *see also Taylor v. St. Vincent's Hosp.*, 523 F.2d 75, 76 (9th Cir. 1975). As Senator Church made clear, "[t]he amendment is meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions . . . . There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." 119 Cong. Rec. S9595. Yet, the Rule's definition of "assist in the performance" extends refusal rights well beyond this focused legislative intent, including to "referral[s]" (despite the separation of these terms in the statutes), thus extending such rights to individuals with little connection to the actual provision of healthcare. For example, HHS explicitly intends this definition to include nonmedical tasks such as "[s]cheduling an abortion or preparing a room and the instruments for an abortion." 84 Fed. Reg. at 23,186. HHS contends that "an individual who schedules a patient's abortion is not outside the scope of the Church Amendments merely because they did not perform the abortion themselves." Mot. 16. Yet this

expansion is exactly what Congress declined to implement.[52]

Referral or Refer for. The Rule's use of the terms "referral or refer for" also go well beyond what Congress intended in Weldon and Coats-Snowe, sweeping in the "provision of information" in any form "where the purpose or reasonably foreseeable outcome . . . is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure." 45 C.F.R. § 88.2. HHS argues that the "addition of the term 'for' following 'refer' indicates that Congress did not intend the statutes to be limited to a referral document, but rather to include any referral for abortion (or other health services) in a more general sense." Mot. 19. That argument strains the plain language of both statutes with respect to who is covered and what information constitutes a referral. Coats-Snowe anchors "refer for" and "referral" to the training of induced abortions and applies only to an "individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n. Weldon uses the term "refer for" in the context of abortion, stating that none of the funds appropriated in the appropriations act may be made available to governmental entities that discriminate against any "institutional or individual health care entity" because the entity "does not provide, pay for, provide coverage of, or refer for abortions." Consolidated Appropriations Act of 2009, Pub. L. No. 111-117, § 508(d)(1), 123 Stat. 3034.[53]

[52] Relying on *Mayo Foundation for Medical Education & Research v. United States* 562 U.S. 44, 52 (2011), HHS argues that the dictionary definitions of several of the challenged definitions illustrate that Congress has "directly spoken" on an issue, satisfying the first step in *Chevron*, Mot. 15, 17, 19. Aside from the broader point that *Chevron* is inapplicable here, *Mayo rejected* the agency's assertion that the dictionary definition proved that Congress had directly addressed the question at issue. And the term at issue in *Mayo* was "student"—not a medical term for which a *medical* dictionary should be consulted. "Assisting in the performance" of a medical procedure has a specific meaning that is not fairly or accurately captured by stitching together two separate definitions from a non-medical dictionary. *See e.g.*, *Ward v. Dixie Nat'l Life Ins.*, 2007 WL 4293319, at *1 (4th Cir. 2007)("'actual charges' [was] a term of art rather than two words to be separately defined"); *Harold v. Corwin*, 846 F.2d 1148, 1151 (8th Cir. 1988); *see also* Chen Dec. ¶¶ 14-16; Zevin Dec. ¶¶ 8-10.

[53] Moreover, the medical regulatory backdrop makes clear that Congress intended the word "referral" to have its normal meaning in the healthcare setting—for a provider to direct a patient to another provider for care. *See, e.g.*, Medicare.gov, *Glossary-R*, https://www.medicare.gov/glossary/r (last visited Sept. 3, 2019) (defining referral as "[a] written order from your primary care doctor for you to see a specialist or get certain medical services"); Ctrs. for Medicare & Medicaid Serv., *Glossary*, https://www.cms.gov/apps/glossary/default.asp?Letter= R&Language

HHS's interpretation would extend the Rule's reach to the provision of any information by anyone employed in the healthcare industry, depriving patients of information relevant to their treatment, without giving them any hint that crucial information for making informed decisions is being withheld from them. There is no statutory support for HHS's position.

Discriminate or Discrimination. Finally, the Rule's definition of "discriminate or discrimination" goes far beyond what Congress intended by placing unprecedented limits on healthcare providers' accommodation policies and preventing them from ensuring patient health and safety. Under the Rule, "[d]iscrimination" means any change to an objecting employee's "position," "status," "benefit[s]," or "privilege[s]" in employment, as well as use of any "policies[] or procedures" that subject the objector to "any adverse treatment." 84 Fed. Reg. at 23,263, § 88.2. The Rule encompasses almost any adverse employment action toward religious objectors without considering what may be legally justifiable—in stark contrast to how discrimination is understood throughout federal civil rights law. In that regard, federal law recognizes a number of rationales and defenses to justify adverse employment actions, including that an employer need not accommodate an employee's religious beliefs when the accommodation would cause undue hardship to the employer. *See* 42 U.S.C. § 2000e(j); *EEOC v. Abercrombie & Fitch Stores, Inc*., 135 S. Ct. 2028, 2032 (2015); *Peterson v. Hewlett-Packard Co*., 358 F.3d 599, 607 (9th Cir. 2004). But under the Rule, a healthcare entity could be deemed to have engaged in unlawful discrimination simply by taking measures that are reasonably necessary to find out about religious objections and to ensure that those objections do not compromise patient care. Only the few actions within the definition's narrow and restrictive exceptions are excluded—and then only if the employee agrees. *See supra* Section III.E.

Congress did not intend its prohibition on "discrimination" to require healthcare entities to put the wishes of religious objectors above the needs of all others. Rather, Congress recognized in, for example, the ACA and EMTALA that providers have obligations to provide healthcare and information, especially in emergency circumstances. Yet in its definition of "discrimination,"

(last visited Sept. 3, 2019) ("referral is defined as an actual document obtained from a provider in order for the beneficiary to receive additional services."); *id*. (referral is a "written OK from your primary care doctor for you to see a specialist or get certain services").

HHS declined to consider the legitimate needs of healthcare providers. And by elevating religious objections over the needs of patients, HHS enables new and unjustified forms of discrimination—turning Congress's mandate not to "discriminate" on its head.

In short, in enacting the Challenged Definitions, HHS effectively used the rulemaking process to rewrite the underlying law. This exceeds HHS's statutory authority.

V. THE RULE CONFLICTS WITH EXISTING HEALTHCARE LAWS

A. The Rule Conflicts with Section 1554 of the ACA

Congress was clear in the ACA's directive to HHS: The Secretary "shall not promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services; [or] (3) interferes with communications regarding a full range of treatment options between the patient and provider." 42 U.S.C. § 18114 . "When Congress speaks clearly," as it did here, "administrative agencies must listen." *Sunrise Coop., Inc. v. U. S. Dep't of Agric.*, 891 F.3d 652, 654 (6th Cir. 2018). The Rule creates barriers to, impedes, and interferes with access to healthcare for women, people with disabilities, LGBT people, and rural communities by permitting discrimination by providers. *See supra* Facts III.A-C. It violates Section 1554 and must be set aside.

Defendants argue that this Court should read Section 1554 into obscurity, but their argument fails. First, Section 1554 prohibits regulations that "create[]," "impede[]," "interfere[] with," "restrict[]," or "violate[]," healthcare access, not the "denial of information or services." *Cf.* Mot. 20. Second, whereas Defendants contend that certain terms in Section 1554 are so open-ended as to be unreviewable under the APA, several courts have applied Section 1554, and none found it too "open-ended" to be enforced.[54] Taking Defendants' argument to its logical conclusion, the APA itself, which defines neither "arbitrary" nor "capricious," would also be unenforceable. *See Chubb Custom Ins. v. Space Sys.*, 710 F.3d 946, 966 (9th Cir. 2013) (it is

[54] *See, e.g.*, *California*, 385 F. Supp. 3d at 998-1000; *Mayor & City Council of Baltimore v. Azar*, 2019 WL 2298808, at *8-9 (D. Md. May 30, 2019); *Oregon v. Azar*, 389 F. Supp. 3d 898, 914-15 (D. Or. 2019), *stayed on other grounds pending appeal*, 928 F.3d 1153 (9th Cir. 2019); *Washington v. Azar*, 276 F. Supp. 3d 1119, 1130 (E.D. Wash.), *stayed on other grounds pending appeal*, 928 F.3d 1153 (9th Cir. 2019).

"inappropriate to adopt a textually dubious construction that threatens to render the entire provision a nullity"). Finally, the canon that the "specific governs the general" is irrelevant unless statutes are irreconcilably conflicting, which HHS admits "they are not." Mot. 22.

Defendants rely on the phrase "[n]otwithstanding any other provision of this Act," arguing that Section 1554's prohibitions do not apply to the conscience statutes. Mot. 21. The plain meaning of that clause is that the Secretary cannot engage in the type of rulemaking proscribed by Section 1554 even if another provision of the ACA could be construed to permit it.[55]

Defendants cite to 42 U.S.C. § 18023(c)(2),[56] arguing that Congress intended the ACA to support, not undermine, federal conscience statutes. But Section 18023(c)(2) and Section 1554 work together because Section 18023(c)(2) does not "create[]," "impede[]," "interfere[] with," "restrict[]," or "violate[]," healthcare rights or access. The Rule does exactly that.

B. The Rule Violates EMTALA

EMTALA requires hospitals participating in the federal Medicare and Medicaid programs with emergency rooms, including those owned and operated by the City and the County, to screen patients to determine "whether or not an emergency medical condition . . . exists" and, if so, to stabilize the patient or transfer her to another facility. 42 U.S.C. §§ 1395dd(a), (b)(1), (c)(1). Courts construing federal conscience protections have concluded that a balancing test is necessary in cases of emergency care. *See, e.g., California v. United States*, 2008 WL 744840, at *4 (N.D. Cal. Mar. 18, 2008) (there is no indication "from the express language of [Weldon] . . . that enforcing . . . EMTALA [or California's equivalent law] to require medical treatment for emergency medical conditions would be considered 'discrimination' under [Weldon] if the required medical treatment was abortion-related services.").[57] The Rule fails to provide for any

[55] Any reliance on *California v. Azar*, 927 F.3d 1068, 1078 (9th Cir. 2019), would be misplaced because this decision is being reheard en banc and "shall not be cited as precedent by or to any court of the Ninth Circuit." *State by & through Becerra v. Azar*, 927 F.3d 1045, 1046 (9th Cir. 2019). And it discusses the "[n]otwithstanding" clause only in dicta. *See* 927 F.3d at 1079 n.4.

[56] "Nothing in this Act shall be construed to have any effect on Federal laws regarding— (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." 42 U.S.C. § 18023(c)(2).

[57] *See also* 151 Cong. Rec. H176-77 (Jan. 25, 2005) (statements by Rep. Weldon acknowledging

balancing. Defendants insist that HHS intends to "harmon[ize]" EMTALA with the federal conscience protection statutes to the fullest extent possible (Mot. 23), but that that empty assurance gives cold comfort to regulated entities like Plaintiffs, who must immediately determine how to comply or risk losing hundreds of millions of dollars in federal funding. Nor does it assuage patients' well-founded fears. HHS's assertion that it is unaware of any instance when a facility's entire emergency medical care staff objected to providing care ignores the examples of real patient harm in the record.[58] The Rule must be vacated on this ground alone.

C. The Rule Violates the ACA's Nondiscrimination Provision

Section 1557 of the ACA prohibits discrimination under any health program or activity on the basis of race, color, national origin, sex, disability, or age. The Rule violates Section 1557 because it permits providers, insurers, plan sponsors (i.e., employers) and other healthcare personnel and entities to exempt themselves from providing a broad range of benefits and services—including contraceptives (84 Fed. Reg. at 23,176), emergency miscarriage management (*id*. at n.27), tubal ligations and hysterectomies (but not vasectomies) (*id*.), and treatment for gender dysphoria (*id*.)—to women and to the LGBT community. *See supra* Facts III.B-C.[59] Though HHS says once again that it "intends" to "harmon[ize]" the law to the fullest extent possible (Mot. 23), that argument again fails for the reasons just explained.

D. The Rule Contravenes Title X

The Rule also contravenes Title X of the Public Health Service Act which states that Title X "family planning projects" "*shall* offer a broad range of acceptable and effective family planning methods and services," 42 U.S.C. § 300(a)—Congress' requirement that "all pregnancy counseling shall be nondirective," e.g., 132 Stat. 2981, 3070-71 (2018)—which Defendants have

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EMTALA and that Weldon prohibits coercion in "nonlife-threatening situations," but when the "mother's life is in danger a healthcare provider must act to protect the mother's life.").

[58] *See* App'x 148, n.8; App'x 49; App'x 74, n.18; App'x 5 at 160898 (ACLU Cal.); 83 Fed. Reg. at 3888 n.36, 3889 (hospital denied emergency medical care to a woman who experienced pregnancy complications likely to result in her injury or death and fetal death); 84 Fed. Reg. at 23,176, n.27 (same); Colwell Dec. ¶¶ 6-10.

[59] *See, e.g.*, *Ferrer v. CareFirst, Inc*., 265 F. Supp. 3d 50, 52-54 (D.D.C. 2017) (denial of full coverage resulting in women paying for lactation services violates the ACA); Commission Decision on Coverage of Contraception, EEOC 2000 WL 33407187 (Dec. 14, 2000).

conceded permits grantees to present pregnant women with options, including abortion, where the provider "is not suggesting or advising one option over another," and where "clients take an active role in [. . .] identifying the direction of the interaction." 84 Fed. Reg. at 7716.[60] The Rule's overbroad definitions of "discrimination" and "assist in the performance of" put Title X grantees in an impossible situation: ensure that they (and their employees) abide by federal statutory mandates and thereby risk violating the Rule, or abide by the Rule and thereby risk violating Title X when employees refuse to "assist in the performance of" family planning methods and services. Because these definitions have expanded the reach of federal conscience statutes, Defendants' argument that the Rule merely implements existing law is meritless. *See supra* Section IV.C. Moreover, Defendants' contention that entities can simply decline to accept Title X funding belies the harm that the Rule will wreak should it go into effect.

VI. THE RULE VIOLATES THE SPENDING CLAUSE

Under the Spending Clause, U.S. Const., art. I, § 8, cl. 1, Congress may not impose conditions on federal funds that are (1) so coercive as to compel (rather than merely encourage) States to comply, (2) ambiguous, (3) retroactive, or (4) unrelated to the federal interest in a particular program. *NFIB*, 567 U.S. at 575–82; *South Dakota v. Dole*, 483 U.S. 203, 206–08 (1987). The Rule violates all four of these prohibitions because it puts states and localities at risk of ruinous sanctions by allowing HHS to wield its newly expanded authority to terminate, deny or withhold federal funds. 45 C.F.R. § 88.7(i)(3)(iv)-(v). Defendants erroneously contend that Plaintiffs are challenging the underlying statutes and they argue that the Rule merely "provides greater clarity" about those statutes. Mot. 31. But Plaintiffs do not challenge the underlying statutes. Rather, Plaintiffs challenge HHS's massive expansion of these laws via an invalid rule.

A. The Rule Is Unconstitutionally Coercive

The Rule is an unconstitutionally coercive "gun to the head." *NFIB*, 567 U.S. at 581. In *NFIB*, the Supreme Court explained that because "Medicaid spending accounts for over 20 percent of the average State's total budget, with federal funds covering 50 to 83 percent of those

[60] Defendants' new interpretation of the nondirective mandate is the subject of separate litigation, *see California*, 385 F. Supp. 3d 960, appeal docketed, No. 19-15974 (9th Cir. May 6, 2019).

costs," and because States "have developed intricate statutory and administrative regimes" in reliance on receiving that funding, the threatened loss of the funding impermissibly affords recipients "no real option but to acquiesce." *Id*. at 581–82. Here, the Rule is even more coercive than the threatened loss of Medicaid funding in *NFIB*. For one, the Rule threatens *all* funding under a vast array of health, education, and employment programs in the State, City, and County. *See supra* Facts IIIA-C. Additionally, the unbounded, discretionary nature of HHS's enforcement authority, *see* 84 Fed. Reg. at 23,272, impermissibly bootstraps the potential consequences of a Weldon violation to apply to two dozen now-expanded federal conscience laws. And whereas the conditions that could result in a loss of funding in *NFIB* were clear, the Rule is not. Given the billions of dollars of federal funding at stake, the loss of which would decimate public services in the country's most populous state and localities, the Rule constitutes "economic dragooning." *NFIB*, 567 U.S. at 581–82.

HHS itself previously recognized the constitutional problem that would arise if, in the name of enforcing long-standing and carefully limited federal conscience laws, the federal government asserted sweeping new authority to strip states of funding, as it has done here. App'x 396. This Court should recognize the same and hold that the Rule is unconstitutionally coercive.

B. The Rule Is Unconstitutionally Ambiguous

If Congress desires to condition Plaintiffs' receipt of federal funds, it "must do so unambiguously." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Because "[t]here can, of course, be no knowing acceptance [of federal funds] if a State is unaware of the conditions or is unable to ascertain what is expected of it," *id.*, courts evaluate statutes "from the perspective of a state official who is engaged in the process of deciding whether the State should accept [the] funds and the obligations that go with those funds." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006).

Contrary to Defendants' contention that the Rule merely "mirror[s]" existing federal law, 84 Fed. Reg. at 23,222, it changes the landscape of religious conscience objections, greatly expanding the power of objectors to deny care via the Rule's apparently unbounded definitions, which are untethered from prior constructions of the supposedly authorizing statutes. Defendants

concede that the Spending Clause demands that States be on "clear notice" as to their federal obligations. Mot. 32. This Rule fails that test. For example, it allows *any* "health care personnel" to deny medical care (or refuse to perform any action that has an "articulable connection" to furthering a procedure) without providing any information about the patient's medical condition or treatment options on the basis of "ethical[] or other reasons." 84 Fed. Reg. at 23,263. Given this sweeping and indefinite language, states and local governments cannot know whether they would violate the Rule if they take action against medical providers or programs that deny care or discriminate against their most vulnerable residents. *Clovis Unified Sch. Dist. v. Cal. Office of Admin. Hr'g*, 903 F.2d 635, 646 (9th Cir. 1990) ("broad interpretations of ambiguous language" in a funding condition are fundamentally unfair and violate the Spending Clause.); *City & Cty. of SF v. Sessions*, 372 F. Supp. 3d 928, 950 (N.D. Cal. 2019). The Rule's ambiguity is exacerbated by HHS's vague assurances that it will "harmonize" the Rule with federal laws such as EMTALA, without providing concrete guidance as to how Plaintiffs should address the interplay.

The Rule is also so broadly and vaguely written that it is impossible to ascertain how Plaintiffs should communicate with and monitor their sub-recipients' compliance (Cantwell Dec. ¶ 7), in a manner that effectively protects governmental funding. 84 Fed. Reg. at 23,180 ("[R]ecipients are responsible for their own compliance with Federal conscience and anti-discrimination laws and implementing regulations, *as well as for ensuring their sub-recipients comply with these laws*.") (emphasis added). This requirement jeopardizes the State's federal funding even if it had no notice or approval of a sub-recipient's violation. The Spending Clause does not allow such an outcome.[61]

C. Conditions on Funding Already Accepted

The federal government cannot "surpris[e] participating States with post-acceptance or

[61] For example, in the Title IX context, a federal funding recipient cannot be held vicariously liable for harassment perpetrated by its employee if it was not on notice of the harassment. *See Franklin v. Gwinnett Cty. Pub. Sch.*, 503 U.S. 60, 74-75 (1992) (holding school vicariously liable for teacher's harassment of student because it was on notice of teacher's discrimination and took no action); *Smith v. Metro. Sch. Dist. Perry Twp.*, 128 F.3d 1014, 1030 (7th Cir. 1997) (holding that "[t]o impute liability to a program or activity" based on one person's actions, "even if [the governmental entity] acted without notice" of the person's actions, "cannot be used to support a monetary award in a Spending Clause case").

'retroactive' conditions." *NFIB*, 567 U.S. at 582-83. Yet the Rule does just that. Congress conferred on HHS no authority to "alter, amend, or repeal" the federal conscience laws. *Cf.* Mot. 32-33. Nevertheless, the agency seeks to override the existing federal conscience protection framework, dramatically expanding not only those who are covered but also what activities are considered protected and how the laws are enforced. For example, Weldon, Church, and Coats-Snowe refer only to specific circumstances in which healthcare providers or certain enumerated healthcare entities may not be required to participate in abortions, sterilizations, or certain health service programs and research activities, but the Rule greatly expands the scope of the circumstances under which the federal conscience laws may be implicated.[62] This is a transformation in kind, not degree.

Public entities such as the State, City, and County accept federal funding with the expectation that they will receive the funds under existing agreements and under existing programs and conditions.[63] State and local programs that depend on pass-through funding would be crippled by being unable to expend anticipated funds because they cannot absorb a loss of such funding without a reduction in staffing, programs, and services.[64] Thus, a sudden disruption in anticipated federal funds would create budgetary and operational chaos for state and local agencies providing critical services for their residents.[65] Notably, DHCS, which administers the State's Medicaid program (Medi-Cal), and other federally funded healthcare programs, will receive more than $63 billion in federal funding for services and operations in Fiscal Year 2018-2019. But much of the Medi-Cal budget is expended up-front by the state in expectation of reimbursement from the federal government. Ghaly Dec. ¶¶ 11, 13. The reconditioning of

[62] Moreover, Defendants' unsupported reversal of their interpretation of Weldon as it relates to the State's abortion coverage requirement creates post-acceptance uncertainties as to what additional state laws and policies may also now be deemed to violate the Rule. Similarly, the January 18, 2019 "Notice of Violation" could, under the Rule, be deemed a "determination" that could "inform funding decision-making," even though it concluded that further remedial action against the State was not warranted. 84 Fed. Reg. at 23,177, 23,262.

[63] Ghaly Dec. ¶¶ 9-10; Sturges Dec. ¶¶ 6-7; Price Dec. ¶ 16; Parmelee Dec. ¶ 7; Nunes Dec. ¶ 11; Lorenz Dec. ¶¶ 22-23.

[64] Sturges Dec. ¶ 5; Ghaly Dec. ¶ 8, 16; Price Dec. ¶¶ 14-15; Parmelee Dec. ¶ 9; Nunes Dec. ¶ 10; Cervinka Dec. ¶¶ 8, 11, 13, 15; Toche Dec. ¶ 12; Lorenz ¶¶ 23-24; Cody ¶¶ 21-22.

[65] Ghaly Dec. ¶¶ 8, 10, 12, 14, 15, 17, 18; Sturges Dec. ¶ 6; Nunes Dec. ¶ 10, Cervinka Dec. ¶ 16; Colwell ¶¶ 11-14; Wagner ¶ 5; Colfax ¶ 23.

existing funding will harm the state's fisc because those funds would not be reimbursed.

D. The Conditions on Funding Are Unrelated to Conscience Objections

The Spending Clause requires that funding conditions "bear some relationship to the purpose of the federal spending," *New York v. United States*, 505 U.S. 144, 167 (1992), and be "reasonably calculated" to address the "particular . . . purpose for which the funds are expended." *Dole*, 483 U.S. at 208-09. "Conditions on federal grants might be illegitimate if they are unrelated to the federal interest in particular national projects or programs." *Id.* at 207 (quotations omitted). The Rule places various federal grants—such as those for Medicaid, HIV prevention, prevention of child abuse and neglect, foster care placement and adoptions assistance, energy assistance for low-income, elderly and disabled individuals, and many others—at risk even though the purposes of those statutes are wholly unrelated to the protection of conscience objections. Ghaly Dec. ¶¶ 8-9, 12-13. The Rule further jeopardizes funding for numerous labor and educational programs, which lack any nexus or relationship whatsoever to the Rule's healthcare restrictions. 84 Fed. Reg. at 23,170, 23,172; 76 Fed. Reg. at 9970; App'x 396; Sturges Dec. ¶¶ 5-8; Parmelee Dec. ¶¶ 5-9. And over 100 million dollars in grants to provide benefits and services to some of SF's neediest residents through programs such as TANF and Foster Care are at risk. Rosenfield Dec. ¶ 5. There is no nexus between these public benefits and religious refusals.

VII. THE RULE VIOLATES THE ESTABLISHMENT CLAUSE

The Rule violates the Establishment Clause principally because it elevates the religious beliefs of objectors over the rights, beliefs, and interests of providers and patients, and because it coerces religious exercise by requiring providers and patients to act in accordance with the objecting employees' religious beliefs. *See generally, e.g.*, *McCreary County v. ACLU of Ky.*, 545 U.S. 844, 860 (2005); *Lee v. Weisman*, 505 U.S. 577, 587 (1992); *Edwards v. Aguillard*, 482 U.S. 578, 584–85 (1987). That some of the statutes that the Rule invokes have been upheld, *cf.* Mot. 33-34, is of no moment because Plaintiffs do not challenge the statutes' constitutionality. Plaintiffs challenge the Rule, which wildly expands the statutes' reach in ways that cannot be squared with Establishment Clause proscriptions or with decisions upholding any statute.

A. The Rule Burdens Patients and Other Third Parties

Governmental accommodations of religion are permissible only if, among other constitutional requirements, they do not detrimentally affect third parties. *See, e.g.*, *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 729 n.37 (2014); *Cutter v. Wilkerson*, 544 U.S. 709, 720 (2005). If the government materially burdens or harms third parties when accommodating religious beliefs or exercise, it impermissibly prefers the religion of those who are benefited over the rights and interests of those who are burdened. *See, e.g.*, *Texas Monthly, Inc. v. Bullock*, 489 U.S. 1, 15 (1989). Thus, in *Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1985), the Supreme Court invalidated a state law requiring employers to accommodate Sabbatarians in all instances, because "the statute t[ook] no account of the convenience or interests of the employer or those of other employees who do not observe a Sabbath," thus impermissibly "command[ing] that . . . religious concerns automatically control over all secular interests at the workplace."[66]

Yet that is precisely what the Rule does: It not only requires Plaintiffs to accede to all religious objections but also mandates that only voluntarily accepted religious accommodations are permissible, affording objecting employees the unilateral and absolute ability to refuse an offered accommodation and to demand more. Plaintiffs, for example, manage hospitals, clinics, and complex health networks with thousands of employees. They maintain policies that are calibrated to accommodate employees' religious objections without harming patients or other employees, and without compromising standards of care, medical ethics, or operational needs. *See* Chen Dec. Ex. A; Weigelt Dec. ¶ 4; Lorenz Dec. ¶¶ 11, 18; Nguyen Dec. ¶ 4; Halladay Dec. ¶ 5; Tullys Dec. ¶ 9; Harris-Caldwell ¶16; Aizuss ¶¶ 17-29; Price ¶ 10. The Rule would supplant these policies and "relieve [workers] of the duty to work" whenever they have a religious reason

[66] Similarly, *Texas Monthly* invalidated a tax benefit for religious periodicals that "burden[ed] nonbeneficiaries markedly" and hence "provide[d] unjustifiable awards of assistance to religio[n]" that "cannot but conve[y] a message of [religious] endorsement" by increasing nonbeneficiaries' tax bills by the amount is needed to offset the benefit bestowed on subscribers to religious publications. And in *Hobby Lobby*, all nine Justices authored or joined opinions recognizing that harmful effects on nonbeneficiaries must be considered in evaluating religious accommodations. 573 U.S. at 693, 729 n.37; id. at 739 (Kennedy, J., concurring); *id*. at 745–46 (Ginsburg, J., dissenting, joined by Breyer, Kagan, & Sotomayor, JJ.); *see also United States v. Lee*, 455 U.S. 252, 261 (1982) (rejecting Amish employer's request for exemption from paying social-security taxes where exemption would impermissibly "operate[] to impose the employer's religious faith on the employees").

for not wanting to perform even essential job duties, "no matter what burden or inconvenience this imposes on the employer or fellow workers"—or on patients. *Caldor*, 472 U.S. at 708-09 (state law impermissibly imposed duty to accommodate even "when the employer's compliance would require the imposition of significant burdens on other employees required to work in the place of" religious objectors); Singh ¶¶ 8-13. And "[t]here is no exception . . . for special circumstances such as" emergencies in which the failure of even one team member to perform his or her duties would put patients' lives at risk. 472 U.S. at 709; Colwell Decl. ¶¶ 7-10.

In other words, the Rule "imposes on employers and employees an absolute duty to conform their business practices to the particular religious practices of the employee," *Caldor*, 472 U.S. at 709, drastically limiting Plaintiffs' ability even to ask about and plan for religious objections; permitting only voluntary transfers or scheduling changes for objecting employees when Plaintiffs do learn about the objections; requiring Plaintiffs to reassign other employees to cover the work that objecting employees refuse to perform, and to bear the resulting costs and burdens of double-staffing, Lorenz Dec. ¶ 18-19; and ultimately allowing patients to be denied needed care and information required for informed consent. These burdens are far more severe than those that required invalidation of the religious accommodations in *Caldor* and *Texas Monthly*. By requiring Plaintiffs to "adjust their affairs to the command of the State whenever [the Rule] is invoked by an employee," 472 U.S. at 709, the Rule violates the Establishment Clause.

The cases that the government cites (Mot. 34-35) do not alter the controlling constitutional standards. *In Kong v. Scully*, 341 F.3d 1132, 1134 (9th Cir. 2003), the accommodation did not harm patients or burden anyone else but instead enabled patients to get the care that they sought: The court upheld a law allowing medical reimbursements to healthcare institutions for "the nonmedical care of persons whose religious tenets lead them to reject medical services." *Id*. The court in *Chrisman v. Sisters of St. Joseph of Peace*, 506 F.2d 308, 311 (9th Cir. 1974), upheld a provision of Church ensuring that federal funding could not be used to compel a hospital to perform medical procedures against its religious mission, emphasizing that the provision preserved governmental "neutrality" with respect to religion. It did not, as here, give special privileges to religion or prefer particular religious views. *See infra* Sections VII.B.-C. *Doe v.*

Bolton, 410 U.S. 179, 198 (1973), did not address the legality of an unchallenged portion of a statute permitting a hospital to decline to provide abortions; rather, it held only that also requiring hospitals to establish a committee to approve abortions was unduly restrictive of patients' rights. And *Corporation of the Presiding Bishop of the Church of Latter-Day Saints v. Amos*, 483 U.S. 327, 339 (1987), supports Plaintiffs, underscoring that the Establishment Clause forbids government to "give[] the force of law to" employees' religious views by "requir[ing] accommodation by the employer regardless of the burden which that constitute[s] for the employer or other employees," or for patients.[67]

B. The Rule Advances and Endorses Certain Religious Beliefs

The Rule also violates the Establishment Clause because the government may require accommodation of religion only to alleviate substantial government-imposed burdens on religious practice. *Cutter*, 544 U.S. at 720; *Cty of Allegheny v. ACLU Greater Pittsburgh Chapter*, 492 U.S. 573, 613 n.59 (1989); *Texas Monthly*, 489 U.S. at 15 (plurality opinion). When there is no "exceptional government-created burden[] on private religious exercise," or when the government goes beyond what is needed to alleviate burdens that it, itself, has imposed (*see Cutter*, 544 U.S. at 720), its action crosses the line of permissible religious accommodation and "devolve[s] into 'an unlawful fostering of religion,'" *Amos*, 483 U.S. at 334–35.

Thus, although the federal government may "lift[] a regulation that burdens the exercise of religion," *Amos* U.S. at 338, when it has imposed that burden to begin with, it may not broadly and absolutely compel *other* entities, whether private actors or state programs, to afford special solicitude to religion, *see City of Boerne v. Flores*, 521 U.S. 507, 532–33, 536 (1997).

Additionally, religious exercise is substantially burdened—and therefore may be subject to accommodation—only if the government "forc[es individuals] to choose between following the

[67] *Amos* concerned a church's firing of an employee who was not in religious good standing. The exemption from Title VII's bar on religious discrimination did not amount to unconstitutional religious favoritism because it avoided interference with church autonomy and internal church governance—core concerns under both the Establishment and Free Exercise Clauses that are not implicated when, as here, the regulated entities are not churches. *See Real Alternatives, Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 352 (3d Cir. 2017). And as the government acknowledges, Mot. 35, any harm to the employee in *Amos* resulted from the church's actions, not the government's, 483 U.S. at 337 & n.15. Here the Rule causes the harms.

tenets of their religion and receiving a governmental benefit . . . or coerce[s them] to act contrary to their religious beliefs by the threat of civil or criminal sanctions." *Navajo Nation v. U.S. Forest Serv.*, 535 F.3d 1058, 1070 (9th Cir. 2008) (applying Religious Freedom Restoration Act); *see also, e.g.*, *Henderson v. Kennedy*, 253 F.3d 12, 16–17 (D.C. Cir. 2001). The Rule is unconstitutionally expansive because it affords religious accommodations for objections that are merely religiously motivated. To comport with the Establishment Clause, the Rule would need at the very least to provide for individualized assessments to determine whether an objector's religious exercise is genuinely at issue and, if so, whether it is substantially burdened as a legal matter. The Rule, however, does none of that.

And finally, the Rule specially favors and protects certain denominations' religious beliefs in opposition to reproductive freedom and LGBT rights over faiths that hold alternative views on those subjects. *Cf.* Elliot N. Dorff, The Jewish Tradition: Religious Beliefs and Healthcare Decisions 10 (2002) (explaining that Jewish law requires preference for life of mother over fetus). It thus constitutes a denominational preference, triggering strict scrutiny and requiring that the Rule be invalidated. *See Larson v. Valente*, 465 U.S. 228, 246 (1982).

C. The Rule Coerces Patients and Healthcare Providers to Adhere to HHS's Favored Religious Practices and Entangles Government with Religion

"[T]he Constitution guarantees that government may not coerce anyone to support or participate in religion or its exercise," *Lee*, 505 U.S. at 587; *Inouye v. Kemna*, 504 F.3d 705, 712–13 (9th Cir. 2007), for "the machinery of the State" must not be used "to enforce a religious orthodoxy," *Santa Fe Independent School District v. Doe*, 530 U.S. 290, 312 (2000). The Rule does not "simply encourage" nondiscrimination, Mot. 35, but instead employs the threat of withholding or clawing back all HHS funds to coerce Plaintiffs to adhere to the religious beliefs and practices of every employee. In doing so, it also forces patients to live in accordance with those religious preferences, which the Establishment Clause flatly forbids. Relatedly, the Rule impermissibly entangles government with religion by making federal and state laws and local policies subservient to certain religious tenets, and by vesting in federal bureaucrats the religious authority to impose their preferred beliefs through discretionary enforcement. *See Larkin v.*

Grendel's Den, Inc., 459 U.S. 116, 126–27 (1982).

VIII. THE RULE VIOLATES EQUAL PROTECTION

The non-governmental plaintiffs in the *Santa Clara* action also challenge the Rule on equal protection grounds on behalf of their patients. The Rule repeatedly mischaracterizes medically-necessary healthcare procedures sought by transgender patients to treat gender dysphoria as "sterilization," inviting religious and moral objections to providing such care. *See* 84 Fed. Reg. at 23,178, 23,205. By targeting transgender patients' transition-related healthcare needs for religious and moral objection, the Rule intentionally discriminates based on sex, gender identity, and transgender status. It is binding precedent in this circuit that classifications based on gender identity or transgender status warrant heightened scrutiny. *See Karnoski v. Trump*, 926 F.3d 1180, 1200–01 (9th Cir. 2019). Additionally, such discrimination is a form of discrimination based on sex and merits heightened scrutiny for this reason, too. *See Norsworthy v. Beard*, 87 F. Supp. 3d 1104, 1119 (N.D. Cal. 2015) (denial of treatment for gender dysphoria constituted sex discrimination). First, a person's gender identity is a sex-related characteristic. *See, e.g.*, *Evancho v. Pine-Richland Sch. Dist.*, 237 F. Supp. 3d 267, 288-89 (W.D. Pa. 2017). Second, discrimination based on gender transition is discrimination based on sex, just as firing an employee because she converts from Christianity to Judaism "would be a clear case of discrimination 'because of religion.'" *Schroer v. Billington*, 577 F. Supp. 2d 293, 306 (D.D.C. 2008). Third, such discrimination is rooted in sex stereotypes, as a transgender person's "inward identity [does] not meet social definitions of masculinity [or femininity]" associated with one's birth-assigned sex. *Schwenk v. Hartford*, 204 F.3d 1187, 1201 (9th Cir. 2000). Accordingly, the burden rests with Defendants to demonstrate that the decision to facilitate the denial of care to transgender patients significantly furthers an exceedingly persuasive governmental interest. *Karnoski*, 926 F.3d at 1200-02. Defendants must also account for the harms that the Rule causes, including dignitary harms resulting from imposition of a second-class status. *See SmithKline Beecham v. Abbott Labs*., 740 F.3d 471, 482 (9th Cir. 2014).

The Rule fails any level of review because it lacks even a rational relationship to a legitimate governmental purpose, and Defendants cannot justify the harms to patients or to the

public health. The Rule arbitrarily elevates religious objections over the health and well-being of patients, contrary to federal law and the operational needs of healthcare providers. An official preference for certain religious beliefs—whether about transgender people and their healthcare or otherwise—cannot rise to the level of even a legitimate governmental interest, much less an exceedingly persuasive one, but instead bespeaks religious purpose, effect, and endorsement that violate the Establishment Clause. *See generally McCreary*, 545 U.S. at 859-60. Additionally, although the Rule speculates about the possibility that an increased number of healthcare providers will enter the field if permitted to deny certain types of care, 84 Fed. Reg. at 23,247, 23,250, HHS admits that it lacks data to support that assertion. Mot. 28-29; *see U.S. v. Virginia*, 518 U.S. 515, 533 (1996) (hypothesized justifications inadequate under heightened scrutiny). And even if those additional providers entered the field, discriminatory denials of care would persist, because the new providers would be ones who want to deny reproductive or transition-related care. HHS acknowledges that some patients will be disadvantaged, but concludes that hypothetical benefits of the Rule *to other people* justify it. 84 Fed. Reg. at 23,251-52. Even if the record provided evidence of those benefits, which it does not, that choice is an impermissible government decision to benefit certain patients at the expense of others. *See Romer v. Evans*, 517 U.S. 620, 633 (1996) (a bare preference for one group of people over another, simply because of who they are, is a "denial of equal protection in the most literal sense"). Government may not facilitate discrimination by private actors that is forbidden for the government to engage in directly. *See Palmore v. Sidoti*, 466 U.S. 429, 433 (1984); *Obergefell v. Hodges*, 135 S. Ct. 2584, 2602 (2015) (government may not put its imprimatur on private discrimination by enacting it into policy). The Rule's wide-ranging, harmful effects easily could be avoided with a rule that respects religious objections while ensuring patient health, as Plaintiffs' existing policies do. The existence of obvious less restrictive options dooms the Rule under the Equal Protection Clause.

IX. THE RULE VIOLATES PLAINTIFFS' PATIENTS' DUE PROCESS RIGHTS

The Fifth Amendment's Due Process Clause protects the right to make intimate decisions concerning procreation, abortion, contraception, gender identity, and self-definition as core to individuals' identity, dignity, autonomy, and ability to "shape [their] destiny." *Obergefell*, 135 S.

Ct. at 2593, 2597, 2599; *see Casey*, 505 U.S. at 857; *Lawrence v. Texas*, 539 U.S. 558, 574 (2003); *Carey v. Population Servs. Int'l*, 431 U.S. 678, 687 (1977). The non-governmental Plaintiffs in *Santa Clara* have adequately pleaded, S.C. Compl. ¶¶ 158-182, and demonstrated through extensive evidence in the administrative record and declarations, that the Rule violates these fundamental rights. Strict scrutiny applies to governmental actions that infringe the rights to contraception, *Carey*, 431 U.S. at 687, or to define and express one's gender identity, *Obergefell*, 135 S. Ct. at 2593; *Arroyo Gonzalez v. Rossello Nevarez*, 305 F. Supp. 3d 327, 334 (D.P.R. 2018); *Karnoski v. Trump*, 2017 WL 6311305, at *1 (W.D. Wash. Dec. 11, 2017), *vacated by stipulation*, Case No. 2:17-cv-01297 (Aug. 5, 2019).[68] And, before viability, the government "may not prohibit any woman from making the ultimate decision to terminate her pregnancy," *Gonzales*, 550 U.S. 124, 146 (2007), or impose an undue burden on that right, *Whole Woman's Health*, 136 S. Ct. at 2300, 2309. Where a law's burdens exceed its benefits, those burdens are by definition undue, and the law is unconstitutional. *Id.* at 2300, 2309-10, 2312, 2318; *see PPGNI v. Wasden*, No. 1:18-CV-00555, 2019 WL 3325800, at *6 (D. Idaho July 24, 2019) (declining dismissal where undue burden plausibly alleged).

The Rule violates these principles by empowering a broad class of individuals to deny or "hinder" access to abortion, contraception, and gender-affirming care. *Casey*, 505 U.S. at 851, 877, 894-96; *Carey*, 431 U.S. at 689 (invalidating law that did not ban contraception directly but limited distribution to pharmacists because it "clearly impose[d] a significant burden on the right of the individuals to use contraceptives" by decreasing access, competition, and privacy). The Constitution prohibits unjustified governmental interference, even when the government invokes the interests of others. *See Casey*, 505 U.S. at 894-96 (invalidating law enabling husband to

[68] The substantive protections of the Due Process Clause protect the right of all people to possess and control their own person, and to "define and express their identity." *Obergefell*, 135 S. Ct. at 2597; *see also Roberts v. U.S. Jaycees*, 468 U.S. 609, 619 (1984) (Constitution protects the "ability independently to define one's identity that is central to any concept of liberty"). Gender is fundamental to a person's identity; it is the internalized, inherent sense of who a person is (*e.g.*, male, female, or non-binary). Ettner Dec. ¶ 14; Valle Dec. ¶ 13. This is as true for a transgender person as for a non-transgender person. Ettner Dec. ¶ 14. A person's gender identity is so fundamental that government may not require them to abandon it. *Hernandez-Montiel v. INS*, 225 F.3d 1084, 1093 (9th Cir. 2000), *overruled on other grounds by Thomas v. Gonzales*, 409 F.3d 1177, 1187 (9th Cir. 2005).

prevent wife from obtaining abortion as his interest did not permit State to empower him with such "troubling degree of authority over his wife"). Further, the Rule will deter patients from seeking abortion, contraception, and gender-affirming care, based on stigma and fear of judgment, discrimination, and compromised care, especially in rural and low-income communities, *see supra* Facts III.B-C,[69] violating the right to make "choices central to personal dignity and autonomy," 505 U.S. at 851; *Lawrence*, 539 U.S. at 574; *see also Obergefell*, 135 S. Ct. at 2602. And the Rule incentivizes healthcare entities to curtail or eliminate this care, despite national shortages, increasing patients' risk of injury and death. *See supra* Facts III.B-C.[70]

Contrary to Defendants' contentions, *see* Mot. 36-37, constitutional protections apply when patients receive services through a government-subsidized program. *See Planned Parenthood of Greater Ohio v. Hodges*, 917 F.3d 908, 912-16 (6th Cir. 2019) (en banc) (holding while "the government may refuse to subsidize abortion services," a funding restriction may not "impose an undue burden on a woman's right to an abortion"); *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 988 (7th Cir. 2012). The government cannot use grant conditions to achieve purposes—pushing healthcare out of hospitals and enabling third-party denials of care—that are otherwise constitutionally impermissible. *See Hodges*, 917 F.3d at 911 (citing *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214 (2013)) ("The government may not deny an individual a benefit, even one an individual has no entitlement to, on a basis that infringes his constitutional rights."). Defendants' reliance on a brief quote from *Rust v. Sullivan*, 500 U.S. 173 (1991), which concluded that a particular funding scheme did not burden abortion rights, fails to refute Plaintiffs' specific showing that the Rule harms patients, will impede access to contraception, abortion, and gender-affirming care, and will deprive transgender patients of the ability to live in accordance with their gender identity for no legitimate

[69] *See also* S.C. Compl. ¶¶ 77-85, 163-165, 175-178. 165-167, 181-187; McNicholas Dec. ¶¶ 8, 23, 28-29, 44-47, 43; Phelps Dec. ¶ 34; Barnes Dec. ¶¶ 20-23, 30; Burkhart ¶22, 26, Ettner Dec. ¶¶ 14, 48-56; Valle Dec. ¶ 13; Shanker Dec. ¶¶ 11-12; Vargas Dec. ¶¶ 13-14; Henn Dec. ¶ 5; Bolan ¶¶ 8-10; Carpenter Dec. ¶ 11; Manley Dec. ¶ 8; Harker Dec. ¶ 14; Cummings Dec. ¶¶ 13-14; Lorenz Dec. ¶ 16; Sproul Dec. ¶ 13; Burkhart Dec. ¶ 22; McNicholas Dec. ¶ 43.

[70] *See also* S.C. Compl. ¶¶ 160-167, 174-182, 190-191, 194-198; Phelps Dec. ¶¶ 18, 29, 30, 35, 49; Backus Dec. ¶¶ 27-39; McNicholas Dec. ¶¶ 19, 27; Shafi Dec. ¶¶ 12-15, 20; Shanker Dec. ¶¶ 13-15; Valle Dec. ¶¶ 16-23; Cummings Dec. ¶¶ 15-19; Manley Dec. ¶¶ 10-13.

purpose, failing any level of scrutiny and imposing an unconstitutional undue burden.

X. THE RULE VIOLATES PLAINTIFFS' PATIENTS' FREE SPEECH RIGHTS

The non-governmental plaintiffs in *Santa Clara* also seek summary judgment on their claim that the Rule violates patients' free speech rights. The Rule impermissibly chills LGBT patients from being open about their gender identity and transgender status, seeking gender-affirming care, and expressing themselves in a manner consistent with their gender identity. Because the Rule targets patients' constitutionally protected speech and expression based on content and viewpoint, it violates the First Amendment. Courts have long held that disclosing one's gender identity or sexual orientation—sometimes referred to as "coming out"—is protected First Amendment expression.[71] Expression of gender identity through one's appearance also is protected expression. *See Doe ex rel. Doe v. Yunits*, 2000 WL 33162199, at *3 (Mass. Super. Oct. 11, 2000). A regulation may impermissibly "burden speech" even if it "stops short of prohibiting it." *Doe v. Harris*, 772 F.3d 563, 572 (9th Cir. 2014).

Here, the Rule has the "inevitable effect of burdening," *Doe*, 772 F.3d at 574, patients' disclosure of their transgender status and gendered expression because they will now reasonably fear denial of healthcare should they make such disclosures, *see Mendocino Envtl. Ctr. v. Mendocino Cty.*, 192 F.3d 1283, 1300 (9th Cir. 1999) (governmental action violates First Amendment if it causes a person of "ordinary firmness" to self-censor). The Rule burdens speech based on content and viewpoint—including by attaching different consequences to the same speech depending on the identity of the speaker, which is a form of impermissible viewpoint discrimination, *see Police Department of Chicago v. Mosley*, 408 U.S. 92, 96 (1972)—thus subjecting the Rule to "the most exacting scrutiny," *Texas v. Johnson*, 491 U.S. 397, 412 (1989) (citation omitted). *See also R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992) (government may not burden speech "because of disapproval of the ideas expressed"); *Rosenberger v. Rector & Visitors of Univ. of Va.*, 515 U.S. 819, 829 (1995). For example, the Rule invites denial of

[71] *See Henkle v. Gregory*, 150 F. Supp. 2d 1067, 1075-77 (D. Nev. 2001); *Weaver v. Nebo Sch. Dist.*, 29 F. Supp. 2d 1279, 1284-85 (D. Utah 1998); *Karnoski*, 2017 WL 6311305, at *9; *Log Cabin Republicans v. United States*, 716 F. Supp. 2d 884, 926 (C.D. Cal. 2010), *vacated as moot*, 658 F.3d 1162 (9th Cir. 2011); *see also* Doc. 36, Case No. 5:19-cv-02916-NC, at 33-35.

treatment to a transgender woman who discloses her transgender status or engages in gendered expression common to all patients, such as by checking the box "female" at her physician's office—but not to a non-transgender woman at the same office who discloses her gender identity (cisgender) or checks the same box.

Defendants mischaracterize Plaintiffs' claims, incorrectly describing them as about "compelled speech" (Mot. 47-48). Quite the opposite. The Rule *chills* LGBT patients' protected speech and expression, coercing them to stay in the closet and self-censor about medical histories and needs, harming both their own health and the public health.[72] Many LGBT patients already fear healthcare providers and are not "out" to their healthcare providers because of past experiences of anti-LGBT bias. Shanker Dec. ¶¶ 10-11; Henn Dec. ¶ 3; *see* Ettner Dec. ¶ 55; *see Conant v. Walters*, 309 F.3d 629, 636-37 (9th Cir. 2002) (recognizing, in a First Amendment challenge, that "barriers to full disclosure would impair diagnosis and treatment"). The Rule's unjustified chilling effect on patient speech distinguishes it from *Rust*, cited by Defendants. *Rust* concerned *physician* disclosures, not patient speech and expression long protected under the First Amendment; and it expressly declined to address First Amendment protections for the doctor-patient relationship. 500 U.S. at 200. The Rule lacks justification for the many harms that it will cause to patients and the public health, *see supra* Section III.A-D, goes well beyond readily available alternatives (like Plaintiffs' extant policies protecting religious objectors), and impermissibly burdens constitutionally protected speech.

XI. THE RULE VIOLATES SEPARATION OF POWERS

The City and the County seek summary judgment on their causes of action that the Rule violates the separation of powers established by the Constitution. These claims are conceptually similar to, but distinct from, Plaintiffs' excess-of-statutory-authority claims. *See City of Arlington v. F.C.C.*, 569 U.S. 290, 297 (2013) ("No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*."). Here, HHS "has not even

[72] Shanker Dec. ¶¶ 11-12; Henn Dec. ¶ 5; Bolan Dec. ¶¶ 8-11 (patients who do not disclose their transgender status may not be given necessary tests and screenings); Carpenter Dec. ¶ 5.

attempted to show that Congress authorized" the sweeping conditions it has imposed on broad swaths of federal funding. *City & Cty. of S.F. v. Trump*, 897 F.3d 1225, 1234 (9th Cir. 2018) (*CCSF*). Nor do Defendants cite any case law in support of their conclusory argument that the Rule comports with this "integral part of the Founders' design." *Id.* at 1232.

"The United States Constitution exclusively grants the power of the purse to Congress," not the Executive Branch. *CCSF*, 897 F.3d at 1231; *see also In re Aiken Cty.*, 725 F.3d 255, 259 (D.C. Cir. 2013) (separation-of-powers "principles apply to the President *and subordinate executive agencies*") (emphasis added). "Congress's power to spend is directly linked to its power to legislate." *CCSF*, 897 F. 3d at 1232. That legislative power is exercised through a "step-by step, deliberate and deliberative process" that cannot be unilaterally altered or amended by the Executive Branch. *I.N.S. v. Chadha*, 462 U.S. 919, 959 (1983). Congress may give agencies some discretion in deciding how to use appropriated funds, but that discretion necessarily is cabined by the scope of the delegation. *City of Arlington*, 569 U.S at 297-98. Imposing conditions on federal funds is a power that the Constitution grants to Congress alone. *See Dole*, 483 U.S. at 206. The Executive Branch, therefore, "does not have unilateral authority to refuse to spend . . . funds" that have been appropriated by Congress "for a particular project or program." *In re Aiken Cty.*, 725 F.3d at 261 n.1. But HHS seeks to do precisely that. It threatens to withhold billions of dollars of critical federal funds if Plaintiffs fail to comply with the Rule.

Congress has not so authorized. Church places conditions only on recipients of funds under the "Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act." 42 U.S.C. §300a-7. But the Rule imposes conditions on recipients of any HHS funds. Weldon conditions receipt of funds appropriated in the specified Act only on nondiscrimination by a "health care entity," as defined in the Act, with respect to refusal to "provide, pay for, provide coverage of, or refer for abortions." 132 Stat. 2981, 3118, Sec. 507(d). But the Rule imposes conditions on those funds for "health care entit[ies]" to whom Weldon does not apply, *see supra* Section III.B, and based on actions and activities unrelated to abortions. Similarly, Coats-Snowe applies to all federal funds, but only with respect to the physicians, medical residents, and other health professional trainees with

respect to refusals to perform, or learn how to perform, abortions. 42 U.S.C. § 238n. None of these statutes delegates *any* authority to HHS to interpret or enforce them. Yet HHS has arrogated to itself the authority to impose conditions on all HHS funds related to the operation of entities not covered by these statutes for behavior not regulated by them, and to investigate and adjudicate compliance with its self-created conditions.

In doing so, not only is HHS acting in excess of its statutory authority, *see supra* Section III.B, but it is also amending federal conscience laws without any authority to do so, unilaterally adding funding conditions, thus usurping the role of Congress and violating separation of powers principles. *Clinton v. City of New York*, 524 U.S. 417, 439 (1998). HHS is impermissibly using appropriated funds in a way that effectively alters the terms of the anchoring statutes, which Congress has "finely wrought and exhaustively considered" via the legislative process. *Id.* at 439-40. The Rule's radical departure from the statutes that ostensibly authorize it places it well outside any authority Congress has delegated. "In this instance, because Congress has the exclusive power to spend and has not delegated authority to the Executive to condition new grants on compliance with" the refusal laws, its "'power is at its lowest ebb.'" *CCSF*, 897 F.3d at 1233.

XII. THE COURT SHOULD VACATE THE RULE

The Court should vacate the Rule because it is contrary to law and unconstitutional. 5 U.S.C. § 706(2)(A)-(B); *Regents of Univ. of Cal. v. U.S. Dep't of Homeland Sec.*, 908 F.3d 476, 511 (9th Cir. 2018) ("'[W]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.'"); *All. for the Wild Rockies v. United States*, 907 F.3d 1105, 1121-1122 (9th Cir. 2018) ("[O]rdinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid.").

Alternatively, the Court should declare that the Rule is unlawful and issue a nationwide injunction prohibiting Defendants from implementing or enforcing the Rule, or taking any actions to enforce the underlying statutes in a manner contrary to the Court's opinion. Defendants argue that a "nationwide remedy" is inappropriate (Mot. 39), but Plaintiffs have demonstrated that nationwide relief is necessary to "give [the] prevailing parties the relief to which they are

entitled." *E. Bay Sanctuary Covenant v. Trump*, 932 F.3d 742, 779 (9th Cir. 2018) (citation omitted). "Plaintiffs have established injury that reaches beyond the geographical bounds of the Northern District of California." *Regents of Univ. of Cal. v. U.S. Dep't of Homeland Sec.*, 279 F. Supp. 3d 1011, 1049 (N.D. Cal. 2018) (Alsup, J.), *aff'd,* 908 F.3d 476 (9th Cir. 2018). Plaintiffs include healthcare providers located throughout the country who will be affected by the Rule, and three national associations of medical professionals whose members work in hundreds, if not thousands, of healthcare facilities nationwide. *See* Vargas Dec. ¶ 2; Phelps Dec. ¶ 3; Harker Dec. ¶ 2. If implemented anywhere, the Rule will frustrate the missions of these Plaintiffs, and undermine access to critical healthcare throughout the country. Backus Dec. ¶ 11; Vargas Dec. ¶¶ 1-2, 10; Harker Dec. ¶¶ 1, 6, 9, 10.[73]

Moreover, the Court should reject Defendants' conclusory severance argument. Defendants' failure to suggest which parts of the Rule should be severed makes it impossible to determine whether HHS "would have adopted the severed portion on its own." *New Jersey v. EPA*, 517 F.3d 574, 584 (D.C. Cir. 2008). Although the Rule declares that any invalid provision should be severed, 84. Reg. at 23,272, "[w]hether the offending portion of a regulation is severable depends upon the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broadcasters Ass'n v. F.C.C.*, 236 F.3d 13, 22 (D.C. Cir. 2001). Here, the Rule's provisions are so intertwined and the provisions Plaintiffs challenge are so central to its operation that the entire Rule must be vacated. At a minimum, if the Court vacates parts of the Rule but believes others may be severable, Plaintiffs request the opportunity to brief the issue after receiving the benefit of the Court's judgment regarding which parts of the Rule are invalid.

CONCLUSION

The Court should grant Plaintiffs' motion, vacate the Rule, and deny Defendants' motion.

[73] No case cited by Defendants involved *vacatur*. And those addressing nationwide injunctions held only that such injunctions must be supported by the record. *Azar*, 911 F.3d at 584; *CCSF*, 897 F.3d at 1244-45. *Azar* and *CCSF* approved nationwide relief "when 'necessary to give Plaintiffs a full expression of their rights.'" *CCSF*, 897 F.3d at 1244 (citation omitted); *accord Azar*, 911 F.3d at 582. Plaintiffs have demonstrated that nationwide relief is necessary here.

Respectfully Submitted,

Dated: September 12, 2019

XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS
Supervising Deputy Attorney General

/s/ Neli N. Palma

NELI N. PALMA
KARLI EISENBERG
STEPHANIE YU
Deputy Attorneys General
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

Dated: September 12, 2019

DENNIS J. HERRERA
City Attorney
JESSE C. SMITH
RONALD P. FLYNN
YVONNE R. MERÉ
SARA J. EISENBERG
JAIME M. HULING DELAYE
Deputy City Attorneys

By: */s/ Sara J. Eisenberg*

SARA J. EISENBERG
Deputy City Attorney
Attorneys for Plaintiff City and County of San Francisco

Dated: September 12, 2019

By: */s/ Lee H. Rubin*

LEE H. RUBIN
lrubin@mayerbrown.com
Mayer Brown LLP
Two Palo Alto Square, Suite 300
3000 El Camino Real
Palo Alto, California 94306-2112
Tel: (650) 331-2000

MIRIAM R. NEMETZ*
mnemetz@mayerbrown.com
NICOLE SAHARSKY*
nsaharsky@mayerbrown.com
ANDREW TAUBER*
Mayer Brown LLP
1999 K Street, Northwest
Washington, DC 2006-1101
Tel: (202) 263-3000
Counsel for Plaintiffs County of Santa Clara, Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: September 12, 2019

By: */s/ Mary E. Hanna-Weir*

JAMES R. WILLIAMS
County Counsel
GRETA S. HANSEN
Chief Assistant County Counsel
LAURA S. TRICE
Lead Deputy County Counsel
MARY E. HANNA-WEIR
SUSAN P. GREENBERG
H. LUKE EDWARDS
Deputy County Counsels
mary.hanna-weir@cco.sccgov.org
Office of the County Counsel,
County of Santa Clara
70 West Hedding Street, East Wing, 9th Floor
San José, California 95110-1770
Tel: (408) 299-5900
Counsel for Plaintiff County of Santa Clara

Dated: September 12, 2019

By: */s/ Richard B. Katskee*

RICHARD B. KATSKEE*
katskee@au.org
KENNETH D. UPTON, JR.*
upton@au.org
Americans United for Separation of Church and State
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234
Counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: September 12, 2019

By: */s/ Genevieve Scott*

GENEVIEVE SCOTT*
gscott@reprorights.org
RABIA MUQADDAM*
rmuqaddam@reprorights.org
Center for Reproductive Rights
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605
Counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: September 12, 2019

By: */s/ Jamie A. Gliksberg*

JAMIE A. GLIKSBERG*
jgliksberg@lambdalegal.org
CAMILLA B. TAYLOR*
ctaylor@lambdalegal.org
Lambda Legal Defense and Education Fund, Inc.
105 West Adams, 26th Floor
Chicago, IL 60603-6208
Tel: (312) 663-4413

OMAR GONZALEZ-PAGAN*
ogonzalez-pagan@lambdalegal.org
Lambda Legal Defense and Education Fund, Inc.
120 Wall Street, 19th Floor
New York, NY 10005-3919
Tel: (212) 809-8585

PUNEET CHEEMA*
pcheema@lambdalegal.org
Lambda Legal Defense and Education Fund, Inc.
1776 K Street NW, 8th Floor
Washington, DC 20006
Tel: (202) 804-6245, ext. 596
Counsel for Plaintiffs Trust Women Seattle, Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBT+Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

** Admitted pro hac vice*

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XAVIER BECERRA, State Bar No. 118517
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
Supervising Deputy Attorney General
KARLI EISENBERG, State Bar No. 281923
STEPHANIE YU, State Bar No. 294405
NELI N. PALMA, State Bar No. 203374
Deputy Attorneys General
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7522
Fax: (916) 322-8288
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, vs. ALEX M. AZAR II, et al., Defendants.	No. C 19-02405 WHA No. C 19-02769 WHA No. C 19-02916 WHA
STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, vs. ALEX M. AZAR, et al., Defendants.	**PLAINTIFFS' REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**
COUNTY OF SANTA CLARA et al,, Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Date: October 30, 2019 Time: 8:00 AM Courtroom: 12 Judge: Hon. William H. Alsup Action Filed: 5/2/2019

In support of Plaintiffs' motion for summary judgment and in support of their opposition to Defendants' motion to dismiss or, in the alternative, for summary judgment, Plaintiffs respectfully request that the Court take judicial notice of the following under Federal Rules of Evidence, rule 201 and *Lee v. City of Los Angeles,* 250 F.3d 668, 688-89 (9th Cir. 2001) (stating that the court may take judicial notice of public records):

1. HHS Budget, available at https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf. A true and correct copy is attached hereto as Exhibit A.
2. HHS, Guidelines for Regulatory Impact Analysis (2016), available at https://aspe.hhs.gov/system/files/pdf/242926/HHS_RIAGuidance.pdf. A true and correct copy is attached hereto as Exhibit B.

Dated: September 12, 2019

Respectfully Submitted,

XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS
Supervising Deputy Attorney General

/s/ Neli Palma

NELI PALMA
KARLI EISENBERG
STEPHANIE YU
Deputy Attorneys General
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

Exhibit A to the Request for Judicial Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 INDEPENDENCE AVENUE S.W., WASHINGTON, D.C. 20201

THIS DOCUMENT IS ALSO AVAILABLE AT HTTP://WWW.HHS.GOV/BUDGET

TABLE OF CONTENTS

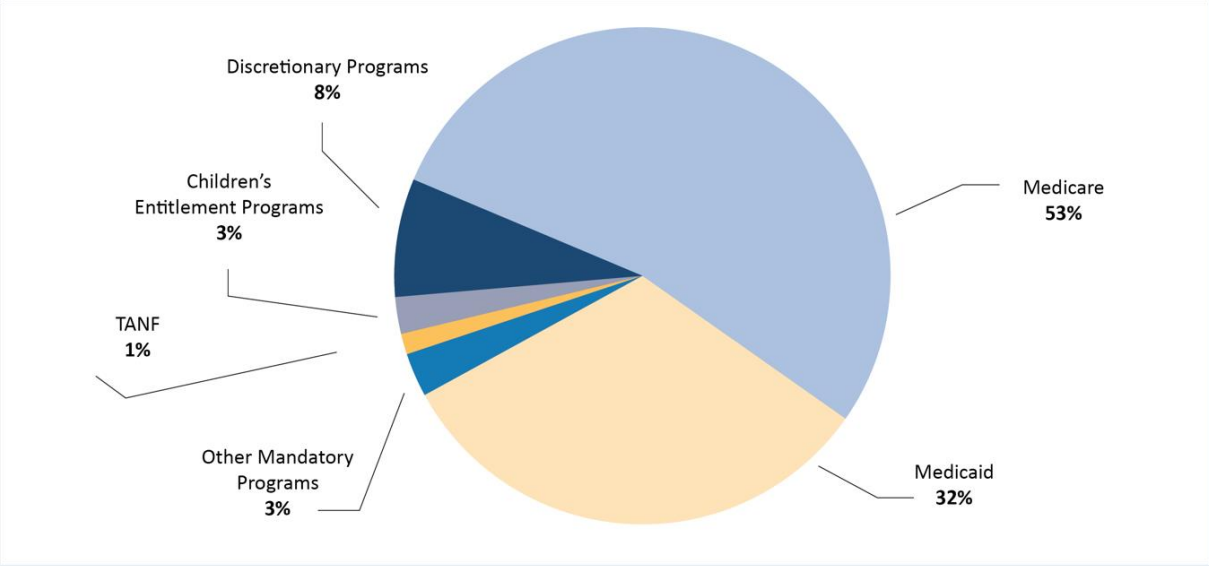
PUTTING AMERICA'S HEALTH FIRST

FY 2020 President's Budget for HHS

dollars in millions	2018	2019/1	2020
Budget Authority /2	1,176,503	1,274,242	1,292,523
Total Outlays	1,120,647	1,230,614	1,286,434
1/ The FY 2019 funding level reflects FY 2019 Enacted for all of HHS except for FDA, IHS, and small components of CDC and NIH, which reflect the FY 2019 Annualized CR, including any funding anomalies and directed or permissive transfers (where applicable). 2/ The Budget Authority levels presented here are based on the Appendix, and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.			

COMPOSITION OF THE FY 2020 BUDGET

$1,286 Billion in Outlays



General Notes

Numbers in this document may not add to the totals due to rounding. Budget data in this book are presented "comparably" to the FY 2020 Budget, since the location of programs may have changed in prior years or be proposed for change in FY 2020. This approach allows increases and decreases in this book to reflect true funding changes. The FY 2019 and FY 2020 mandatory figures reflect current law and mandatory proposals reflected in the Budget.

PUTTING AMERICA'S HEALTH FIRST

The mission of the U.S. Department of Health and Human Services (HHS) is to enhance and protect the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

The President's Fiscal Year (FY) 2020 Budget supports HHS's mission by prioritizing key investments that work towards fulfilling the Administration's commitments to improve American health care, address the opioid crisis, lower the cost of drugs, and streamline federal programs. The Budget reforms the Department's programs to better serve and safeguard the American people, while prioritizing key investments within them.

The Budget proposes $87.1 billion in discretionary budget authority and $1.2 trillion in mandatory funding for HHS. It reflects HHS's commitment to making the federal government more efficient and effective by focusing spending in areas with the highest impact.

REFORM, STRENGTHEN, AND MODERNIZE THE NATION'S HEALTH CARE SYSTEM

Reforming the Individual Market for Insurance

The Budget proposes bold reforms to build a stronger health care system and fix the damage done by Obamacare. These reforms return the management of health care to the states, which are more capable of tailoring programs to their unique markets, increasing options for patients and providers, and promoting financial stability and responsibility, while protecting people with pre-existing conditions and high health care costs.

The Budget includes proposals to make it easier to open and use Health Savings Accounts and reform the medical liability system to allow providers to focus on patients instead of lawsuits.

Lowering the Cost of Prescription Drugs

Putting America's health first includes improving access to safe, effective, and affordable prescription drugs. The Budget proposes to expand the Administration's work to lower prescription drug prices and reduce beneficiary out-of-pocket costs. The Administration has proposed and, in many cases, made significant strides to implement bold regulatory reforms to increase competition, improve negotiation, create incentives to lower list prices, reduce out-of-pocket costs, improve transparency, and end foreign free-riding. Congress has already taken bipartisan action to end pharmacy gag clauses, so patients can work with pharmacists to lower their out-of-pocket costs. The Budget proposes to:

- Stop regulatory tactics used by brand manufacturers to impede generic competition;
- Ensure federal and state programs get their fair share of rebates, and enact inflation penalties to prevent the growth of prescription drug prices beyond inflation;
- Improve the Medicare Part D program to lower seniors' out-of-pocket costs, create an out-of-pocket cap for the first time, and end the incentives that reward list price increases;
- Improve transparency and accuracy of payments under Medicare Part B, including imposing payment penalties to discourage pay-for-delay agreements; and
- Build on America's successful generic market with a robust biosimilars agenda, by improving the efficient approval of safe and effective biosimilars, ending anti-competitive practices that delay or restrict biosimilar market entry, and harnessing payment and cost-sharing incentives to increase biosimilar adoption.

Reforming Medicare and Medicaid

Millions of Americans rely on Medicare and Medicaid for their health care. The Budget supports reforms to make these programs work better for the people they serve and reduce unnecessary spending. The FY 2020 Medicare budget aligns incentives within the Part D program to lower drug costs, continues to drive Medicare toward a value-based payment system, and combats the opioid crisis. The FY 2020 Medicaid budget provides additional flexibility to states, puts Medicaid on a path to fiscal stability by restructuring its financing and reducing waste, and refocuses on the low-income populations Medicaid was originally intended to serve: the elderly, people with disabilities, children, and pregnant women.

Paying for Value

The Administration is focused on ensuring federal health programs produce quality outcomes and results at the lowest possible cost for the American people. The Budget supports an expansion of value-based payments in Medicare. That expansion, along with implementation of a package of other reforms, will improve quality, promote competition, reduce the federal burden on providers and patients, and focus payments on value instead of volume or site of service. Two of these reforms are: 1) a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers; and, 2) a consolidated hospital quality program in Medicare to reduce duplicative requirements and create a focus on driving improvements in patients' health outcomes.

PROTECT THE HEALTH OF AMERICANS WHERE THEY LIVE, LEARN, WORK, AND PLAY

Combating the Opioid Crisis

The Administration has made historic investments to address opioid misuse, abuse, and overdose, but significant work must still be done to fully turn the tide of this public health crisis. The Budget supports HHS's five-part strategy to:

- Improve access to prevention, treatment, and recovery services, including the full range of medication-assisted treatments;
- Better target the availability of overdose-reversing drugs;
- Strengthen our understanding of the crisis through better public health data and reporting;
- Provide support for cutting edge research on pain and addiction; and
- Improve pain management practices.

The Budget provides $4.8 billion to combat the opioid overdose epidemic. The Substance Abuse and Mental Health Services Administration (SAMHSA) will continue all current opioid activities at the same funding level as FY 2019, including the successful State Opioid Response Program and grants, which had a special focus on increasing access to medication-assisted treatment - the gold standard for treating opioid addiction. The Budget also provides new funding for grants to accredited medical schools and teaching hospitals to develop substance abuse treatment curricula.

In FY 2020, the Health Resources and Services Administration (HRSA) will continue to make investments to address substance abuse, including opioids abuse, through the Rural Communities Opioid Response Program, the National Health Service Corps, behavioral health workforce programs, and the Health Centers Program.

Medicare and Medicaid policies and funding will also play a critical role in combating the opioid crisis. The Budget proposes allowing states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder. The Budget also proposes to set minimum standards for Drug Utilization Review programs, allowing for better oversight of opioid dispensing in Medicaid. Additionally, it proposes a collaboration between the Centers for Medicare & Medicaid Services and the Drug Enforcement Administration to stop providers from inappropriate opioid prescribing.

Ending the HIV Epidemic: A Plan for America

Recent advances in HIV prevention and treatment create the opportunity to not only control the spread of HIV, but to end the epidemic of the disease in America. By accelerating proven public health strategies, HHS will aim to reduce new infections by 90 percent within ten years, ending the epidemic in America. The Budget invests $291 million in FY 2020 for the first phase of this initiative, which will target areas with the highest infection rates with the goal of reducing new diagnoses by 75 percent in five years.

This effort focuses on investing in existing, proven activities and strategies and putting new public health resources on the ground, with collaboration across many parts of HHS. This initiative includes a new $140 million investment in the Centers for Disease Control and Prevention (CDC) to test and diagnose new cases, rapidly link newly infected individuals to treatment, connect at-risk individuals to pre-exposure prophylaxis (PrEP), expand HIV surveillance, and directly support states and localities in the fight against HIV.

Clients receiving medical care through the Ryan White HIV/AIDS Program (RWHAP) were virally suppressed at a record level of 85.9 percent in 2017. The Budget includes $70 million in new funds for RWHAP within HRSA to increase direct health care and support services, further increasing viral suppression among patients in the target areas. The Budget includes

$50 million in HRSA for expanded PrEP services, outreach, and care coordination in community health centers. Additionally, the Budget also prioritizes the reauthorization of RWHAP to ensure federal funds are allocated to address the changing landscape of HIV across the United States.

For the Indian Health Service (IHS), the Budget includes $25 million in new funds to screen for HIV and prevent and treat Hepatitis C, a significant burden among persons living with HIV/AIDS. The initiative also leverages the National Institutes of Health's regional Centers for AIDS Research to refine implementation strategies to assure effectiveness of prevention and treatment interventions.

Together, these HHS investments will be the first step towards ending the HIV epidemic in America and saving hundreds of thousands of lives.

In addition to this effort, the Budget funds other activities that address HIV/AIDS including $54 million for the Minority AIDS Initiative within the Office of the Secretary and $116 million for the Minority AIDS program in SAMHSA. These funds allow HHS to target funding to communities and individuals disproportionately impacted by HIV infection.

Prioritizing Biodefense and Preparedness

The Administration prioritizes the nation's safety, including its ability to respond to acts of bioterrorism, natural disasters, and emerging infectious diseases. HHS is at the forefront of the nation's defense against public health threats. The Budget provides approximately $2.7 billion to the Public Health and Social Services Emergency Fund within the Office of the Secretary to strengthen HHS's biodefense and emergency preparedness capacity. The Budget also proposes a new transfer authority that will allow HHS to enhance its ability to respond more quickly to public health threats. Additionally, the Budget supports the government-wide implementation of the President's National Biodefense Strategy.

The Budget supports advanced research and development of medical countermeasures against chemical, biological, radiological, nuclear, and infectious disease threats, including pandemic influenza. The Budget also funds late-stage development and procurement of medical countermeasures for the Strategic National Stockpile and emergency public health and medical assistance to state and local governments. These investments protect our nation against health security threats such as anthrax, botulism, Ebola, and chemical, radiological, and nuclear agents.

STRENGTHEN THE ECONOMIC AND SOCIAL WELL-BEING OF AMERICANS ACROSS THE LIFESPAN

Promoting Upward Mobility

The Budget promotes independence and personal responsibility, supporting the proven notion that work empowers parents and lifts families out of poverty. To ensure Temporary Assistance for Needy Families (TANF) enables participants to work, the Budget includes a proposal both ensuring states will invest in creating opportunities for low-income families, and simplifying and improving the work participation rate states must meet under TANF. The Budget also proposes to create Opportunity and Economic Mobility Demonstrations, allowing states to streamline welfare programs and tailor them to meet the specific needs of their populations.

The Budget supports Medicaid reforms to empower individuals to reach self-sufficiency and financial independence. The Budget includes a proposal to permit states to include asset tests in identifying an individual's economic need, allowing more targeted determinations than are possible with the use of a Modified Adjusted Gross Income standard alone.

Improving Outcomes in Child Welfare

The Budget supports implementation of the Family First Prevention Services Act of 2018 and includes policies to further improve child welfare outcomes and prevent child maltreatment. The Budget also expands the Regional Partnership Grants program, which addresses the considerable impact of substance abuse, including opioid abuse, on child welfare.

Strengthening the Indian Health Service

The Budget provides $5.9 billion for IHS, which is an additional $392 million above the FY 2019 Continuing Resolution. The increase expands direct health care services across Indian Country, including hospitals and health clinics, Purchased/Referred Care, dental health, mental health and alcohol and substance abuse services. The Budget invests in new programs to improve patient care, quality, and oversight. It fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, ensuring tribes have the resources required to successfully manage

key programs. This investment reflects HHS's commitment to improve the health and well-being of American Indians and Alaska Natives.

FOSTER SOUND, SUSTAINED ADVANCES IN THE SCIENCES

Promoting Research and Prevention

The National Institutes of Health (NIH) is the leading biomedical research agency in the world, and its funding supports scientific breakthroughs that save lives. The Budget supports strategic investments in biomedical research and activities with significant national impact.

NIH launched the Helping to End Addiction Long-term (HEAL) initiative in April 2018 to advance research on pain and addiction. Toward this goal, NIH announced funding opportunities for the historic HEALing Communities Study, which will select several communities to measure the impact of investing in the integration of evidence-based prevention, treatment, and recovery across multiple health and justice settings. The Budget provides $500 million to continue the HEAL initiative in FY 2020.

The Budget supports a targeted investment in the National Cancer Institute to accelerate pediatric cancer research. Cancer is the leading cause of death from disease among children in the United States. Approximately 16,000 children are diagnosed with cancer in the United States each year. While progress in treating some childhood cancers has been made, the science and treatment of childhood cancers remains challenging. Through this initiative, NIH will enhance drug discovery, better understand the biology of all pediatric cancers, and create a national data resource for pediatric cancer research. This initiative will develop safer and more effective treatments, and provides a path for changing the course of cancer in children.

The new National Institute for Research on Safety and Quality (NIRSQ) proposed in the Budget will continue key research activities currently led by the Agency for Healthcare Research and Quality. These activities will support researchers by developing the knowledge, tools, and data needed to improve the health care system.

Addressing Emerging Public Health Challenges

CDC is the nation's leading public health agency, and the Budget supports its work putting science into action. Approximately 700 women die each year in the United States as a result of pregnancy or delivery complications or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Findings from Maternal Mortality Review Committees indicate that more than half of these deaths are preventable. The Budget supports data analysis on maternal deaths and efforts to identify prevention opportunities.

The United States must address emerging public health threats, both at home and abroad, to protect the health of its citizens. The Budget invests $10 million to support CDC's response to Acute Flaccid Myelitis (AFM), a rare but serious condition that affects the nervous system and weakens muscles and reflexes. With this funding, CDC will work closely with national experts, health care providers, and state and local health departments to thoroughly investigate AFM.

The Budget also provides $100 million for CDC's global health security activities. Moving forward, CDC will implement a regional hub office model and primarily focus their global health security capacity building activities on areas where they have seen the most success: lab and diagnostic capacity, surveillance systems, training of disease detectives, and establishing strong emergency operation centers. In addition, CDC will continue on-going efforts to identify health emergencies, track dangerous diseases, and rapidly respond to outbreaks and other public health threats around the world. These activities support the Department's Ebola response activities and ensure preparedness for other emerging health threats.

The Budget strengthens the health security of our nation and prioritizes CDC activities to save lives and protect people from health threats. The Budget continues CDC's support to state and local government partners in implementing programs, establishing guidelines, and conducting research to improve the health, safety and well-being of the United States.

Innovations in the Food and Drug Administration

The Food and Drug Administration (FDA) plays a major role in protecting public health by assuring the safety of the nation's food supply and regulating medical products and tobacco. The responsibility to advance public health places FDA at the forefront of scientific

innovation. The Budget provides $6.1 billion for FDA, which is an additional $643 million above the FY 2019 Continuing Resolution. The Budget includes resources to promote competition and foster innovation, such as modernizing generic drug review and creating a new medical data enterprise. The Budget advances digital health technology to reduce the time and cost of market entry for digital health technologies, supports FDA opioid activities at international mail facilities to increase inspections of suspicious packages, strengthens the outsourcing facility sector to ensure quality compounded drugs, and pilots a pathogen inactivation technology to ensure the blood supply continues to be safe. FDA will continue to modernize the food safety system in FY 2020.

PROMOTE EFFECTIVE AND EFFICIENT MANAGEMENT AND STEWARDSHIP

Almost one quarter of total federal outlays are made by HHS. The Department employs nearly 78,000 employees and administers more grant dollars than all other federal agencies combined. Efficiencies in HHS management have a tremendous impact on federal spending as a whole. The Budget demonstrates the Department's commitment to responsible stewardship of taxpayer dollars.

Advancing Fiscal Stewardship

HHS recognizes its immense responsibility to manage taxpayer dollars wisely. HHS ensures the integrity of all its financial transactions by leveraging financial management expertise, implementing strong business processes, and effectively managing risk.

HHS oversees Medicare and Medicaid, large federal health care programs serving millions of Americans. These activities must operate efficiently and effectively, both to rein in wasteful spending and to better serve beneficiaries. HHS is implementing actions such as enhanced provider screening, prior authorization, and sophisticated predictive analytics technology, to reduce improper payments in Medicare and Medicaid without increasing burden on providers. HHS continues to work with law enforcement partners to target fraud and abuse in health care. The Budget includes a series of proposals to strengthen Medicare and Medicaid oversight, including increasing prior authorization and enhancing Part D plans' ability to address fraud, and strengthening the Department's ability to recoup overpayments made to states on behalf of ineligible Medicaid beneficiaries. Finally, the Budget increases investment in health care fraud and abuse activities overall.

Implementing ReImagine HHS

HHS eagerly took up the call in the Administration's Government-wide Reform Plan to more efficiently and effectively serve the American people. HHS developed a plan –"ReImagine HHS"– organized around core goals, such as accelerating clinical innovation, maximizing talent, and facilitating independence. HHS has already identified the actions necessary to meet these goals, and is now working to implement them.

ReImagine HHS is identifying ways to reduce federal spending through more efficient operations. For example, the Buy Smarter initiative streamlines the procurement process by using new and emerging technologies.

HHS also recognizes the importance of a workforce that is equipped to thrive in the 21st century. Through a ReImagine HHS initiative – Maximize Talent – the Department is working to enhance employee engagement and recognition for high performance, as well as modernize human resources information technology infrastructure. These actions can further ensure HHS remains one of the best places to work in the federal government.

HHS BUDGET BY OPERATING DIVISION /1

dollars in millions	2018	2019	2020
Food and Drug Administration /2,4			
Budget Authority	2,397	2,956	3,329
Outlays	2,057	2,766	2,837
Health Resources and Services Administration			
Budget Authority	11,703	11,995	11,004
Outlays	11,058	11,488	11,864
Indian Health Service /2			
Budget Authority	5,741	5,815	6,104
Outlays	5,003	6,358	5,970
Centers for Disease Control and Prevention /2			
Budget Authority	8,741	7,909	6,767
Outlays	7,976	7,595	7,877
National Institutes of Health /2,3,4			
Budget Authority	36,396	38,201	33,669
Outlays	32,716	35,454	36,652
Substance Abuse and Mental Health Services Administration			
Budget Authority	5,539	5,609	5,535
Outlays	3,833	4,912	5,684
Agency for Healthcare Research and Quality /4			
Program Level	432	451	0
Budget Authority	333	338	0
Outlays	324	230	299
Centers for Medicare & Medicaid Services /5			
Budget Authority	1,042,407	1,137,937	1,169,091
Outlays	999,392	1,098,072	1,156,333
Administration for Children and Families			
Budget Authority	58,618	58,299	52,121
Outlays	53,897	56,267	53,208
Administration for Community Living			
Budget Authority	2,115	2,148	1,997
Outlays	1,942	2,223	2,238
Departmental Management /6			
Budget Authority	493	506	340
Outlays	447	996	503

HHS BUDGET BY OPERATING DIVISION /1

dollars in millions	2018	2019	2020
Non-Recurring Expense Fund			
Budget Authority	-	-400	-400
Outlays	242	-93	-201
Office of Medicare Hearings and Appeals			
Budget Authority	182	182	186
Outlays	185	235	186
Office of the National Coordinator			
Budget Authority	60	60	43
Outlays	54	111	48
Office for Civil Rights			
Budget Authority	40	38	30
Outlays	35	26	43
Office of Inspector General			
Budget Authority	84	87	82
Outlays	84	123	83
Public Health and Social Services Emergency Fund			
Budget Authority	2,033	2,625	2,667
Outlays	1,970	2,826	2,861
Program Support Center (Retirement Pay, Medical Benefits, Misc. Trust Funds)			
Budget Authority	750	731	749
Outlays	561	1,819	741
Offsetting Collections			
Budget Authority	-963	-631	-629
Outlays	-963	-631	-629
Other Collections			
Budget Authority	-166	-163	-163
Outlays	-166	-163	-163
Total, Health and Human Services			
Budget Authority	**1,176,503**	**1,274,242**	**1,292,523**
Outlays	**1,120,647**	**1,230,614**	**1,286,434**

1/ The Budget Authority (BA) levels presented here are based on the Appendix and potentially differ from the levels displayed in the individual Operating or Staff Division Chapters.

2/ FDA, IHS, ASTDR and SuperFund BA reflect the annualized level of the 2019 Continuing Resolution. IHS BA includes a $15 million funding anomaly.

3/ The 2020 Budget includes $256 million to consolidate the Agency for Healthcare Research and Quality's activities within the National Institutes of Health.

4/ FDA and NIH BA include the full allocations provided in 21st Century Cures Act.

5/ Budget Authority includes non-CMS Budget Authority for Hospital Insurance and Supplementary Medical Insurance for the Social Security Administration and the Medicare Payment Advisory Commission.

6/ Includes the Pregnancy Assistance Fund, the Health Insurance Reform Implementation Fund, and transfers from the Patient-Centered Outcomes Research Trust Fund; and payments to the State Response to the Opioid Abuse Crisis Account.

COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

dollars in millions	2018	2019	2020	2020 +/-2019
Discretionary Programs (Budget Authority):				
Food and Drug Administration /2,4,6	2,964	2,964	3,326	+362
Program Level	*5,361*	*5,499*	*6,142*	*+643*
Health Resources and Services Administration	6,730	6,853	5,853	-1,000
Program Level	*11,416*	*11,714*	*10,733*	*-981*
Indian Health Service /2	5,538	5,553	5,945	+392
Program Level	*6,890*	*6,905*	*7,297*	*+392*
Centers for Disease Control and Prevention /2, 7	6,899	6,553	5,277	-1,276
Program Level	*12,642*	*12,107*	*11,954*	*-153*
National Institutes of Health /2,3,4,5	36,151	38,010	33,477	-4,533
Program Level	*37,224*	*39,306*	*34,368*	*-4,939*
Substance Abuse and Mental Health Services Administration	5,507	5,597	5,535	-62
Program Level	*5,654*	*5,744*	*5,679*	*-65*
Agency for Healthcare Research and Quality /3	333	338	0	-338
Program Level	*432*	*451*	*0*	*-451*
Centers for Medicare & Medicaid Services	3,965	3,975	3,579	-395
Program Level	*6,260*	*6,531*	*6,255*	*-277*
Administration for Children and Families	22,997	23,210	18,327	-4,883
Program Level	*22,997*	*23,210*	*18,327*	*-4,883*
Administration for Community Living	2,136	2,169	2,033	-137
Program Level	*2,219*	*2,253*	*2,088*	*-164*
Office of the Secretary:				
General Departmental Management	470	481	340	-140
Program Level	*566*	*585*	*425*	*-160*
1/ Unless otherwise noted, the FY 2018 column reflects the 2018 Enacted levels (post UAC transfer and disaster supplemental).				
2/ FDA, IHS, ASTDR and Superfund (NIH) BA reflect the annualized level of the 2019 Continuing Resolution. IHS BA includes a $15 million funding anomaly.				
3/ The 2020 Budget includes $256 million to consolidate the Agency for Healthcare Research and Quality's activities within the NIH.				
4/ FDA and NIH BA include the full allocations provided in the 21st Century Cures Act.				

COMPOSITION OF THE HHS BUDGET DISCRETIONARY PROGRAMS

dollars in millions	2018	2019	2020	2020 +/-2019
Office of Medicare Hearings and Appeals	182	182	182	+0
Program Level	182	182	186	+4
Office of the National Coordinator	60	60	43	-17
Program Level	*60*	*60*	*43*	*-17*
Office for Civil Rights	39	39	30	-9
Program Level	48	52	53	+1
Office of Inspector General /6	82	87	80	-7
Program Level	*367*	*381*	*403*	*+22*
Public Health and Social Services Emergency Fund /7	2,557	2,631	2,667	+36
Program Level	*2,557*	*2,631*	*2,667*	*+36*
Discretionary HCFAC	745	765	792	+27
Accrual for Commissioned Corps Health Benefits	32	29	30	+1
Total, Discretionary Budget Authority	**97,388**	**99,496**	**87,515**	**-11,981**
NEF Cancellation and Rescissions	-240	-400	-400	-
Less One-Time Rescissions	*-6,773*	*-7,665*	*-19,748*	*-12,083*
Revised, Discretionary Budget Authority	**90,375**	**91,431**	**67,367**	**-24,064**
Discretionary Outlays	**87,695**	**97,167**	**96,902**	**-265**
5/ NIH BA reflects a $5 million directed transfer to OIG.				
6/ FDA BA reflects a $1.5 million directed transfer to OIG.				
7/ HHS administratively transferred the Strategic National Stockpile from CDC to ASPR in FY 2019. Funding in FY 2018 is comparably adjusted and includes a Secretarial transfer of $6.1 million to CDC for transition costs. Funding in FY 2019 does not reflect an additional Secretarial transfer of $6.1 million to CDC.				

COMPOSITION OF THE HHS BUDGET
MANDATORY PROGRAMS

	2018	2019	2020	2020 +/-2019
Mandatory Programs (Outlays):/1				
Medicare	582,011	644,827	683,932	+39,105
Medicaid	389,157	418,681	418,151	-530
Temporary Assistance for Needy Families /2	17,081	17,133	15,205	-1,928
Foster Care and Adoption Assistance	8,581	7,876	8,435	+559
Children's Health Insurance Program /3	17,282	18,634	16,882	-1,752
Child Support Enforcement	4,137	4,235	4,356	+121
Child Care Entitlement	2,358	2,819	3,562	+743
Social Services Block Grant	1,587	1,619	487	-1,132
Other Mandatory Programs	11,721	18,254	39,151	+20,897
Offsetting Collections	-963	-631	-629	+2
Subtotal, Mandatory Outlays	1,032,952	1,133,447	1,189,532	+56,085
Total, HHS Outlays	**1,120,647**	**1,230,614**	**1,286,434**	**+55,820**

1/ Totals may not add due to rounding.

2/ Includes outlays for TANF, and the TANF Contingency Fund. Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.

3/ Includes outlays for the Child Enrollment Contingency Fund.

Lowering the Cost of Prescription Drugs

For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. We have access to the greatest medicines in the world, but access is meaningless without affordability.

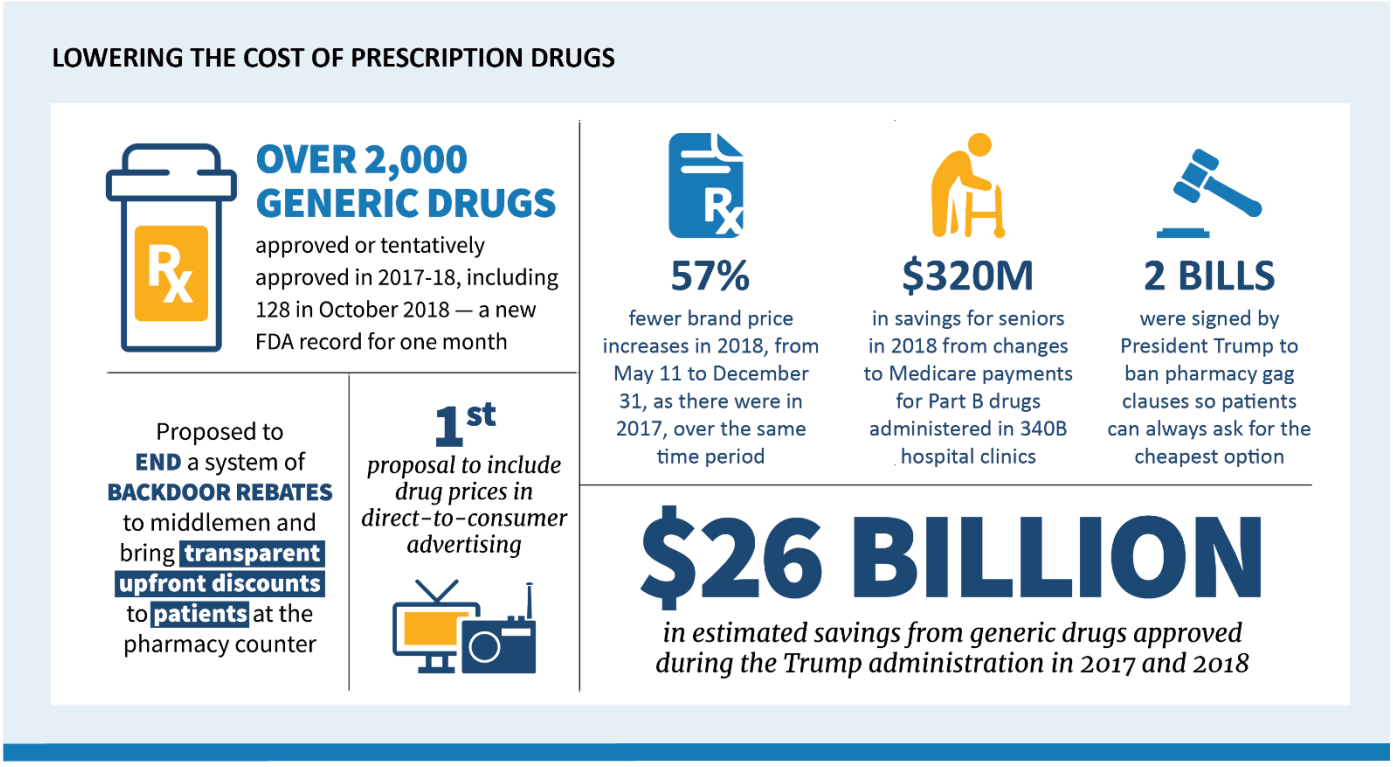
To address this issue, in May 2018, President Trump and Secretary Azar released the *American Patients First* Blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs, using four key strategies for reform: increased competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs.

Recognizing that the status quo is indefensible, HHS has rapidly taken administrative steps where the Department has authority to turn the President's vision into action. These actions include proposals to create competition for physician-administered drugs, improve competition and negotiation between Medicare's prescription drug plans, increase price transparency for drugs advertised on television, end the payment of kickbacks by drug companies and demanded by pharmacy benefit managers that are artificially driving up prices, ensure beneficiaries are benefiting from price concessions at the pharmacy counter, and address foreign free-riding so that Americans pay prices closer to what patients in other countries pay for the same drugs.

HHS will continue to use all of its administrative tools to achieve these goals, and recognizes Congress has the authority to implement more sweeping changes. The Administration looks forward to working with Congress on bipartisan solutions that lower costs, increase transparency, and protect patient access and safety.

The FY 2020 Budget legislative proposals complement the many successful administrative actions HHS has already taken to lower the cost of prescription drugs. These proposals:

- Protect seniors and taxpayers by modernizing Medicare Part D, and improving transparency and accuracy of payments under Medicare Part B;
- Ensure manufacturers pay their fair share of Medicaid rebates covering all price increases for a drug;
- Give the Health Resources and Services Administration (HRSA) the resources and



regulatory authority to better manage the 340B program; and
- Allow the Food and Drug Administration (FDA) to close loopholes in the drug approval and patent systems that allow manufacturers to engage in anti-competitive practices.

2020 LEGISLATIVE PROPOSALS

Increased Competition

Medicare

Reduce Average Sales Price Based Payments When the Primary Patent Expires to Increase Competition and Reduce Gaming

When a drug is about to go off patent, manufacturers often pay generic and biosimilar competitors to delay release of generic or biosimilar drugs, extending the time during which those drugs do not have competition. Likewise, when a biologic's 12-year market exclusivity period is set to expire, manufacturers may engage in other forms of patent disputes to block a competitor brand from coming to market. These "pay-for-delay" agreements and patent and exclusivity extending tactics slow the entry of generic, biosimilar, and biologic competition and keep drug prices high. Effective Calendar Year (CY) 2020, this proposal reduces payment for innovator drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action after the primary patent or market exclusivity period expires, whichever date is earliest. Once a competitor is commercially available, the Centers for Medicare & Medicaid Services (CMS) will pay for both innovator and competitor drugs at ASP plus 6 percent. These changes will create a financial disincentive to anti-competitive behavior. [Budget impact not available]

FDA

Reform Exclusivity for First Generics to Spur Greater Competition and Access

Currently, some generic drug applicants who file first limit competition by intentionally delaying seeking final approval in order to not trigger their 180-day exclusivity, thereby blocking subsequent generic competitors. Effective FY 2020, first-to-file generic applicants awarded a 180-day exclusivity period will not be able to unreasonably and indefinitely block subsequent generics from entering the market beyond the exclusivity period. The proposal will trigger an initial generic drug applicant's 180-day exclusivity when a subsequent application is tentatively approved, subject to specific conditions. [$960 million in Medicare savings over 10 years; $200 million in Medicaid savings over 10 years]

Amend the 180-Day Forfeiture Provision Addressing Failure to Obtain Tentative Approval

Currently, first applicants with a deficient application for a generic drug before FDA can avoid forfeiting their 180-day exclusivity by claiming the failure is caused by a change in or a review of the requirements for approval imposed after the date on which the application is filed. Some first applicants have taken advantage of ambiguities of this provision, avoiding forfeiture and delaying generic competition. This legislative proposal closes this loophole by limiting it to instances where the change in the requirements for approval was the only reason the applicant failed to obtain tentative approval. As with the other proposal for ending gaming of the exclusivity period, this measure will mean more generics on the market, faster. [Budget impact not available]

Codify FDA's Approach to Determining New Chemical Entity Exclusivity

Some stakeholders have questioned the validity of FDA's current approach to determining what constitutes a new chemical entity. This proposal codifies the approach FDA has taken in interpreting the law, known as "active moiety" approach. Five-year new chemical entity exclusivity will apply only to drugs with significant changes to their chemical structure compared to current drugs. This proposal codifies a narrow definition to avoid awarding exclusivity to products that do not represent a true innovation. [Budget impact not available]

Provide FDA Enhanced Authority to Address Abuse of the Petition Process

Sham citizen petitions, which are requests to FDA with the intent to delay approval of new generic drugs, do not promote generic drug competition. This proposal provides FDA with greater flexibility to summarily deny these petitions, and eliminate the mandatory 150-day response timeframe for these petitions, which FDA believes is unnecessary because all generic drug applications have goal dates under law and language is no longer needed to prevent delay of approval. These changes would speed the approval of new generic

drugs and increase competition. [Budget impact not available]

Encourage Biosimilar Development

Biosimilars must meet the same monograph standards issued by the U.S. Pharmacopeia as other non-biologic products, which include standards for strength, quality, packaging and labeling. This requirement can impede biosimilar innovation and competition. This proposal amends the Public Health Service Act so that biological products do not have to meet separate standards designed specifically for drugs. This change will make it easier for biosimilars to enter the market and increase competition, which is essential to reducing costs for biologic products. [No budget impact]

Better Negotiation

Medicare

Authorize the HHS Secretary to Leverage Medicare Part D Plans' Negotiating Power for Certain Drugs Covered Under Part B

Under Part B, providers have limited ability to negotiate for cheaper Part B drug prices. Beginning in CY 2020, this proposal provides the Secretary with authority to consolidate certain drugs currently covered under Part B into Part D when savings can be gained from price competition. The Secretary would not use this authority when it limits a beneficiaries' access to the drug or increases beneficiary cost-sharing. Beneficiary cost-sharing for any drugs shifted from Part B to Part D may be counted toward the Medicare Advantage out-of-pocket limit for plans that have a combined Part D benefit. Moving certain Part B drugs to Part D, when appropriate, will allow HHS to leverage Part D plans' negotiating power to bring down prices and lower patient out-of-pocket costs. [Budget impact not available]

Give the Secretary Authority to Contract with Pharmaceutical Manufacturers Entering into New Coverage Gap Discount Program Agreements on a Quarterly Basis

The Coverage Gap Discount Program was created in 2010 to close the Medicare Part D "donut hole" and requires manufacturers of brand drugs to provide discounts to beneficiaries during the coverage gap phase of the Part D benefit. Manufacturers are required to have a Coverage Gap Discount Program agreement with CMS before their drugs can be covered under Medicare Part D. Because manufacturers of new drugs are eager to get their drugs covered as soon as possible, they sometimes pay other manufacturers for the right to "piggy back" on their existing agreements, creating unnecessary costs to the system and administrative burden for CMS. This proposal allows the Secretary to initiate new contracts with pharmaceutical manufacturers on a quarterly, rather than an annual, basis. Increasing the frequency of the coverage gap discount program contracting process would ensure Medicare beneficiaries have continued access to a wide range of drugs, including newly approved drugs, without incurring additional costs for new manufacturers and the Medicare program. [Budget impact not available]

Improve Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates

CMS relies on manufacturers to submit their sales data to calculate ASPs for Part B drugs, but not all manufacturers are required to report such data. When manufacturers choose not to report ASPs, Medicare sets the payment rate based only on the reported ASP data, and the rate does not truly reflect the average price. If no manufacturers report ASPs for a drug, CMS must resort to pricing drugs using alternative, potentially inflated, measures of price such as wholesale acquisition cost (WAC). Beginning in 2020, this proposal requires all Part B drug manufacturers to report ASP data and gives the Secretary the authority to penalize manufacturers who do not report required data. The penalties would be similar to those currently used in Medicaid, where manufacturers face civil monetary penalties of up to $10,000 per day if data is not reported within 30 days of the end of the quarter. Requiring that all manufacturers of Part B drugs report ASP data improves the accuracy of CMS' drug payments and prevents CMS from relying on other, less accurate pricing mechanisms. [No budget impact]

Reduce Wholesale Acquisition Cost (WAC)-Based Payments

When ASP data are not available, Medicare pays for some single-source Part B drugs at 106 percent of WAC. Unlike an ASP, a drug's WAC does not incorporate rebates or other discounts. If discounts are available on these Part B drugs, Medicare is paying an inflated price compared to the ASP-based payment rate. Beginning in 2020, this proposal reduces the payment rate for single-source drugs, biologics, and biosimilars from 106 percent to 103 percent of WAC to reduce excessive payments. [Budget impact not available]

Medicaid

Clarify Definitions under the Medicaid Drug Rebate Program to Prevent Inappropriately Low Manufacturer Rebates

The Medicaid Drug Rebate Program allows state Medicaid agencies to receive manufacturer rebates, which offset some of their drug costs. Manufacturers must sign a rebate agreement with HHS to have their outpatient drugs covered by state Medicaid agencies. Ongoing misclassification of brand and generic drugs can result in lower rebates paid to the state and federal governments. This proposal clarifies the Medicaid definition of brand and over-the-counter drugs as well as drugs approved under a biologics license application by codifying existing regulations to ensure appropriate Medicaid drug rebates. [$347 million in savings over 10 years]

Test Allowing State Medicaid Programs to Negotiate Prices Directly with Drug Manufacturers and Set Formulary for Coverage

Even though prescription drug coverage is an optional Medicaid benefit that all states cover, states do not have the same flexible tools that commercial payers have to manage their prescription drug programs. As part of an Administration-wide effort to address the high cost of prescription drugs and provide states with more purchasing flexibility, this proposal includes a statutory demonstration authority allowing up to five states to test a closed formulary under which states negotiate prices directly with manufacturers, rather than participating in best price reporting or the Medicaid Drug Rebate Program. Participating states will include an appeals process so beneficiaries can access drugs outside the formulary based on medical necessity. [$410 million in savings over 10 years]

Impose Greater Penalties for Manufacturer Reporting of False Information or False Product Data under the Medicaid Drug Rebate Program

Current civil monetary penalties for drug manufacturers that submit false or late reports to the Medicaid Drug Rebate program are too low to provide an effective deterrent. This proposal would increase the civil monetary penalty paid by drug manufacturers for providing false or late reporting of information to the Medicaid Drug Rebate Program. It would also apply the same penalty to drug companies that make false product data submissions under the Medicaid Drug Rebate Program, such as misclassifying a brand drug as a generic drug. These changes will help to hold drug companies accountable for misleading or late disclosures. [Budget impact not available]

Exclude Brand Name and Authorized Generic Drug Prices from Medicaid's Federal Upper Limit

A state's Medicaid Federal Upper Limit (FUL) limits the federal match for pharmacy reimbursement to 175 percent of the weighted average of the Average Manufacturer Price of all therapeutically and pharmaceutically equivalent multiple-source drugs. When a state's FUL includes non-generic drug prices, it discourages generic prescribing. This proposal removes brand name and authorized generic drugs from the FUL calculation for drugs where there are generic options, reducing the maximum federal reimbursement. This change will encourage the use of generics by aligning the FUL with generic prices. [$980 million in savings over 10 years]

Clarify Authorized Generic Drug Sales under the Medicaid Drug Rebate Program

Some drug manufacturers may be inappropriately reducing their rebates to the Medicaid program. They interpret current law and regulations as allowing the inclusion of heavily discounted authorized generic sales to secondary manufacturers in the primary manufacturer's average price. This proposal clarifies that the primary manufacturer's average price must exclude these sales. As a result, manufacturers will no longer be able to exploit a loophole that allows them to pay inappropriately low drug rebates to the Medicaid program. [$150 million in savings over 10 years]

Incentives for Lower List Prices

Medicaid

Allow Rebates on Drugs that Exceed 100 Percent of the Average Manufacturer Price

When the Affordable Care Act (ACA) capped the Medicaid rebates from manufacturers at 100 percent of their Average Manufacturer Price, it enabled manufacturers to increase drug prices excessively without having to pay increased rebates. This proposal removes the ACA's cap on Medicaid rebates, allowing rebates to offset the cost of drugs when list prices exceed the rate of inflation. By eliminating the cap on Medicaid drug rebates that manufacturers pay for brand or generic drugs, this proposal protects Medicaid from the cost of excessive price spikes and incentivizes lower list prices. [Budget impact not available]

HRSA

Establish and Collect User Fees from 340B Drug Pricing Program Participating Covered Entities

Currently, HRSA lacks a reliable, continuous funding source for managing the 340B Drug Pricing Program. This proposal allows HRSA to collect a user fee set at 0.1 percent of total 340B drug purchases from participating covered entities, which would support improvements to the 340B public database, program audits and oversight, and the program's automated compliance management tool. [Budget impact not available]

Lowering Out-of-Pocket Costs

Medicare

Address Abusive Drug Pricing by Manufacturers by Establishing an Inflation Limit for Reimbursement of Part B Drugs

Manufacturers have dramatically increased prices for many Part B drugs in recent years because nothing currently restricts them from doing so. Effective CY 2020, this proposal caps the growth of the ASP payment of Part B drugs at the Consumer Price Index for all Urban Consumers (CPI-U). Each quarter when CMS establishes the ASP plus 6 percent payment amounts, CMS would pay the lesser of the actual ASP plus 6 percent or the inflation-adjusted ASP plus 6 percent as measured by the CPI-U. The base for a drug's price increase will be the initial ASP, or the first quarter of CY 2018 for drugs that had an ASP prior to the date of enactment. This proposal will protect Medicare beneficiaries from substantial price increases for individual drugs and save taxpayer dollars. [Budget impact not available]

Modify Payment for Drugs Hospitals Purchased through the 340B Discount Program and Require a Minimum Level of Charity Care for Hospitals to Receive a Payment Adjustment Related to Uncompensated Care

A CY 2018 Medicare regulation reduced outpatient hospital payment for 340B drugs from ASP plus 6 percent to ASP minus 22.5 percent, a conservative calculation of the average discount 340B hospitals receive. This has already lowered out-of-pocket costs for beneficiaries who use these drugs and pay the 20 percent copayment. However, the law requires the savings be redistributed across Medicare payments to outpatient hospitals in a budget neutral manner. Beginning in CY 2020, this proposal allows CMS to apply savings from these lower payments for drugs purchased under the 340B program in a non-budget neutral way. Hospitals providing at least 1 percent of patient care costs in uncompensated care will receive redistributed savings based on the percentage of all uncompensated care they provide compared with other outpatient hospitals. Hospitals not meeting that threshold will be ineligible for the redistribution, and the savings from their payment reduction will be returned to the Medicare Trust Funds. These changes will save money not just for Medicare, but ensure the savings from the 340B program are passed on to patients as the program intended. [No budget impact]

Eliminate Pass-Through Payments for Drugs, Biologicals, and Biosimilars

The current system of pass-through payments rewards new drugs, even if they offer no additional value or clinical benefit, unnecessarily increasing outpatient spending, and allowing for manufacturer gaming.

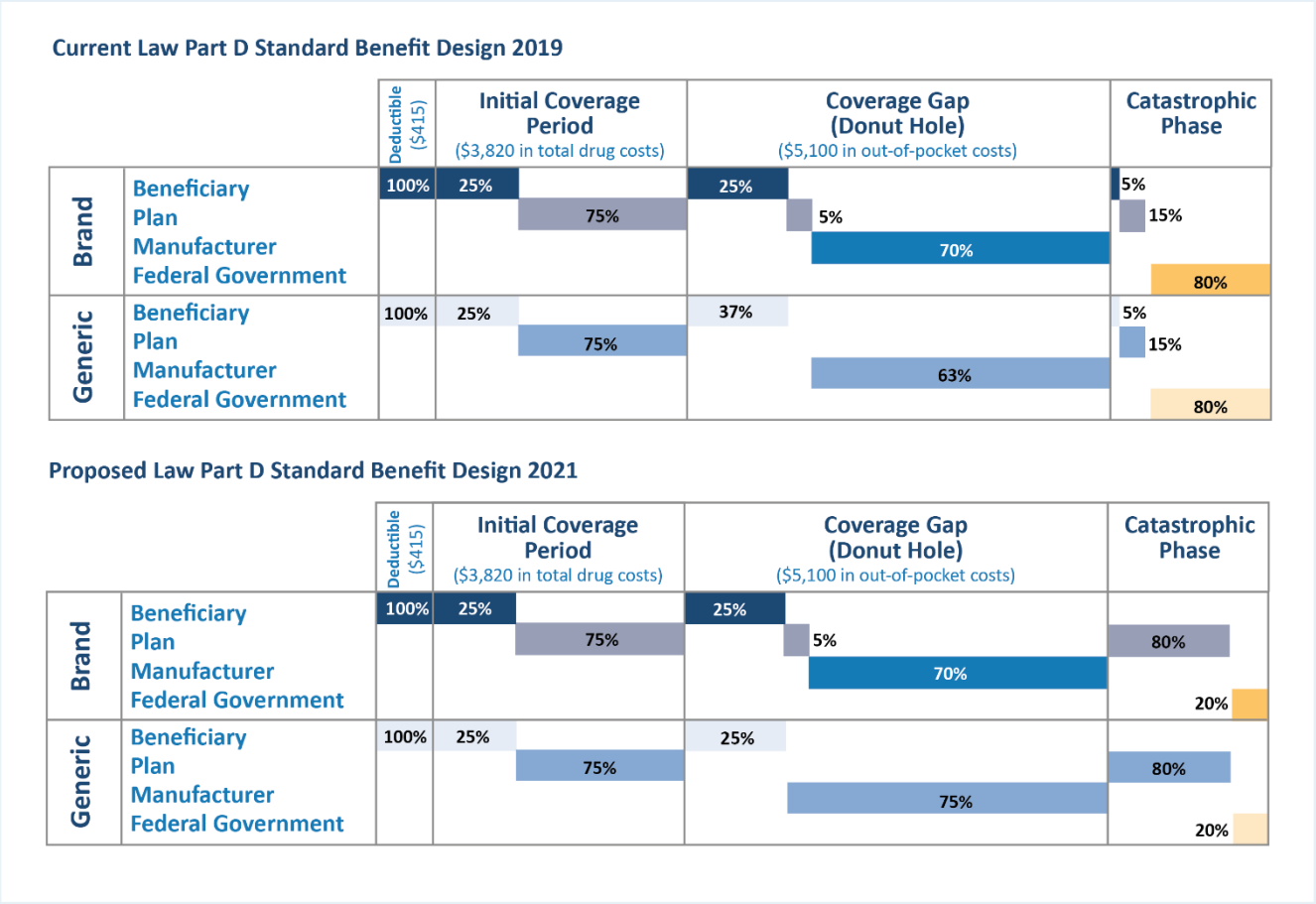
The Medicare Outpatient Prospective Payment System (OPPS) currently pays for a newly approved drug, biologic, or biosimilar at ASP plus 6 percent for three years when the cost exceeds a certain threshold. These payments are known as "pass-through payments." Effective CY 2020, this proposal removes transitional pass-through payment for drugs, biologicals, and biosimilars from the OPPS. Eliminating pass-through payment for drugs, biologicals, and biosimilars will lower cost by making them eligible for the reduced 340B payment level, or immediate bundling under the OPPS, if applicable. Manufacturers will no longer have an incentive to make small changes to their products in order to qualify for higher pass-through payments, which adds costs to the system without true innovation. [$4.3 billion in Medicare savings over 10 years]

Permanently Authorize a Successful Pilot on Retroactive Medicare Part D Coverage for Low-Income Beneficiaries

Under current law, newly eligible low-income subsidy beneficiaries are randomly assigned to a qualifying Part D plan, which in turn is paid based on the standard Part D prospective payment regardless of a beneficiary's actual utilization of Part D services. This proposal permanently authorizes a current demonstration that allows CMS to contract with a single plan to provide Part D coverage to low-income beneficiaries while their eligibility is processed. This

MEDICARE PART D STANDARD BENEFIT DESIGN

Current law and proposed law comparison



plan serves as the single point of contact for beneficiaries seeking reimbursement for retroactive claims. Under the demonstration, the plan is paid using an alternative methodology whereby payments are closer to actual costs incurred by beneficiaries during this period. The current demonstration, which runs through the end of 2019, has shown the proposed approach to both save money and be less disruptive to beneficiaries. [$300 million in savings over 10 years]

HRSA

Establish Requirements Regarding the Use of Savings and Expand Rulemaking Authority for the 340B Drug Pricing Program for Program Integrity

General regulatory authority over all aspects of the 340B Program would allow HRSA to create clear, enforceable standards for the 340B program. This proposal also requires all 340B covered entities to report the savings achieved from the 340B program and their uses. [Budget impact not available]

Modernize Medicare Part D to Realign Incentives and Enhance Benefit Management

When the Part D benefit began in 2006, it was designed to encourage a robust benefit and plan participation. But 13 years later, the drug market has changed. With new high-cost specialty drugs and unconstrained price increases on existing drugs, it is time to realign incentives and bring down costs for beneficiaries and the government. The Budget modernizes Part D to better protect beneficiaries from high drug prices, give plans more tools to manage spending, and address misaligned incentives of the Part D drug benefit structure. The three part proposal will:

- Enhance Part D plans' negotiating power with manufacturers;

- Encourage utilization of higher value drugs;
- Discourage drug manufacturers' price and rebate strategies that increase spending for both beneficiaries and the government; and
- Provide beneficiaries with more predictable annual drug expenses through the creation of a new out-of-pocket spending cap.

Descriptions of each component are below.

Exclude Manufacturer Discounts from the Calculation of Beneficiary Out-of-Pocket Costs in the Medicare Part D Coverage Gap

Under the current benefit structure, Part D plans are incentivized to encourage beneficiaries to use costly brand drugs in order to accelerate their progression through the coverage gap into the catastrophic phase, where Medicare covers 80 percent of costs. Required discounts paid by brand drug and biosimilar manufacturers in the coverage gap are included in the calculation of a beneficiary's "true out-of-pocket costs (TrOOP)," which are a combination of a beneficiary's actual out of pocket costs and these discounts. In contrast, generic drugs are not subject to a manufacturer discount that counts toward TrOOP. Once a beneficiary's out-of-pocket spending reaches the annually updated TrOOP threshold, a beneficiary moves out of the coverage gap and into the catastrophic phase of the benefit. The manufacturer discounts mean that patients using generic drugs are required to spend more out of their own pockets before reaching this threshold, compared with patients using brand drugs. This proposal restructures the coverage gap discount program to exclude manufacturer discounts from the calculation of true out-of-pocket costs in order to correct this misaligned incentive that encourages plans to promote costly brand drugs. [$74.7 billion in savings over 10 years]

Eliminate Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Beneficiaries

Low-income subsidy (LIS) beneficiaries are three times more likely than non-LIS beneficiaries to have drug spending high enough to enter the catastrophic phase of the benefit. LIS beneficiaries use more prescriptions, and are less likely than overall Part D enrollees to select a generic drug when one is available. This proposal encourages the use of higher value products among LIS beneficiaries by reducing cost sharing to $0 for generics, biosimilars, and preferred multiple source drugs. [$930 million in savings over 10 years]

Establish a Beneficiary Out-of-Pocket Maximum in the Medicare Part D Catastrophic Phase

The Part D benefit creates a perverse incentive structure for plans, wherein drug price increases shift more drug spending into the catastrophic phase, where Medicare pays 80 percent of costs. Beneficiaries who reach the catastrophic phase continue to be responsible for five percent of their drug costs, which can be a substantial financial burden for those using high cost specialty drugs, such as those used to treat Hepatitis C. This proposal:

- Increases Part D plan sponsors' risk in the catastrophic phase by increasing plan liability over 4 years from 15 percent to 80 percent;
- Decreases Medicare's reinsurance liability from 80 to 20 percent; and,
- Eliminates beneficiary coinsurance, creating a true out-of-pocket maximum in Part D for the first time in the program's history.

Together, these changes provide beneficiaries with more predictable annual drug expenses and incentivize plans to better manage spending throughout the entirety of the benefit. [$14.0 billion in costs over 10 years]

Lowering the Cost of Prescription Drugs

FY 2020 Lowering the Cost of Prescription Drugs Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Increased Competition			
Medicare			
Reduce Average Sales Price-Based Payments when the Primary Patent Expires to Increase Competition and Reduce Gaming	*	*	*
FDA			
Reform Exclusivity for First Generics to Spur Greater Competition and Access	-75	-455	-1,160
Medicare Impact (non-add)	*-60*	*-370*	*-960*
Medicaid Impact (non-add)	*-15*	*-85*	*-200*
Amend the 180-Day Forfeiture Provision Addressing Failure to Obtain Tentative Approval	*	*	*
Codify FDA's Approach to Determining New Chemical Entity Exclusivity	*	*	*
Provide FDA Enhanced Authority to Address Abuse of the Petition Process	*	*	*
Encourage Biosimilar Development	*	*	*
Better Negotiation			
Medicare			
Authorize the HHS Secretary to Leverage Medicare Part D Plans' Negotiating Power for Certain Drugs Covered Under Part B	*	*	*
Give the Secretary Authority to Contract with Pharmaceutical Manufacturers Entering into New Coverage Gap Discount Program Agreements on a Quarterly Basis	*	*	*
Improve Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates	-	-	-
Reduce Wholesale Acquisition Cost (WAC)-Based Payments	*	*	*
Medicaid			
Clarify Definitions under the Medicaid Drug Rebate Program to Prevent Inappropriately Low Manufacturer Rebates	-26	-143	-347
Test Allowing State Medicaid Programs to Negotiate Prices Directly with Drug Manufacturers and Set Formulary for Coverage	-5	-120	-410
Impose Greater Penalties for Manufacturer Reporting of False Information or False Product Data under the Medicaid Drug Rebate Program	*	*	*
Exclude Brand Name and Authorized Generic Drug Prices from Medicaid's Federal Upper Limit	-90	-480	-980
Clarify Authorized Generic Drug Sales under the Medicaid Drug Rebate Program	-15	-75	-150
Incentives for Lower List Prices			
Medicaid			
Allow Rebates on Drugs that Exceed 100 Percent of the Average Manufacturer Price	*	*	*
HRSA			
Establish and Collect User Fees from 340B Drug Pricing Program Participating Covered Entities	*	*	*

FY 2020 Lowering the Cost of Prescription Drugs Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Lowering Out of Pocket Costs			
Medicare			
Address Abusive Drug Pricing by Manufacturers by Establishing an Inflation Limit for Reimbursement of Part B Drugs	*	*	*
Modify Payment for Drugs Hospitals Purchased through the 340B Discount Program and Require a Minimum Level of Charity Care for Hospitals to Receive a Payment Adjustment Related to Uncompensated Care	-	-	-
Eliminate Pass-Through Payments for Drugs, Biologicals, and Biosimilars	-150	-1,500	-4,270
Permanently Authorize a Successful Pilot on Retroactive Medicare Part D Coverage for Low-Income Beneficiaries	-20	-120	-300
HRSA			
Establish Requirements Regarding the Use of Savings and Expand Rulemaking Authority for the 340B Drug Pricing Program for Program Integrity	*	*	*
Modernize Medicare Part D to Realign Incentives and Enhance Benefit Management			
Exclude Manufacturer Discounts from the Calculation of Beneficiary Out-of-Pocket Costs in the Medicare Part D Coverage Gap	-	-23,440	-74,730
Eliminate Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Beneficiaries	-	-350	-930
Establish a Beneficiary Out-of-Pocket Maximum in the Medicare Part D Catastrophic Phase	-	6,310	14,030
Subtotal, Medicare	**-230**	**-19,470**	**-67,160**
Subtotal, Medicaid	**-151**	**-903**	**-2,087**
Subtotal, HRSA	*	*	*
Subtotal, FDA	*	*	*
TOTAL, Lowering the Cost of Prescription Drugs FY 2020 Budget Proposals	**-381**	**-20,373**	**-69,247**

* Budget impact unavailable as of the publication date of the FY 2020 President's Budget.

Food and Drug Administration

	dollars in millions			
	2018 /1	2019 /2	2020 /3	2020 +/- 2019
FDA Programs				
Foods	1,070	1,070	1,122	+52
Human Drugs	1,634	1,713	1,980	+266
Biologics	364	379	432	+52
Animal Drugs and Feeds	200	220	240	+19
Medical Devices	513	523	632	+109
National Center for Toxicological Research	65	65	67	+2
Tobacco Products	627	627	762	+135
Headquarters and Office of the Commissioner	289	298	320	+22
White Oak Operations	51	51	59	+8
GSA Rental Payment	238	241	241	-0
Other Rent and Rent Related Activities	122	124	146	+22
Subtotal, Salaries and Expenses	**5,172**	**5,311**	**5,999**	**+688**
Export Certification Fund	5	5	9	+4
Color Certification Fund	10	10	11	+0
Rare Pediatric Priority Review Vouchers	8	8	8	+0
Buildings and Facilities	12	12	12	--
21st Century Cures Act	60	60	75	+15
Opioids - International Mail Facilities	94	94	--	-94
Over-the Counter Monograph	--	--	28	+28
Total, Program Level	**5,361**	**5,499**	**6,142**	**+643**
Current Law User Fees /4				
Prescription Drug	911	1,010	1,062	+52
Medical Device	193	205	220	+15
Generic Drug	494	502	512	+10
Biosimilars	40	39	40	+1
Animal Drug	18	30	31	+0
Animal Generic Drug	9	18	19	+0
Family Smoking Prevention and Tobacco Control Act	672	672	712	+40
Food Reinspection	6	6	7	+0
Food Recall	1	1	1	+0
Mammography Quality Standards Act	21	21	21	+1
Export Certification	5	5	5	--
Color Certification Fund	10	10	11	+0
Rare Pediatric Priority Review Vouchers	8	8	8	+0
Voluntary Qualified Importer Program	5	5	6	+0
Third Party Auditor Program	1	1	1	+0
Outsourcing Facility	1	2	2	+0
Subtotal, Current Law User Fees	**2,396**	**2,535**	**2,655**	**+120**
Proposed Law User Fees				

	dollars in millions			
	2018 /1	2019 /2	2020 /3	2020 +/- 2019
Export Certification	--	--	4	+4
Over-the Counter Monograph	--	--	28	+28
Innovative Food Products	--	--	28	+28
Increase to the Tobacco User Fee	--	--	100	+100
Subtotal, Proposed Law User Fees	**--**	**--**	**161**	**+161**
Less Total, User Fees	**2,396**	**2,535**	**2,816**	**+281**
Total Discretionary Budget Authority	**2,964**	**2,964**	**3,326**	**+362**
Full-Time Equivalents	17,018	17,607	18,062	**+455**

1/ Reflects FY 2018 Final, post required and permissive transfers and rescissions.
2/ Reflects the annualized level of the Continuing Resolution and directed transfers.
3/ All figures comparable to the FY 2020 Budget and assume implementation of a working capital fund.
4/ Does not reflect priority review voucher user fee for Medical Countermeasures as FDA continues to develop an estimated fee level.

The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. FDA also advances the public health by helping to efficiently advance innovations that make medicines more effective, safer, and affordable; and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health. Furthermore, FDA has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. Finally, FDA plays a significant role in the nation's counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally occurring public health threats.

The Food and Drug Administration (FDA) protects and advances public health through an array of activities from safeguarding the nation's blood supply, to overseeing the safety of food, and advancing safe and effective medical products. The products FDA is responsible for regulating account for more than 20 percent of every consumer dollar spent on products in the United States.

The Fiscal Year (FY) 2020 Budget includes $6.1 billion in total resources for FDA—an increase of $643 million or 12 percent above FY 2019. The FY 2019 funding level for FDA in the Budget reflects the annualized level of the Continuing Resolution. The Budget increases user fees by $281 million and budget authority by $362 million. It invests in priority activities, including: modernizing food safety, strengthening foodborne illness response, helping fight the opioid crisis, promoting the development of innovative medical products, investing in blood pathogen reduction technology, and supporting the preparedness infrastructure.

ADVANCING ACCESS TO SAFE AND EFFECTIVE MEDICAL PRODUCTS

FDA's responsibilities to ensure safe and effective medical products are wide-ranging. FDA oversees the safety, quality, and effectiveness of an extensive scope of products, including: prescription and over-the-counter drugs; biologics, such as vaccines, blood products, and gene therapies; radiation-emitting products; and medical devices ranging from dental devices to surgical implants. FDA continuously ensures regulated products are marketed according to federal standards and that products are safe, especially as new clinical information becomes available. FDA incorporates cutting-edge regulatory science into its evaluations to support patient access to safe and effective medical products. This work is supported by

centers across FDA to establish effective and efficient review pathways.

FDA Accomplishments

In the past year, FDA had several notable innovations that will result in meaningful difference for patients. In November 2018, FDA approved the second cancer treatment based on a common biomarker across different types of tumors, rather than based on a specific type of tumor or location in the body. This approval marks an important milestone in the development of cancer drugs that are tissue agnostic. FDA also approved the first generic version of the EpiPen and EpiPen Jr. auto-injector for the emergency treatment of allergic reactions, including life-threatening ones such as anaphylaxis. FDA also launched a new device review pilot program to reduce review time by one-third for well understood, low-risk medical devices. FDA also approved seven biosimilars in 2018, marking a record for the number of biosimilar approvals in a single calendar year.

Leveraging Cutting-Edge Science to Improve Oversight

Areas of novel and emerging science such as gene therapy, targeted medicine, and digital health pose regulatory challenges, because traditional regulatory approaches are not well-suited for such products. To meet these challenges, FDA is adapting and modernizing its regulatory approach to enable technology development, while maintaining FDA's gold standard for product review and consumer protection. For example, FDA is promoting work that will enable the agency to use real-world data such as post-market safety and adverse event data in regulatory decision-making. In December 2018, FDA announced its Framework for the Real-World Evidence Program, a new, strategic approach aimed at leveraging information gathered from patients and the medical community to inform and shape FDA's decisions across its drug and biologic development efforts.

Innovations in Human Drug and Device Review

FDA continues to implement the 21st Century Cures Act, and applies an innovative and nimble regulatory approach, consistent with the goals of the Act. For example, FDA encourages state-of-the-art innovations such as adaptive trials, modeling, and simulations to evaluate a product's safety and effectiveness. FDA also deploys modeling and simulation tools to predict clinical outcomes, inform trial design, support evidence of effectiveness, and evaluate adverse event mechanisms. The drug and biologic centers are updating guidance to assist sponsors in incorporating modeling and simulation and applying these tools, for instance, to optimize product dosing based on individual physiology and genetics.

In FY 2020, the Budget requests a total of $3.8 billion for medical product safety investments, which is $428 million above FY 2019. This total includes $1.8 billion in budget authority and $1.9 billion in user fees. The Budget advances FDA's highest priority activities to ensure safe and effective medical products for the American public. The Budget includes $220 million to continue proposing several initiatives promoting public health and spur growth in the domestic economy.

Supporting the Administration's Drug Pricing Initiative with Increased Competition

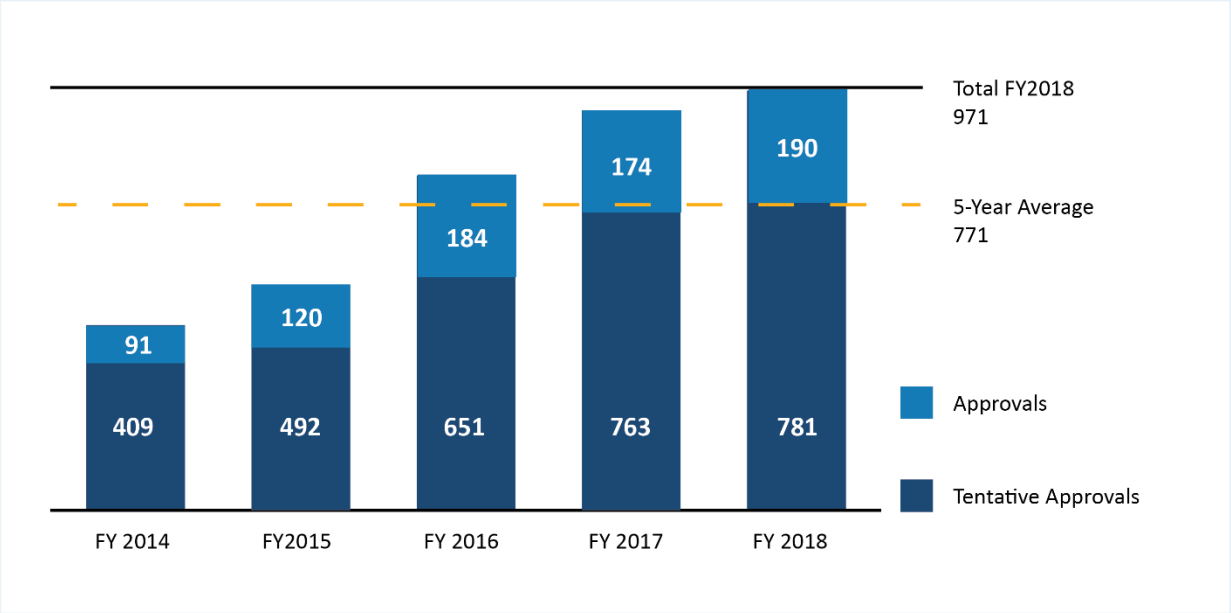
In support of the Administration's drug pricing initiative, FDA has taken significant steps to promote competition that can help lower costs and broaden patient access. FDA has focused on ensuring that regulatory requirements are efficient, predictable, and science-based, which can ultimately help reduce the time, uncertainty, and cost of generic and biosimilar product development. In FY 2018, FDA approved a record number of generic approvals in a fiscal year.

Moving forward, FDA will build on these successes. In 2019, FDA will encourage generic entry for drugs that face inadequate competition by laying out new, efficient guidelines for the use of a novel pathway that provides incentives for developing generic versions of drugs that currently face little or no competition. FDA is also taking additional new actions to advance the Biosimilar Action Plan and promote competition in the biologics space, including limiting the ability of branded drug companies from preventing biosimilar sponsors access to product samples needed for testing to support their product applications.

The Budget will include five FDA legislative proposals to support the Administration's drug pricing initiative, including a legislative proposal to eliminate a loophole manufacturers are exploiting to reduce generic competition on the market. Currently, a first applicant for a generic drug forfeits their 180-day exclusivity if they fail to obtain tentative approval for their application within a specific timeframe. A first applicant can avoid forfeiture under this provision if the failure to obtain tentative approval is caused by a change in or a review of the requirements for approval

APPROVAL OF GENERICS

FDA Sets a Record for the Greatest Number of Generics Approved in a Single Fiscal Year



imposed after the application filing date. Currently, first applicants with deficient applications are taking advantage of this provision by avoiding forfeiture even though they have deficiencies in their application unrelated to any change in or review of the requirements for approval. The legislative proposal clarifies the exception to avoid exploitation, so the exception to forfeiture will only apply if the change in or review of the requirements for approval was the only cause of the applicant's failure to obtain tentative approval. This change will result in increased generic competition and choice for consumers. FDA can proceed with final approval of competing generic drugs that otherwise would generally have had to wait until the first applicant with the deficient application had been approved and the 180-day exclusivity period had run out before being approved by FDA.

Additional details on the remaining FDA legislative proposals can be found in the "Lowering the Cost of Prescription Drugs" chapter.

Fighting the Opioids Epidemic

The Budget provides an additional $55 million to support FDA's opioids activities. FDA's overall approach to the opioids epidemic focuses on four priorities:

- Decrease exposure to prescription opioids to reduce the rate of new addiction;
- Support the treatment of those with opioid use disorder;
- Foster development of novel pain treatment therapies; and
- Increase enforcement activities to crack down on illegal sales of opioids.

For this last priority, FDA is focused on illicit drugs sold online and typically shipped through the mail. Funding will be dedicated to hiring additional key staff, from Consumer Safety Officers who examine these mail facilities to scientists that provide laboratory support. This investment will support an increase of the inspection of packages at international mail facilities. These FDA activities help prevent illegal products from flowing across our borders, including products ordered online.

In 2018, FDA launched major operations with other federal partners, including Customs and Border Protection and the Drug Enforcement Administration

to target shipments and accurately estimate the number of illegal opioid mail shipments.

FIGHTING ILLICIT DRUG SHIPMENTS

Various loose blister packs and unmarked, unlabeled capsules at the John F Kennedy AIrport International Mail Facility

Transform Medical Device Safety, Cybersecurity, Review, and Innovation

FDA has been improving policies and processes to address scientific advances and enhance the safety of medical devices. These improvements are critical to protect patients and foster innovation. FDA's fragmented information technology systems are not well-suited to support these activities. The Budget proposes $55 million for an initiative to build an integrated knowledge management system and portal for medical devices using modern, agile information technology systems. These systems will have secure cloud-based data storage that will enable safety issues to be monitored along the total life cycle of the device, from bench testing to premarket clinical trials to postmarket adverse events and real-world evidence. This capability to better leverage pre-existing and new data in near real time is essential for implementing FDA's new approaches for digital health technologies, breakthrough devices, use of real-world evidence, and cybersecurity. Overall, it will make device reviews, postmarket surveillance, and cybersecurity efforts significantly more efficient and informative. These efforts could shorten review cycles, quickly identify and address safety signals and cyber vulnerabilities, and spur the development of innovative, safer, more effective devices.

Integrated Blood Pathogen Reduction

The Budget includes $20 million to pilot a robust, simple technology that could eliminate contaminating viruses and other microorganisms from whole blood and still allow its subsequent separation into various blood components. The current level of safety of the blood supply was achieved through a combination of deferral of at-risk individuals and laboratory testing. Existing and emerging infectious diseases present a continued risk to blood safety, as they are spreading faster and are more quickly emerging. Continued vigilance against emerging threats is critical, including the introduction of new technologies to keep the blood supply safe. This investment could ensure availability of the blood supply even in the event of an emerging pathogen.

Supporting Quality Compounded Drugs

FDA continues to find significant problems at many outsourcing facilities it inspects, including conditions that could lead to product contamination and patient harm. The sector is new and would greatly benefit from more frequent and in-depth engagement by the FDA to support their efforts to improve compounding quality. The Budget invests in strengthening the establishment of the outsourcing facility sector to provide quality compounded drugs. The Budget provides $76 million, an increase of $25 million above FY 2019, for compounding activities such as to regulate this sector and inform facility, process, and system design; establish a list of bulk drug substances; and increase engagement with industry to promote compliance and identify ongoing gaps at facilities. With this funding increase, outsourcing facilities are better positioned to meet health care providers' and patients' needs for quality compounded drugs.

Over-the-Counter Drug Monograph Reform

The Budget also includes a legislative proposal to modernize the over-the-counter drug monograph system. The current monograph system has not kept up in product innovation, leaving a framework that does not well serve consumers or industry. FDA still has not been able to complete many monographs begun decades ago. Nor has it been able to make timely monograph modifications to account for evolving science and emerging safety issues, or to accommodate product innovation or marketing changes. Approximately one third of the monographs are not yet final.

The Budget envisions a framework that converts the current burdensome process to a streamlined administrative order process that: removes barriers to innovation, implements a new mechanism for quickly responding to urgent safety issues, and reduces the backlog by finalizing unfinished monographs. To support this effort, FDA will create a user fee program for over-the-counter monograph drugs and collect an estimated $28 million in user fee resources in FY 2020.

Office of Laboratory Science and Safety

In FY 2020, FDA will continue to carry out high-priority medical product safety activities, including strengthening FDA's standard for regulatory decision making. The Budget includes $17 million for the Office of Laboratory Science and Safety, an increase of $1 million from FY 2019. This funding will support improved IT solutions for laboratory science, security, and environmental and occupational safety and health program management. It will also improve FDA-wide training programs and implement quality management systems to ensure oversight for the science, security, and environmental management components of FDA's mission.

MODERNIZING THE FOOD SAFETY SYSTEM

Since 2011, FDA has carried out its responsibilities under the FDA Food Safety Modernization Act (FSMA) and set new standards for a prevention-based food safety system. Entering the next decade, FDA will continue to ensure compliance with these standards, operating within a new food safety system.

The Budget includes $1.4 billion for food safety across FDA programs, an increase of $67 million above FY 2019. This total includes $1.4 billion in budget authority—an increase of $38 million—and $44 million in user fees, flat with FY 2019. This work will be supported by centers across FDA that ensure that our approach to food safety is preventive, not reactive, and based on risk strategies.

Signal Detection of Foodborne Illness

The Budget includes an increase of $16 million to improve signal detection of foodborne illness and strengthen FDA's response to human and animal food contamination. FDA urgently needs additional resources to increase capacity for evaluating and responding to foodborne outbreaks for both human and animal food. In FY 2018, FDA's Coordinated Outbreak Response and Evaluation network evaluated a record 122 potential human food safety outbreak incidents. That is a 20 percent increase from FY 2017, which saw 101 evaluations, and almost a 70 percent increase from FY 2016 and 2015. Of those signal evaluations, in FY 2015, 18 evolved into large scale outbreak responses. FDA will add new staff and resources to enhance signal detection, response to outbreaks, and post-response evaluations. FDA will also add staff to oversee its recall process and make the recall process timelier.

Implementing the Food Safety Modernization Act

The Budget also includes an increase of $16 million to advance implementation of FSMA. FDA will support state cooperative agreements to increase preventive controls inspections and human food produce safety inspections. These additional resources are essential to successful implementation of FSMA and are key to protecting public health by ensuring that manufacturing and processing facilities comply with the new FSMA requirements. Most critically, FDA does not have the existing resources to conduct additional preventive controls inspections, which are complex and lengthy.

Food and Feed Ingredient Review

FDA supports industry as it develops and implements new technologies in food, cosmetics, and veterinary products, including biotechnology products. The Budget invests $36 million above FY 2019 to provide FDA additional capacity to review human food and animal feed ingredients. This total includes establishing a new user fee program that would collect $28 million in its first year. This initiative will ensure that FDA keeps pace with how changes in the marketplace affect the human and animal food supply.

Food Safety Activities

With its food safety resources, FDA will continue to support other priority food and feed safety activities, such as implementing mandatory standards for imported food, rapidly detecting and responding to major foodborne illness outbreaks, and providing consumers with information about healthy choices using the most up-to-date science. FDA will continue support for food safety research, cosmetics safety, partnerships with academic institutes, and international capacity building.

FDA INFRASTRUCTURE AND FACILITIES

FDA infrastructure and facilities, including 56 laboratories strategically located across the continental United States and Puerto Rico, provide the necessary capabilities to meet the agency's regulatory responsibilities, strategic priorities, and program initiatives. FDA relies on optimally functional facilities to foster scientific innovation, improve health care, expand access to medical products, and advance public health. The Budget funds high-priority infrastructure that directly supports FDA's mission-critical work to ensure food and medical product safety. The Budget invests a total of $458 million, $30 million above FY 2019, in FDA infrastructure, which will support increased facility needs for rent, utilities, and maintenance, as well as continued rent costs at current laboratories and facilities.

The Budget also provides $12 million for repairs and improvements to FDA's owned site infrastructure, offices, and laboratories across the country. The current backlog of maintenance and repairs is $192 million.

ADVANCING MEDICAL COUNTERMEASURES

FDA works with partners at all levels of government—local, state, national and international—to support medical-countermeasure-related public health preparedness and response efforts. This includes working closely with federal partners through the Public Health Emergency Medical Countermeasures Enterprise to build and sustain the medical countermeasures programs necessary to respond effectively to chemical, biological, radiological, and nuclear (CBRN) threats and emerging public health threats, such as pandemic influenza, as well as with the Department of Defense to support the development of medical products needed to protect American military personnel. In FY 2018, FDA approved 28 medical countermeasures, including the first drug with an indication for treatment of smallpox.

The Budget includes $128 million for medical countermeasure activities, of which $31.5 million is for the Medical Countermeasure Initiative, an increase of $7 million above FY 2019. This investment will increase FDA capacity to facilitate the development and availability of medical countermeasures to respond to CBRN and emerging infectious disease threats by furthering the establishment of clear, scientifically supported regulatory pathways for medical countermeasures, filling critical scientific gaps, and advancing platform and manufacturing technologies for medical countermeasures.

REDUCING THE USE AND HARMS OF TOBACCO

The 2009 Family Smoking Prevention and Tobacco Control Act provides FDA authority to regulate the manufacturing, distribution, and marketing of tobacco products. Through the Center for Tobacco Products, FDA executes its regulatory and public health responsibilities to reduce initiation, decrease the harms, and encourage cessation of tobacco product use. Tobacco use remains the leading cause of preventable disease and death in the United States, causing more than 480,000 deaths every single year.

From 2017 to 2018, there was a 78 percent increase in e-cigarette use among high school students and a 48 percent increase among middle school students. In response to this epidemic of e-cigarette use among youth, FDA is acting across the full range of the agency's regulatory authorities, including increased enforcement of age- and identification-verification requirements. FDA is re-examining aspects of FDA's comprehensive plan on tobacco and nicotine regulation in order to strengthen the Youth Tobacco Prevention Plan.

The Budget includes a total of $812 million in user fees to support the FDA tobacco program. The Budget includes a legislative proposal to increase the user fee collected in support of the tobacco program by $100 million and adds electronic nicotine delivery system manufacturers and importers as entities subject to the user fees. The proposal supports FDA's goal to prevent a new generation of children from becoming addicted to nicotine through e-cigarettes.

USER FEES

FDA user fee programs help the agency to fulfill its mission of protecting the public health and accelerating innovation in the industry. User fees are an important resource that supplement, not replace, appropriated dollars. FDA has benefited from fees since the enactment of the Prescription Drug User Fee Act in 1993. Industry fees support FDA capacity to carry out its food and medical product safety responsibilities. The Budget increases overall currently authorized user fee programs by $220 million, when including the fee

total for tobacco. It adds new manufacturers and importers to the list of entities subject to that user fee. The Budget proposes new fee programs for over-the-counter monograph and innovative food activities.

In 2018, Congress enacted the Animal Drug and Animal Generic Drug User Fee Amendments, allowing FDA to continue collecting medical product user fees through 2023. These two user fee programs enhance the FDA's ability to maintain a predictable and timely animal drug review process, foster innovation in drug development, and expedite access to new therapies for food-producing and companion animals.

Health Resources and Services Administration

HRSA
Health Resources & Services Administration

	dollars in millions			
	2018/1	2019	2020	2020 +/- 2019
Primary Health Care				
Health Centers	5,332	5,506	5,506	--
Discretionary Budget Authority [non-add]	*1,507*	*1,506*	*1,506*	--
Current Law Mandatory [non-add]	*3,825*	*4,000*	--	*-4,000*
Proposed Law Mandatory [non-add]	--	--	*4,000*	*+4,000*
Health Centers Tort Claims	115	120	120	--
Free Clinics Medical Malpractice	1	1	1	--
Subtotal, Primary Care	**5,448**	**5,627**	**5,627**	**--**
Health Workforce				
National Health Service Corps	415	430	415	-15
Discretionary Budget Authority [non-add]	*105*	*120*	*105*	-15
Current Law Mandatory [non-add]	*310*	*310*	--	*-310*
Proposed Law Mandatory [non-add]	--	--	*310*	*+310*
Training for Diversity	88	88	--	-88
Training in Primary Care Medicine	49	49	--	-49
Oral Health Training	41	41	--	-41
Teaching Health Centers Graduate Medical Education	127	127	127	--
Discretionary Budget Authority [non-add]	--	--	--	--
Current Law Mandatory [non-add]	*127*	*127*	--	*-127*
Proposed Law Mandatory [non-add]	--	--	*127*	*+127*
Area Health Education Centers	38	39	--	-39
Health Care Workforce Assessment	6	6	5	-1
Public Health and Preventive Medicine Programs	17	17	--	-17
Nursing Workforce Development	249	234	83	-151
Children's Hospital Graduate Medical Education	314	325	--	-325
National Practitioner Data Bank User Fees	19	19	19	--
Other Workforce Programs	151	177	111	-66
Subtotal, Health Workforce	**1,514**	**1,552**	**760**	**-792**
Maternal and Child Health				
Maternal and Child Health Block Grant	650	678	661	-17
Sickle Cell Demonstration Program	4	4	-	-4
Autism and Other Developmental Disorders	49	51	-	-51
Heritable Disorders	16	16	-	-16
Healthy Start	110	123	123	--
Universal Newborn Hearing Screening	18	18	-	-18
Emergency Medical Services for Children	22	22	-	-22
Pediatric Mental Health Care Access Grants	10	10	--	-10
Screening and Treatment for Maternal Depression	5	5	--	-5
Family-to-Family Health Information Centers	6	6	6	--
Discretionary Budget Authority [non-add]	--	--	--	--

	dollars in millions			
	2018/1	2019	2020	2020 +/ 2019
Current Law Mandatory [non-add]	*6*	*6*	--	*-6*
Proposed Law Mandatory [non-add]	--	--	*6*	*+6*
Home Visiting [Mandatory]	400	400	400	--
Subtotal, Maternal and Child Health	**1,291**	**1,333**	**1,189**	**-144**
Ryan White HIV/AIDS Program				
Emergency Relief - Part A	656	656	656	--
Comprehensive Care - Part B	1,309	1,315	1,315	--
AIDS Drug Assistance Program [non-add]	*894*	*900*	*900*	--
Early Intervention - Part C	201	201	201	--
Children, Youth, Women, and Families - Part D	75	75	75	--
AIDS Education and Training Centers - Part F	34	34	34	--
Dental Services - Part F	13	13	13	--
Special Projects of National Significance (SPNS)	25	25	25	--
Ending HIV Epidemic Initiative	--	--	70	+70
Subtotal, Ryan White HIV/AIDS	**2,313**	**2,319**	**2,389**	**+70**
Healthcare Systems				
Organ Transplantation	25	26	28	+2
Cord Blood Stem Cell Bank	15	16	12	-4
C.W. Bill Young Cell Transplantation Program	24	25	25	--
Poison Control Centers	21	23	23	--
340B Drug Pricing Program	10	10	29	+19
Discretionary Budget Authority [non-add]	*10*	*10*	*10*	--
User Fees [non-add]	--	--	*19*	*+19*
Hansen's Disease Programs	16	16	14	-2
Subtotal, Healthcare Systems	**111**	**115**	**130**	**+15**
Rural Health				
Rural Outreach Grants	71	78	41	-37
Rural Hospital Flexibility Grants	49	54	-	-54
Telehealth	23	25	10	-15
Rural Health Policy Development	9	9	5	-4
State Offices of Rural Health	10	10	-	-10
Radiation Exposure Screening and Education	2	2	2	--
Black Lung Clinics	10	11	11	--
Rural Communities Opioids Response Program	100	120	120	--
Rural Residency Program	15	10	--	-10
Subtotal, Rural Health	**290**	**318**	**189**	**-129**
Other Activities				
Family Planning	286	286	286	--
Program Management	155	155	152	-3
Vaccine Injury Compensation Program Direct Operations	9	9	11	+2
Subtotal, Other Activities	**450**	**450**	**449**	**-1**

	dollars in millions			
	2018/1	2019	2020	2020 +/ 2019
Total, Discretionary Budget Authority	**6,730**	**6,853**	**5,853**	**-1,000**
Mandatory Funding	4,668	4,843	4,843	--
User Fees	19	19	38	+19
Total, Program Level	**11,416**	**11,714**	**10,733**	**-981**
Full-Time Equivalents	**2,108**	**2,130**	**2,099**	**-31**

1/ Reflects FY 2018 required and permissive transfers. Funding level does not include supplemental hurricane appropriations ($60 million).

The mission of the Health Resources and Services Administration (HRSA) is to improve health and achieve health equity through access to quality services, a skilled health workforce and innovative programs.

Tens of millions of Americans receive quality, affordable health care and other services through the Health Resources and Services Administration's (HRSA) 90-plus programs and more than 3,000 grantees across the United States. HRSA works across diverse populations—across the lifespan—to ensure people in the United States can access a broad range of essential health care and public health services. HRSA also supports training for health professionals, helps assure sufficient providers in areas that need them most, and improves health care delivery. In addition, HRSA oversees organ, bone marrow, and cord blood donation; compensates individuals harmed by vaccination; and maintains databases used to protect against health care malpractice, waste, fraud and abuse.

The Fiscal Year (FY) 2020 Budget requests $10.7 billion for HRSA. This total includes $5.9 billion in discretionary budget authority and $4.8 billion in mandatory funding. The Budget prioritizes:

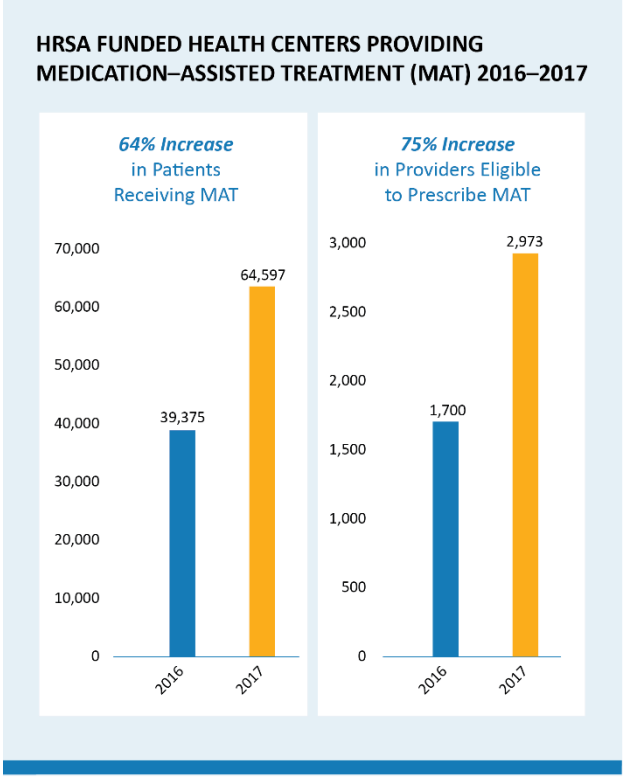
- Direct health care services through key programs such as Health Centers and the Ryan White HIV/AIDS program,
- Workforce enhancement by increasing the number of health care professionals working in communities facing shortages,
- Combatting the opioids epidemic and reducing maternal mortality, and
- Contributing to the Department-wide initiative to end the HIV epidemic in America by expanding access to pre-exposure prophylaxis (PrEP) and HIV care and treatment.

ENSURING ACCESS TO DIRECT HEALTH CARE SERVICES

The FY 2020 Budget prioritizes direct health care services, including through Health Centers and the Ryan White HIV/AIDS Program. These safety-net providers deliver critical health care services to low-income and vulnerable populations across the United States.

Health Centers

For more than 50 years, Community Health Centers have delivered affordable, accessible, high-quality, and cost-effective primary health care services to patients. The FY 2020 Budget provides $5.6 billion for Health



Centers, which includes $4 billion in mandatory resources in each of FYs 2020 and 2021.

Health centers use a holistic approach to patient care. They treat the entire person by integrating mental health, oral health, substance use disorder and primary medical care services. Approximately 1,400 health centers operate nearly 12,000 service delivery sites nationwide, serving more than 27 million people.

Primary care settings are increasingly a gateway to integrated care for individuals with substance use disorder and primary care needs. Patients with opioid or alcohol use disorders were significantly more likely to receive treatment and to abstain from alcohol and drugs when they received a collaborative care intervention at their primary care clinic.

In FY 2020, the Health Center Program will continue to support access to substance use disorder services, including medication-assisted treatment and pain management services. In 2017 alone, nearly 65,000 health center patients received medication-assisted treatment services, and the number of health center clinicians providing medication-assisted treatment increased by 75 percent between 2016 and 2017. Additionally, 90 percent of HRSA-funded health centers across the nation provide mental health services.

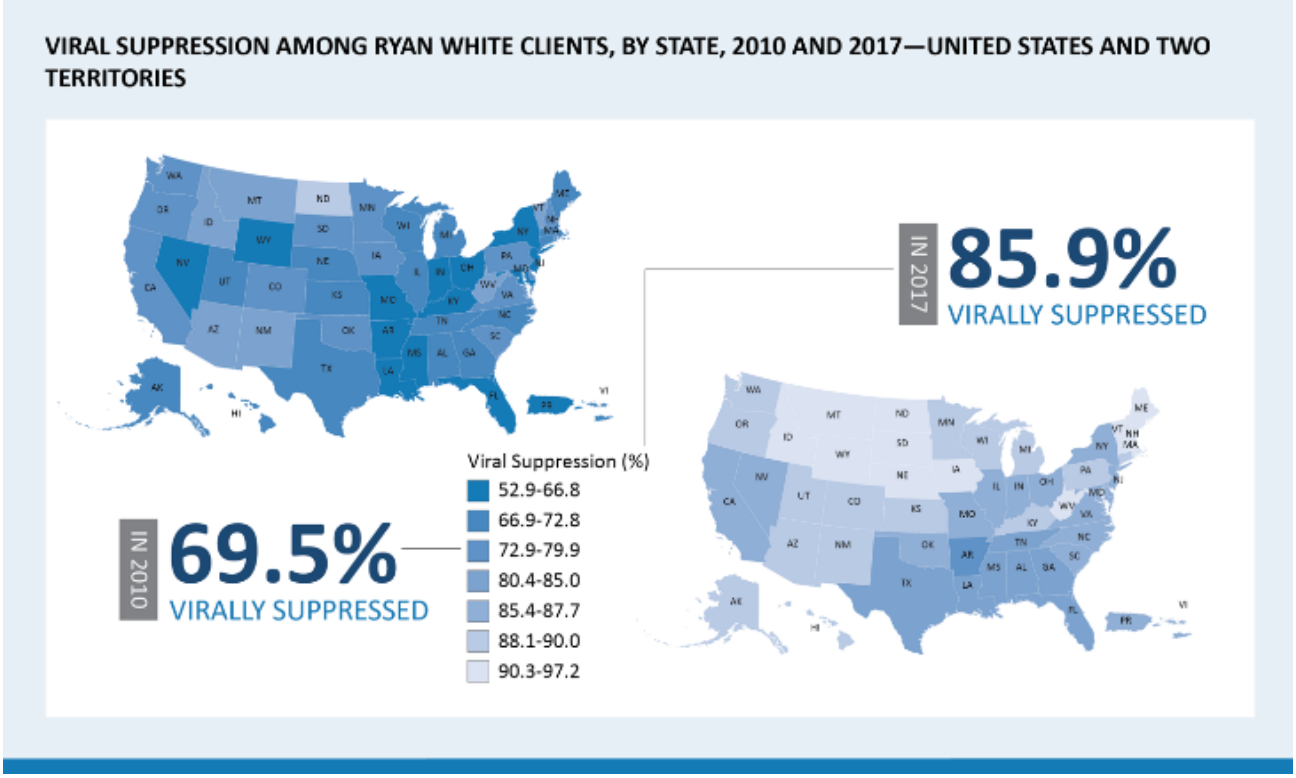
In FY 2020, the Health Center Program will support the Ending HIV Epidemic: A Plan for America Initiative coordinated by HHS. The Health Center Program will dedicate $50 million to expand PrEP and HIV/AIDS services, outreach, and care coordination.

Ryan White HIV/AIDS Program

HRSA's Ryan White HIV/AIDS Program is an integral part of the Administration's initiative to end the HIV epidemic in America. The program funds grants to cities, counties, states, and local community-based organizations to provide comprehensive HIV primary medical care, essential support services, and medications for low-income people living with HIV. It serves approximately 50 percent of people living with diagnosed HIV infection in the United States.

As the largest domestic federal program providing HIV/AIDS care, the Ryan White HIV/AIDS Program increases access to health services for underserved populations, improves retention in care and survival, reduces use of more costly inpatient care, and reduces HIV transmission.

The FY 2020 Budget requests $2.4 billion, which is $70 million above FY 2019, for the Ryan White HIV/AIDS Program. To support the Ending HIV Epidemic Initiative, the Budget also proposes to reauthorize the Ryan White HIV/AIDS Program to



ensure Federal funds are allocated to target populations experiencing high or increasing levels of HIV infections and diagnoses while continuing to support Americans already living with HIV across the Nation. The proposed reauthorization will include data-driven programmatic changes and will simplify, modernize, and standardize certain statutory requirements and definitions to be consistent across the Ryan White Parts to reduce burden on recipients.

The requested funding level provides $900 million for the AIDS Drug Assistance Program, maintains other Ryan White programs at the FY 2019 level, and adds $70 million for the initiative to end the HIV epidemic in America to reduce new HIV infections by 75 percent within 5 years, and by 90 percent within 10 years. As part of this Department-wide initiative, the Ryan White HIV/AIDS Program will increase funds for Part A and B jurisdictions within high-need areas identified by the Centers for Disease Control and Prevention to deliver additional care and treatment for people living with HIV.

Title X Family Planning

For more than 40 years, title X family planning clinics have ensured access to a broad range of family planning and related health services for millions of low-income or uninsured individuals. The FY 2020 Budget provides $286 million, the same level as FY 2019, to support family planning and related services for nearly 4 million persons. Approximately 90 percent of those served have family incomes at or below 200 percent of the federal poverty level.

OPTIMIZING THE NATION'S HEALTH WORKFORCE

The FY 2020 Budget provides $760 million in mandatory and discretionary resources for HRSA health workforce programs. The Budget prioritizes funding for health workforce programs requiring service commitments in underserved areas, training health care professionals to deliver integrated behavioral health services, and the National Center for Health Workforce Analysis.

National Health Service Corps

The National Health Service Corps provides scholarships and loan repayment to health care professionals in return for service commitments in communities with a shortage of health professionals. Approximately 50,000 primary care medical, dental, and mental and behavioral health professionals have served in the National Health Service Corps since it began in 1972.

The FY 2020 Budget requests $415 million for the National Health Service Corps, $105 million in discretionary budget authority and $310 million in mandatory resources for FY 2020 and 2021. In FY 2018, an estimated 11.5 million patients received care from more than 10,900 National Health Service Corps clinicians. Another 1,725 future primary care professionals are either in school or residency preparing for future service with the Corps programs. In addition to primary care, mental health and dental care, National Health Service Corps clinicians provide opioid and other substance use treatment to their patients. One in three National Health Service Corps clinicians is a behavioral health provider.

NURSE Corps Scholarship and Loan Repayment Program

The NURSE Corps Program awards scholarships and loan repayment to nurses, nursing students, and nurse faculty. By supporting nurses, healthier communities are built across the country, especially in areas of greatest need. The Budget provides $83 million to support over 1,400 NURSE Corps clinicians providing care i rural and underserved communities. The Budget proposes to expand tax-exempt status to the Nurse Corps Scholarship Program and the Nurse Corps Loan Repayment Program similar to that provided to the National Health Service Corps to enhance recruitment of students and clinicians who have committed to serve in critical shortage facilities in underserved communities. In FY 2020, NURSE Corps will also support improved access to opioid treatment and prevention services.

Teaching Health Center Graduate Medical Education

The Teaching Health Center Graduate Medical Education Program increases the number of primary care physician and dental residents across the nation and supports training in community-based ambulatory care settings. The Budget requests $127 million in mandatory funding for both FY 2020 and FY 2021 to support 750 resident slots.

KEEPING FAMILIES AND COMMUNITIES HEALTHY

Reducing Maternal Mortality

Maternal mortality rates in the United States have more than doubled over the past few decades. Each year, about 700 women die of pregnancy-related causes in the United States. The most common causes of maternal death are hemorrhage, severe high blood pressure, and venous thromboembolism. Notwithstanding advances in medicine and medical technologies, pregnancy-related morbidity in the United States continues to affect 50,000 women. Yet, according to the CDC Foundation's report from Nine Maternal Mortality Review Committees, 60 percent of these deaths are preventable.

HRSA is a leader in addressing maternal mortality and morbidity through health promotion, risk prevention, and training of health care professionals to identify and treat early warning signs. In FY 2020, HRSA-supported maternal and child health programs will provide services to nearly 54 million mothers and children in the United States, including two-thirds of all pregnant women and half of all infants and children.

The FY 2020 Budget requests $661 million for the Maternal and Child Health Block Grant to support federal and state partnerships to address gaps in services to mothers, children, and their families in all 50 states, the District of Columbia, and the territories. In FY 2017, nearly 56 million mothers and children nationwide benefitted from a Block Grant-supported service, including 86 percent of pregnant women, 99 percent of infants, and 55 percent of children (including children with special health care needs).

Within the requested funding level, $23 million will support grants for State Maternal Health Innovation and data capacity, which focuses on implementing evidence-based interventions, assessing their effectiveness, and reducing disparities in maternity services and outcomes.

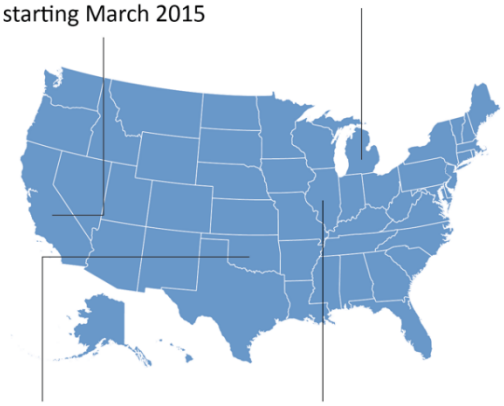
An additional $3 million will continue the expanded implementation of the Alliance for Innovation in Maternal Health Initiative maternal safety bundles to all 50 U.S. states, the District of Columbia, the territories, and tribal entities. Safety bundles are straightforward sets of evidence-based practices proven to improve patient outcomes when performed in a health care setting. Expanded implementation of safety bundles in birthing facilities across the United States will address the leading causes of maternal death, such as hemorrhage and hypertension, and enhance the delivery of safe, high-quality, comprehensive maternity care services.

ALLIANCE FOR INNOVATION IN MATERNAL HEALTH INITIATIVE

Nearly 2 Million Annual Births, 23 States and Growing, Highlights Include...

California
Reduced severe maternal hemorrhage by 20% over 12 months starting March 2015

Michigan
Decreased maternal hemorrhage by 18% since November 2015



Oklahoma
Reduced severe maternal morbidity by 20.5% since April 2015

Illinois
Reduced morbidity due to hypertension by 19.9% since April 2015

The Budget provides $123 million for the Healthy Start Program to support community-based strategies to reduce disparities in infant mortality and improve perinatal outcomes for women and children in high-risk areas. In FY 2020, the program will address maternal mortality by continuing to place clinical service providers at Healthy Start sites to provide direct access to well woman care and maternity care services. This will reduce barriers in access to care and better address health disparities among high-risk and underserved women.

Rural Health

The FY 2020 Budget requests $189 million for the Federal Office of Rural Health Policy for grants to enhance health care delivery in rural communities, conduct research on rural health care issues, and provide technical assistance, such as training and

dissemination of best practices to rural communities and stakeholders. The Budget targets critical rural health activities and services such as Telehealth, Rural Health Policy Development, and Black Lung Clinics, and the Rural Communities Opioids Response Program (RCORP).

The FY 2020 Budget requests $120 million for RCORP, which supports treatment and prevention of substance use disorder, including opioid abuse, in the highest-risk rural communities. The Budget will target some of the RCORP funding to specific initiatives, such as maternal and child health and telehealth activities focused on reducing opioid abuse. In FY 2018, HRSA awarded 95 RCORP planning grants to strengthen infrastructure and capacity within rural communities to provide needed prevention, treatment, and recovery services to rural residents.

OTHER HRSA PROGRAMS

340B Drug Pricing Program

The 340B Drug Pricing Program requires drug manufacturers, as a condition of participating in Medicaid, to provide discounts on outpatient prescription drugs to certain safety net health care providers. The Budget proposes to authorize a new user fee for the 340B Drug Pricing Program, and provides $29 million for the administration and oversight of the 340B Program, of which $10 million is discretionary budget authority and $19 million is funded by the new user fee on covered entities to improve the program's operations and oversight.

The FY 2020 Budget proposes to improve 340B program integrity, and to ensure that the benefits of the program are used to help low-income and uninsured patients. The FY 2020 Budget proposes general regulatory authority for the 340B Drug Pricing Program to establish enforceable standards for program participation and to require all covered entities to report on the use of program savings. These reforms would strengthen program integrity and oversight.

Organ Transplantation

The Budget requests $28 million for the Organ Transplantation Program, an increase of $2 million above FY 2019. The Organ Transplantation Program extends and enhances the lives of individuals with end-stage organ failure for whom an organ transplant is the most appropriate therapeutic treatment. In 2018, there were more than 145 million people registered to be organ donors–an all-time high. In FY 2020, HRSA will be working to increase financial support of certain living donors and provide educational awareness about living organ donation.

Program Management

The Budget requests $152 million, which is $3 million below FY 2019, to support program management activities such as oversight of grant and contracts, program integrity, information technology investments, and other operations costs.

Indian Health Service

	dollars in millions			
	2018 /1	2019 /2	2020 /3	2020 +/- 2019
Services Programs				
Clinical Services	3,606	3,616	3,997	+382
Hospitals and Health Clinics (non-add)	*2,055*	*2,055*	*2,363*	*+309*
Quality Improvement and Certification/4 (non-add)	*58*	*58*	*68*	*+10*
Ending HIV Epidemic/Hepatitis C Initiative (non-add)	*--*	*--*	*25*	*+25*
National Community Health Aide Program (non-add)	*--*	*--*	*20*	*+20*
Electronic Health Record System	*--*	*--*	*25*	*+25*
Purchased/Referred Care (non-add)	*963*	*964*	*968*	*+5*
Indian Health Care Improvement Fund (non-add)	*72*	*72*	*72*	*--*
Preventive Health	167	171	118	-53
Public Health Nursing (non-add)	*84*	*86*	*92*	*+6*
Health Education (non-add)	*19*	*20*	*--*	*-20*
Community Health Representatives (non-add)	*62*	*63*	*24*	*-39*
Other Services	179	179	171	-8
Tribal Management Grant Program (non-add)	*2*	*2*	*--*	*-2*
Direct Operations (non-add)	*72*	*72*	*74*	*+2*
Subtotal, Services Programs	**3,952**	**3,966**	**4,287**	+321
Contract Support Costs				
Contract Support Costs	763	718	855	+137
Subtotal, Contract Support Costs	**763**	**718**	**855**	+137
Facilities Programs				
Health Care Facilities Construction	243	243	166	-78
Sanitation Facilities Construction	192	192	193	+1
Facilities and Environmental Health Support	241	242	251	+9
Maintenance and Improvement	168	168	169	+1
Medical Equipment	24	24	24	--
Subtotal, Facilities Programs	**868**	**869**	**803**	-66
Total Discretionary Budget Authority	**5,582**	**5,553**	**5,945**	**+392**
Funds from Other Sources				
Health Insurance Collections	1,194	1,194	1,194	--
Rental of Staff Quarters	9	9	9	--
Diabetes Grants	150	150	150	--
Subtotal, Other Sources	**1,352**	**1,352**	**1,352**	--
Total Program Level	**6,935**	**6,905**	**7,297**	**+392**
Full-Time Equivalents	15,285	15,285	15,399	+114

1/ Reflects the FY 2018 Final level including actual Contract Support Costs and a $25 million reprogramming notified to Congress on August 28, 2018.

2/ Reflects the annualized level of the continuing resolution and directed or permissive transfers. Includes an anomaly of $15.3 million for staffing of newly-constructed health care facilities.

3/ The Budget requests a total of $97.5 million for staffing of newly-constructed health care facilities and $68.8 million for current services, which is allocated across several funding lines.

4/ Includes $58 million for accreditation emergencies in order to meet CMS Conditions of Participation.

The mission of the Indian Health Service is to raise the physical, mental, social, and spiritual health of American Indians and Alaska Natives to the highest level.

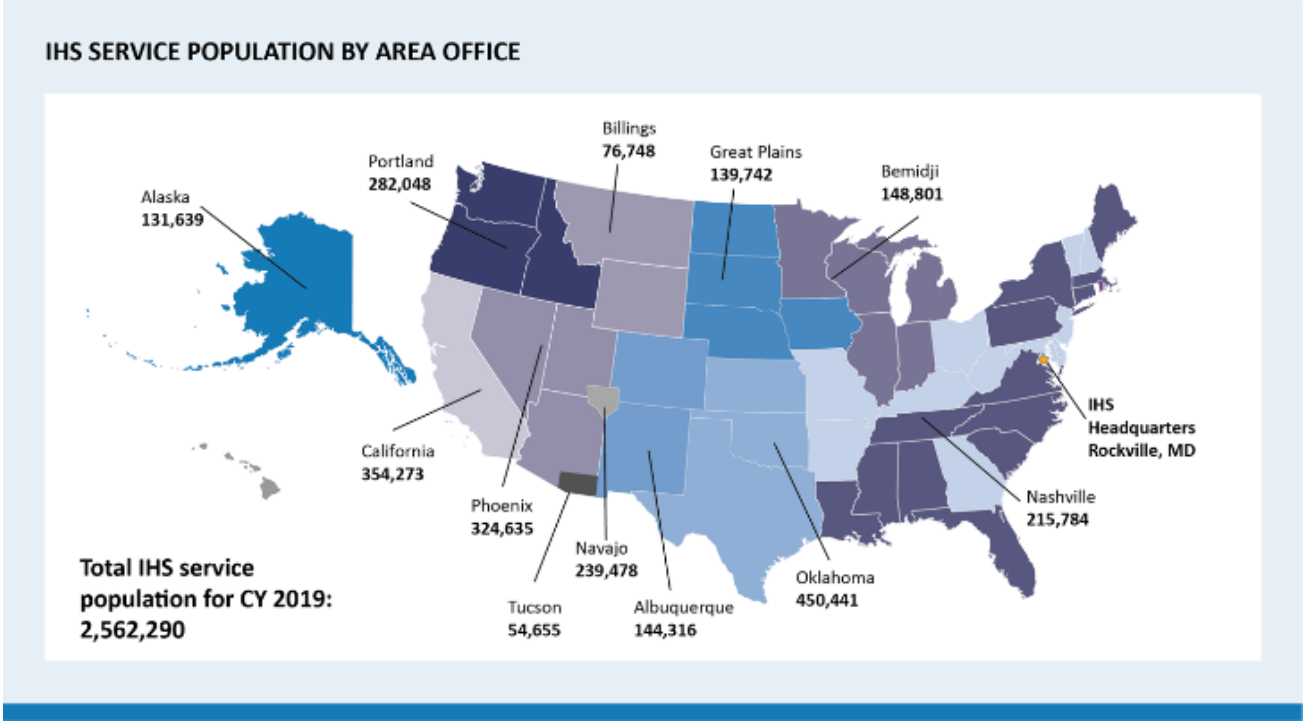
The Fiscal Year (FY) 2020 Budget requests $5.9 billion for the Indian Health Service (IHS), an increase of $392 million or 7 percent above FY 2019. The Budget strengthens the Administration's commitment to improve the health and well-being of American Indians and Alaska Natives through strategic investments across Indian Country.

The FY 2020 Budget increases investments in programs making the greatest impact in Indian Country. These programs provide direct health care services through hospitals and health clinics and address dental health, mental health, and alcohol and substance abuse. The Budget fully funds staffing for new and replacement facilities, new tribes, and Contract Support Costs, which supports tribes that administer their own health programs and facilities.

The Budget invests in new programs to improve patient care, including: quality and oversight, recruitment and retention of health care professionals, Hepatitis C prevention and treatment, the National Community Health Aide Program, and the Electronic Health Record System transition. The Budget also provides $69 million for current services for pay and medical inflation costs, so that purchasing power is not diminished. These funding increases support IHS's goal to ensure that comprehensive, culturally acceptable public health services are available and accessible to American Indian and Alaska Native people.

FULFILLING THE UNIQUE ROLE OF THE INDIAN HEALTH SERVICE BY EXPANDING ACCESS TO CARE

The federal government has a unique government-to-government relationship with 573 tribes. More than sixty percent of the IHS budget funds services that are administered directly by tribes. IHS consults and partners with tribes to maximize participation in administering the programs that impact their



communities. IHS and tribes provide a comprehensive health service delivery system to nearly 2.6 million American Indians and Alaska Natives.

In line with tribal recommendations, the Budget expands health care services delivered through a federal and tribal network of 45 hospitals, 335 health centers, 83 health stations, and 134 Alaska village clinics across the nation. IHS also provides contracts and grants to 41 nonprofit urban Indian organizations providing health care services at 59 locations throughout the United States. The FY 2020 Budget provides $4 billion for Clinical Services, an increase of $382 million above FY 2019. This increase will support direct health care services across the IHS system, including inpatient, outpatient, ambulatory care, dental care, and medical support services such as laboratory, pharmacy, nutrition, behavioral health services, and physical therapy.

Purchased/Referred Care

IHS contracts with hospitals and health care providers through the Purchased/Referred Care program for the services it cannot directly provide within its network. The Budget provides $968 million for this program, an increase of $5 million above FY 2019, to support medical care for catastrophic injuries, specialized care, and other critical care services. IHS supports a growing number of medical services in several areas across the country, and this increase continues that expansion.

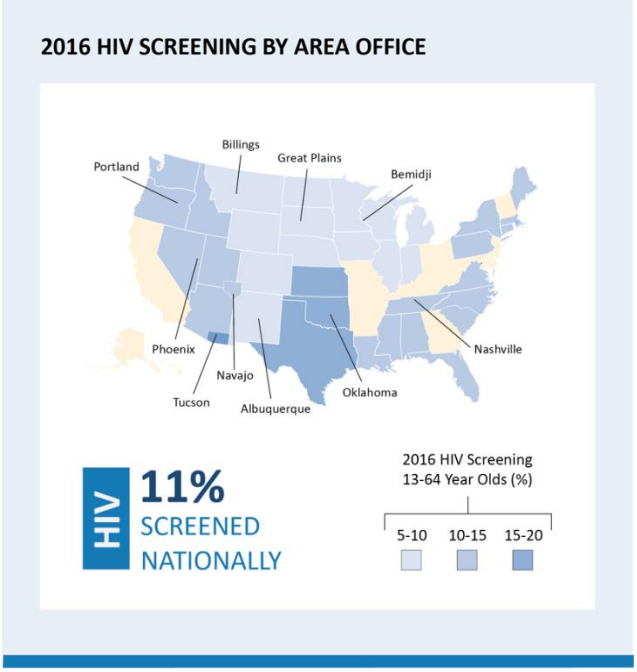
Addressing Behavioral Health Disparities

Substance use disorders, mental health disorders, suicide, violence, and behavior-related chronic diseases disproportionately impact the health of American Indian/Alaska Native individuals, families, and communities. IHS programs prioritize integrated behavioral health and primary care while respecting the balance, wellness, and resilience of American Indian and Alaska Native people. To combat these disparities, the Budget requests a total of $356 million for Mental Health, Alcohol and Substance Abuse programs, an increase of $27 million above FY 2019.

Eliminating Hepatitis C in Indian Country and Ending the HIV Epidemic: A Plan for America

The Budget provides $25 million for establishing the Eliminating Hepatitis C and HIV/AIDS in Indian Country Initiative to provide treatment and case management services to prevent Hepatitis C infection and enhance HIV testing and linkages to care in support of the Administration's Ending HIV Epidemic Initiative.

The new Initiative will also aim to diagnose all individuals with HIV as early as possible after infection, treat the infection rapidly and effectively to achieve sustained viral suppression, protect individuals at risk of HIV using proven prevention approaches, and respond rapidly to growing HIV clusters to prevent new HIV infections. The Initiative will work to reduce new infections in the United States by 75 percent in the next five years and by 90 percent in the next 10 years. American Indians and Alaska Natives are ranked fourth in the nation for the rate of new infections of HIV when compared with all other races and ethnicities.[1]

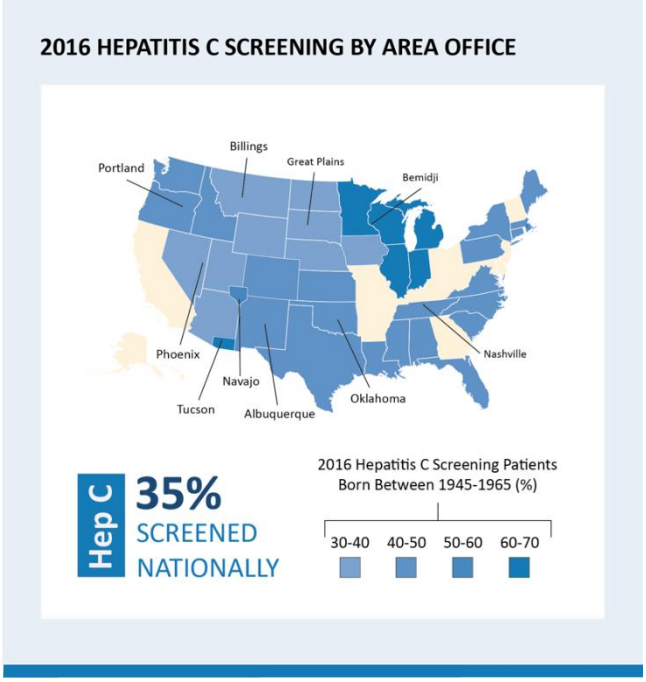


American Indian and Alaska Native people are also disproportionately affected by Hepatitis C infection. National data reveal that American Indian and Alaska Native people experience more than double the

[1] U.S. Centers for Disease Control and Prevention. (2018, April 3). IV Among American Indians and Alaska Natives in the United States. Accessed February 26, 2019, from https://www.cdc.gov/hiv/group/racialethnic/aian/index.html

national rate of Hepatitis C-related mortality and have the highest rate of acute Hepatitis C.[2]

The Initiative focuses on both Hepatitis C and HIV/AIDS to maximize public health benefits and make the most of taxpayer dollars. Hepatitis C prevention and treatment services help reduce active transmission of HIV/AIDS, a frequent co-infection. The Health Resources and Services Administration estimates about 25 percent of people living with HIV also have Hepatitis C, and people who are co-infected are more likely to have life-threatening complications from Hepatitis C.



Quality Improvement and Certification

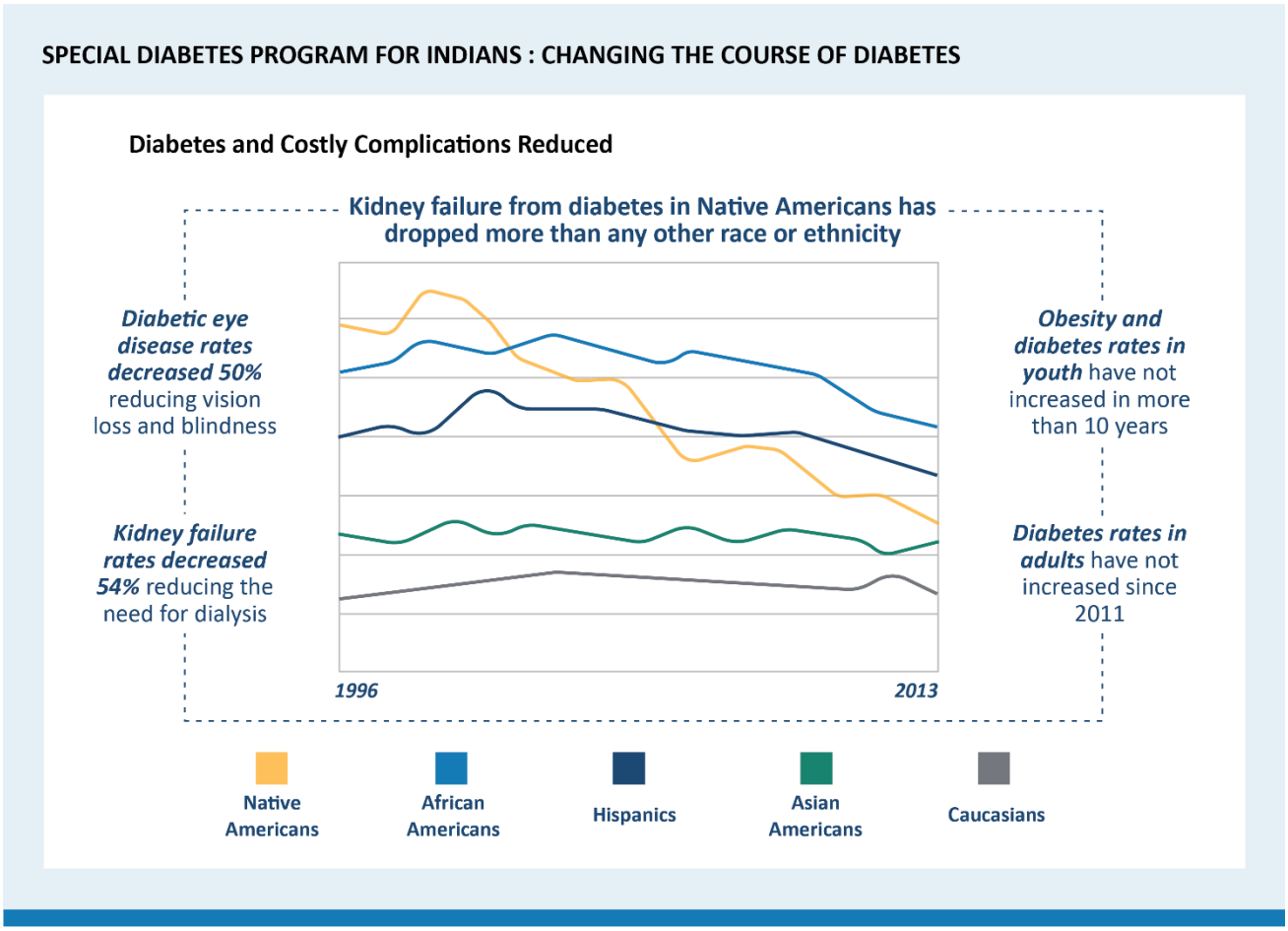
The Budget prioritizes quality health care services at $68 million, an increase of $10 million above FY 2019, to implement nationwide quality and recruitment programs, and assist facilities to meet and maintain CMS quality health care standards. This total includes $8 million for a new Recruitment and Retention Initiative to implement a variety of strategies, including housing subsidies, compensation supplements, and additional IHS Loan Repayment and Scholarship awards to improve recruitment and retention of qualified health care professionals. The Budget also includes $2 million for a new Quality and Oversight Initiative to implement nationwide evidence-based quality assurance tools and practices to improve quality care.

Preventive Health Services

The Budget includes $118 million for Preventive Health Services to invest in evidence-based and outcome-driven programs that improve the health of American Indians and Alaska Natives. The Budget reforms in-home clinical health care services through nationwide expansion of the evidence-based Community Health Aide Program and starts phase out of the Community Health Representatives Program. The new National Community Health Aide Program will build a network of health aides to partner with health care providers and provide health care, health promotion, and disease prevention services. Aides will help expand access to health services in areas that are challenging to serve due to proximity to health care facilities and provider vacancies.

The Budget funds Public Health Nursing at $92 million, an increase of $6 million, and immunization programs to deliver direct health care services and expand access to care for rural and isolated communities.

[2] U.S. Centers for Disease Control and Prevention, Division of Viral Hepatitis. Viral Hepatitis Surveillance-United States, 2016. Accessed February 27, 2019.



Special Diabetes Program for Indians

In 1997, Congress established the Special Diabetes Program for Indians in response to the diabetes epidemic among American Indians and Alaska Natives. The Budget provides $150 million in mandatory funding each year in FY 2020 and FY 2021 for this results-driven grant program that has changed the course of diabetes across Indian Country. The program serves an estimated 780,000 people each year.

The Special Diabetes Program has reduced diabetes and costly complications among American Indian and Alaska Natives, who are substantially more likely than the general population to be diagnosed with diabetes. For example, diabetic eye disease rates have decreased by 50 percent, reducing vision loss and blindness. Kidney failure rates have decreased by 54 percent, reducing the need for dialysis. Additionally, youth obesity and diabetes rates have not increased in more than ten years, and diabetes rates in adults have not increased since 2011.

Staffing Increases

The Budget provides $98 million to fully fund staffing and operating costs for four newly-constructed health care facilities, including Cherokee Nation Regional Health Center, Oklahoma; Yakutat Tlingit Health Center, Alaska; Northern California Youth Regional Treatment Center, California; and Ysleta Del Sur Health Center, Texas. These investments will expand health care services and address critical needs in these communities. Three of the facilities, Cherokee Nation Regional Health Center, Yakutat Tlingit Health Center, and Ysleta Del Sur Health Center, are part of the Joint Venture Construction program where tribes provide funding for the construction of a new or replacement facility, and IHS works with Congress to fund staffing and operating costs.

Health Information Technology

Health Information Technology provides the framework for comprehensive management of health information and its secure exchange between consumers, providers, government quality entities, and insurers. Health Information Technology also offers tools to improve quality, safety, and efficiency of the

health care delivery system. In FY 2020, the Budget invests $25 million to begin transition to a new and modernized Electronic Health Record system. This funding will lay the groundwork to improve the quality of care, reduce the cost of care, promote interoperability, simplify IT service management, increase the security of patient data, enhance cybersecurity, and update infrastructure across rural locations to enable a successful Electronic Health Record transformation.

Health Insurance Reimbursements

The Indian Health Care Improvement Act authorizes IHS to collect Medicaid, Medicare, Veterans Health Administration, and private health insurance reimbursements for services provided by IHS to eligible beneficiaries. The Budget request for IHS estimates $1.2 billion in health insurance reimbursements, which have been used to maintain accreditation standards through hiring additional medical staff, purchasing and updating equipment, and making necessary building improvements.

FACILITIES AND CONSTRUCTION

IHS supports a comprehensive health care facilities program, including the construction and maintenance of health care facilities, and the purchase and maintenance of medical equipment in those facilities. IHS and tribally-run facilities total 17 million square feet in 37 states across the country. The Budget provides $803 million for facilities programs, prioritizing direct health care services.

Health Care Facilities Construction

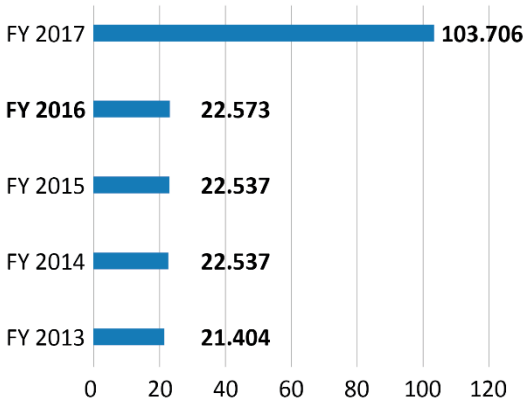
The Budget provides $166 million for health care facilities construction to complete the construction of Bodaway Gap Health Center in Arizona and the Albuquerque West Facility in New Mexico. The 1993 Health Facilities Construction Project Priority List, developed by IHS in consultation with tribes in 1992, governs new and replacement facilities construction. The 2010 reauthorization of the Indian Health Care Improvement Act incorporated the priority list into the statute. In addition to federally-funded facilities construction, IHS administers the Joint Venture Construction program, which authorizes IHS to fund and staff facilities constructed by tribes.

Sanitation Facilities Construction

The Indian Health Care Improvement Act requires IHS to identify sanitation facility needs for existing American Indian and Alaska Native homes by documenting deficiencies and proposing projects to address their needs. These projects provide new and existing homes with first time services such as water wells, onsite wastewater systems, or connecting homes to community water and wastewater facilities. As a result of this program, infant mortality rates and mortality rates for gastroenteritis and other environmentally-related diseases have dropped approximately 80 percent since 1973. The Budget requests $193 million for these activities to continue progress of this successful activity.

MEDICAL EQUIPMENT INVESTMENTS (DOLLARS IN MILLIONS)

Due to Department-Wide investments through the Non-Recurring Expenses Fund, as displayed below, the current IHS medical equipment backlog has been significantly reduced from $103 million in FY 2013 to $33 million in FY 2018.



Includes appropriated funding and funding provided through the Non-Recurring Expenses Fund.

Other Facilities Programs

The Budget includes $444 million for maintenance and improvement, medical equipment, and the Facilities and Environmental Health Support program, $11 million above FY 2019. These programs fund IHS's ability to maintain, repair, and improve existing IHS and tribal health care facilities, purchase medical equipment, and support an extensive array of real property, community and institutional environmental health, and injury prevention programs.

FURTHERING INDIAN SELF-DETERMINATION

IHS recognizes that tribal leaders and members are in the best position to understand the health care needs and priorities of their communities. The number of Tribal Self-Governance Program success stories grows each year, and IHS offers information, technical assistance, and policy coordination to enable this success. Today, tribes directly administer over 60 percent of the IHS budget through Indian Self-Determination and Education Assistance Act contracts and compacts.

Contract Support Costs

Contract support costs cover the reasonable costs incurred by tribes for activities necessary for administering Federal programs. The Budget fully funds Contract Support Costs at an estimated $855 million and continues the use of an indefinite appropriation, allowing IHS to guarantee full funding of this program.

Centers for Disease Control and Prevention

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Programs				
Immunization and Respiratory Diseases	797	798	730	-68
Prevention and Public Health Fund (non-add)	324	321	153	-168
Vaccines for Children	4,389	4,176	4,761	+586
HIV/AIDS, Viral Hepatitis, STI and TB Prevention	1,116	1,125	1,318	+193
Emerging and Zoonotic Infectious Diseases	604	612	509	-103
Prevention and Public Health Fund (non-add)	52	52	137	+85
Chronic Disease and Health Promotion	1,160	1,188	951	-237
Prevention and Public Health Fund (non-add)	248	255	604	+349
Birth Defects, Developmental Disabilities, Disabilities and Health	140	156	112	-44
Environmental Health	205	209	157	-52
Prevention and Public Health Fund (non-add)	17	17	--	-17
Injury Prevention and Control	648	649	629	-20
Public Health and Scientific Services	497	504	468	-36
PHS Evaluation Funds (non-add)	--	--	423	+423
Occupational Safety and Health	334	336	190	-146
Global Health	495	496	457	-39
Public Health Preparedness and Response /1	846	855	825	-30
Buildings and Facilities /2	510	30	30	--
CDC-Wide Activities and Program Support	274	324	155	-169
Prevention and Public Health Fund (non-add)	160	160	--	-160
Agency for Toxic Substances and Disease Registry (ATSDR) /3	75	75	62	-13
User Fees	2	2	2	--
Total Program Level	**12,642**	**12,107**	**11,954**	**-153**
Less Funds from Other Sources				
Vaccines for Children	4,389	4,176	4,761	+586
Energy Employee Occupational Illness Compensation Program	50	55	55	--
World Trade Center Health Program	470	517	541	+25
Childhood Obesity Research Demonstration Project	30	--	--	--
PHS Evaluation Funds	--	--	423	+423
Prevention and Public Health Fund	801	805	894	+89
User Fees	2	2	2	--
Total Discretionary Budget Authority	**6,899**	**6,553**	**5,277**	**-1,276**
Full-Time Equivalents	11,583	11,693	11,715	22

1/ The FY 2019 Enacted funding for the Strategic National Stockpile was administratively transferred from CDC to ASPR, effective October 1, 2018. The FY 2018 level is comparably adjusted.
2/ The FY 2018 Enacted bill provided $480 million in one-time funding to support the construction of a high-containment lab.
3/ FY 2019 is comparably adjusted for the FY 2020 Budget and reflects the annualized continuing resolution level for ATSDR.

The Centers for Disease Control and Prevention (CDC) works 24/7 to protect America from health, safety, and security threats, both foreign and in the United States. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the Nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish its mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

The Centers for Disease Control and Prevention (CDC) is the nation's leading public health agency, dedicated to saving lives and protecting the health of Americans. CDC keeps America secure by preventing and controlling disease outbreaks, protecting against foodborne illnesses, helping people avoid leading causes of death such as heart disease, cancer, stroke, and diabetes, and working globally to reduce threats to the nation's health.

CDC accomplishes its public health mission through three main strategies: putting science into action; developing the public health workforce; and fighting diseases before they reach our nation's borders.

CDC saves lives by responding to emergencies, providing expertise, and detecting disease outbreaks wherever they arise. CDC's scientists collect and analyze data to determine how health threats affect specific populations. This work protects people from public health threats every day. By connecting state and local health departments across the United States, CDC can discover patterns of disease and respond effectively. CDC strengthens local and state public health departments and promotes health programs that are proven to work. Approximately 78 percent of CDC's domestic funding is provided directly to state and local entities to detect and control disease, prevent the leading causes of death, and prepare for health threats.

The Fiscal Year (FY) 2020 Budget for CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) requests $12.0 billion. This total includes $5.3 billion in budget authority, $894 million from the Prevention and Public Health Fund, and $423 million in Public Health Service (PHS) Evaluation Funds.

The Budget prioritizes funding where CDC can have the greatest impact, including: fighting opioid abuse, misuse, and overdose; working towards ending the HIV epidemic in America; strengthening global health security; and focusing efforts to prevent and control infectious diseases. The Budget prioritizes flexible funding, allowing CDC to efficiently adapt and support mission-critical programs driven by cutting-edge science and public health expertise, and current events.

HIV/AIDS, VIRAL HEPATITIS, SEXUALLY TRANSMITTED INFECTIONS AND TUBERCULOSIS PREVENTION

CDC protects the nation and helps Americans lead healthier and longer lives through programs that prevent and control HIV, viral hepatitis, sexually transmitted infections and tuberculosis. CDC identifies and disseminates proven, cost-effective interventions to achieve the greatest impact. These programs support state, tribal, local, and territorial health departments as they respond to disease outbreaks, and CDC's laboratories make vital discoveries and develop cutting-edge technology to prevent the spread of infection. The FY 2020 Budget includes a total of $1.3 billion for these activities, which is $193 million above FY 2019.

Ending the HIV Epidemic: A Plan for America

The Budget includes $929 million for CDC's domestic HIV/AIDS surveillance and prevention efforts, which is $140 million above FY 2019. The FY 2020 Budget provides $140 million for CDC to begin a new multi-year strategic initiative to end the HIV epidemic in America. Medical and technological advancement provides the United States the unprecedented opportunity to control the HIV epidemic. These investments will lay the foundation to reduce new HIV diagnoses by 75 percent over the next five years and 90 percent over the next ten years.

This Initiative will be coordinated across HHS, with efforts from CDC, the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), and the National Institutes of Health (NIH). CDC will leverage its HIV prevention infrastructure to plan and implement a targeted strategy in collaboration with other HHS Operating Divisions. CDC's efforts will be focused on reducing new HIV infections by working closely with State and local health departments on

intensive testing and referral to care and other efforts. This strategy will develop and deploy innovative data management solutions, and implement strategic testing linked to immediate treatment. The Initiative will also utilize the clinical care system to expand the use of pre-exposure prophylaxis (PrEP) by people at high risk, and develop approaches to better detect and respond to clusters of HIV.

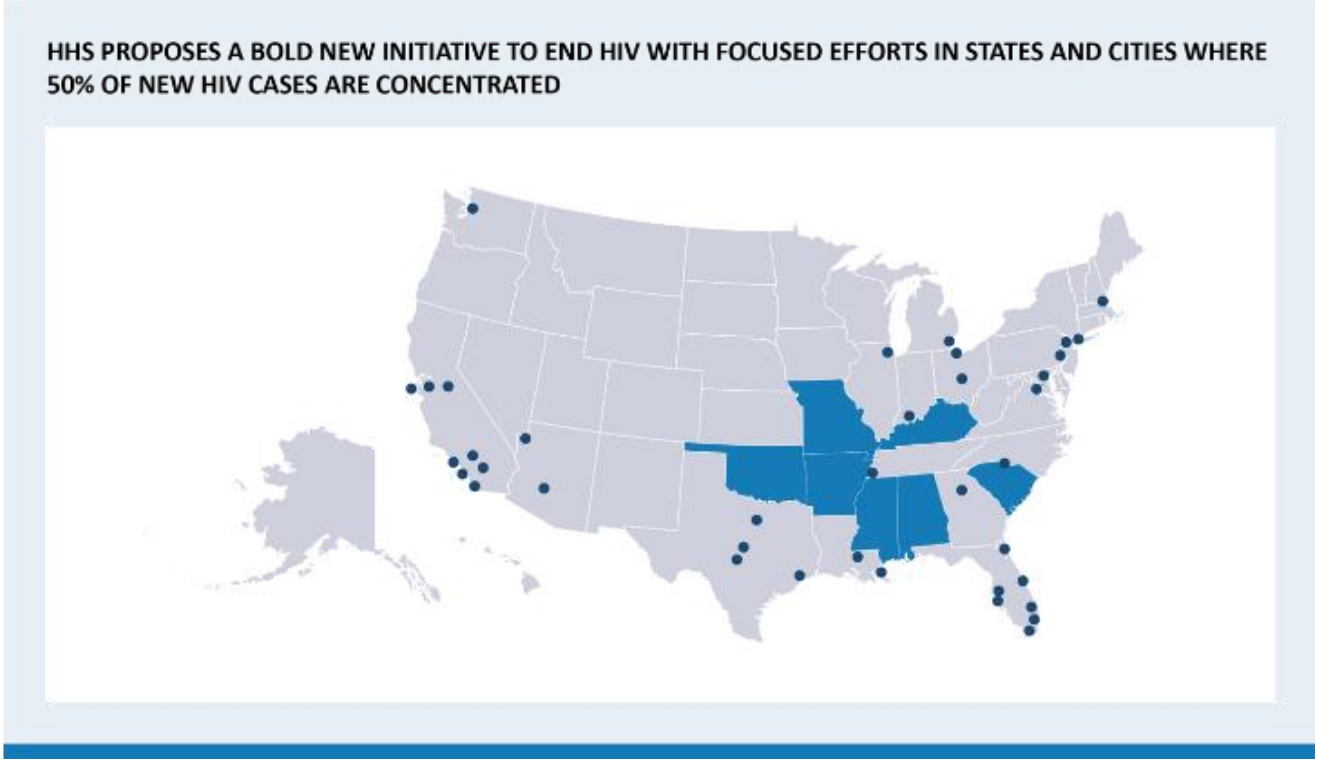
Half of all new HIV diagnoses are concentrated in a relatively limited geographic area. By using existing data to target scientifically proven approaches, the United States can prevent new infections and control the HIV epidemic. Through these activities in FY 2020, CDC will begin to 'bend the curve' of the HIV epidemic and take the first steps toward HIV epidemic control.

Infectious Diseases

CDC estimates that nearly 2.4 million Americans–1 percent of the adult population–were living with hepatitis C from 2013 through 2016, with rising infections due to the opioid crisis and related injection drug use. Yet, while new infections are rising at an alarming rate, hundreds of thousands of Americans have also been cured now that new, more effective, therapies are available. We can win the fight against viral hepatitis. The FY 2020 Budget includes $39 million to invest in partnerships with state and local health departments, universities, medical centers, and community-based organizations to prevent and control viral hepatitis.

CDC data indicates the United States is experiencing a steep and sustained increase in sexually transmitted infections. The FY 2020 Budget includes $157 million to support CDC's continued national leadership, research, and policy development to prevent sexually transmitted infections nationwide. Funding will support health departments, health care providers, and non-government organizations to expand prevention training programs and develop new technologies and surveillance methods. CDC is working with HHS in calendar year 2019 to develop an STD Action Plan that will focus on how the agencies' combined efforts can turn the tide on the rising rates of STDs in the United States.

CDC is the lead agency for eliminating tuberculosis (TB) in the United States, and is a global leader in the science of TB elimination. HHS is the only United States Government agency with a mandate to carry out programmatically relevant domestic TB research. The Budget includes $135 million which reflects the realignment of $7 million for global tuberculosis activities to CDC's Center for Global Health. CDC's TB program works to eliminate tuberculosis in the United States through increased testing and treatment among people who are at high risk for TB, aggressive case



finding and treatment for active tuberculosis disease, and research on drug regimens and diagnostic tools. CDC's clinical and programmatic research form the evidence base for U.S. TB elimination guidelines, which in turn, inform global strategies and recommendations. CDC has contributed to the reduction of TB infections through investigating every reported domestic case of TB, identifying contacts and providing treatment to prevent future cases, and ensuring medical care, laboratory testing and other services support the complete cure of infected TB patients to halt further transmission. Progress to reduce the number of new TB infections has slowed. The Budget will allow CDC to continue to make progress towards eliminating TB in America.

Due to the opioid epidemic, the United States is experiencing increases in certain infectious diseases as well as an increased number of disease outbreaks. The FY 2020 Budget provides $58 million to increase CDC's Infectious Diseases and the Opioid Epidemic activities, $53 million above FY 2019. This program addresses the infectious disease consequences of the opioid epidemic and supports prevention and surveillance interventions in high-risk areas to reduce the spread of infectious disease.

IMMUNIZATION AND RESPIRATORY DISEASES

CDC prevents disease, disability, and death of children, adolescents, and adults through immunization and control of respiratory and related diseases. CDC promotes immunization and infection control practices, which are critical in defending against public health threats. CDC supports epidemiology and laboratory capacity, and leads preparedness planning for pandemic influenza. CDC also improves access to immunization through the discretionary-funded immunization program and the mandatory-funded Vaccines for Children program.

The FY 2020 Budget includes $5.5 billion for these activities, of which $730 million is for discretionary immunization programs.

Combatting Acute Flaccid Myelitis

Acute Flaccid Myelitis (AFM) is a rare but serious condition that affects the nervous system, particularly in children. CDC works closely with national experts, health care providers, and state and local health departments to thoroughly investigate AFM. The Budget includes $10 million to expand efforts to monitor AFM nationwide, and, where possible, to update diagnosis and treatment guidelines.

Addressing the Threat of Influenza

Influenza is a serious disease that can lead to hospitalization and sometimes death, even among healthy people. In the United States, millions of people are sickened, hundreds of thousands are hospitalized, and tens of thousands of people die from flu every year. CDC provides scientific expertise, resources, and leadership to support diagnosis, prevention, and control of influenza domestically and address the threat posed by seasonal and pandemic influenza.

The Budget includes $198 million to support these activities, which is $10 million above FY 2019. In FY 2020, CDC will support high-priority seasonal influenza activities, including efforts to help modernize the seasonal influenza vaccine and remove obstacles that prevent people from getting vaccinated.

Vaccines for Children

Through the Vaccines for Children Program, CDC provides immunizations at no cost to children who might not otherwise have access to recommended childhood vaccines. Approximately 50 percent of young children and one-third of adolescents in the United States are eligible for this program. CDC estimates vaccinations prevented 25 million hospitalizations and 855,000 deaths among children born in the last 20 years, which resulted in net savings of $1.7 trillion in total societal costs. The Budget includes $4.8 billion in mandatory funding to support the Vaccines for Children program in FY 2020.

EMERGING AND ZOONOTIC INFECTIOUS DISEASES

CDC works throughout the United States and around the world to prevent illness, disability, and death caused by a wide range of infectious diseases. These programs protect Americans from rare but deadly diseases like anthrax and Ebola, and also more common threats like foodborne disease and health care-associated infections. CDC provides infectious disease expertise to help identify and prevent illness and contain outbreaks that sometimes span many states. The Budget includes $509 million to support CDC's National Center for Emerging and Zoonotic Infectious Diseases.

Vector-Borne Diseases

Vectors are mosquitoes, ticks, and fleas that spread pathogens. A person who gets bitten by mosquitoes, ticks, fleas or other such arthropods and gets sick has a vector-borne disease. Between 2004 and 2016, the number of reported cases of disease from mosquito, tick, and flea bites more than tripled in the United States. The number of Americans at risk of vector-borne diseases continues to increase as global travel and urbanization contribute to vector-borne disease outbreaks in new regions and countries. The Budget includes $51 million for vector-borne disease activities. CDC will continue support for public health programs that address emerging diseases from mosquitoes and ticks, advance innovation and discovery, and support states, particularly those that are at the greatest risk of outbreaks.

Antibiotic Resistance

Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics, and at least 23,000 people die from these infections. The Budget includes $137 million for CDC to prevent, detect, and respond to resistant infections. CDC will invest in states and communities across the United States, expand laboratory capacity for antibiotic resistant testing, and support innovation to determine successful practices in combatting antibiotic resistance and share these practices to inform how the nation responds to some of the most serious antibiotic-resistant threats.

PUBLIC HEALTH SCIENTIFIC SERVICES

The factors affecting our health are wide-ranging—from new and changing health threats, natural disasters, bioterrorism, access to health care, and the growing burden of noncommunicable diseases. These issues require strategic thinking, new ideas, flexibility, and readiness to connect across disciplines. CDC leads, promotes, and facilitates science standards and policies to reduce the burden of diseases in the United States and globally. The Budget includes $468 million for these activities.

The National Center for Health Statistics is the nation's principal health statistics agency, and provides statistical information to guide actions and policies to improve the health of the American people. The Budget includes $155 million for health statistics.

INJURY PREVENTION AND CONTROL

In the United States, injury is the leading cause of death for children and adults between the ages of 1 and 45. Unintentional injuries and intentional violence affect all Americans, regardless of age, race, or economic status. The FY 2020 Budget includes $629 million for injury prevention and control activities. CDC collaborates with national organizations, state health agencies, and other key groups to develop, implement, and promote effective injury and violence prevention and control practices. CDC tracks injuries and deaths to identify trends, develops prevention strategies, and supports states to implement effective prevention programs.

Effective prevention strategies incorporate the unique factors of a community. To better understand localized factors, CDC will continue support for the National Violent Death Reporting System (NVDRS) in all 50 states, the District of Columbia, and Puerto Rico. The FY 2020 Budget includes $24 million for NVDRS. NVDRS is a state-based surveillance system that links data from law enforcement, coroners and medical examiners, vital statistics, and crime laboratories to identify violence trends at national and regional levels. This allows states to access all important data elements from one central database, and informs the development and implementation of tailored interventions.

Fighting the Opioids Epidemic

From 2013 to 2017, drug overdose death rates increased in 35 of 50 states and Washington, D.C., and significant increases in death rates involving synthetic opioids occurred in 15 of 20 states, likely driven by illicitly manufactured fentanyl. From 2016 to 2017, overdose deaths involving all opioids and synthetic opioids increased, but deaths involving prescription opioids and heroin remained stable but still high. The opioid overdose epidemic continues to evolve because of the continuing increase in deaths involving synthetic opioids. Provisional data from 2018 indicate potential improvements in some drug overdose indicators; however, analysis of final data from 2018 is necessary for confirmation. Over 399,000 people have died from overdoses involving prescription or illicit opioids in the United States from 1999 to 2017.

The FY 2020 Budget continues to prioritize opioid activities at CDC, with a total funding level of $476 million. CDC is committed to fighting the opioid overdose epidemic and supporting states and communities as they collect data, respond to overdoses, and provide care to those in their communities. CDC's efforts support the Department's five-point strategy to combat the opioid crisis. Accurate and timely data on the opioid epidemic is essential to implement the most effective interventions for each community. CDC improves data quality and tracks trends to better understand and quickly respond to the epidemic. CDC collects and analyzes data on opioid-related overdoses to identify high-risk areas and evaluate prevention efforts. CDC supports states with funding, resources, and information to: aid data collection; prevent opioid use disorder, overdose, and death; and helps improve access to safer and more effective pain treatment.

The FY 2020 Budget supports state efforts to combat prescription and illicit opioid abuse and overdose. CDC will enhance state capacity for opioid overdose surveillance through support to all 50 states. This program supports activities to build capacity at the state-level for overdose monitoring, tracking problematic prescribing patterns, and identifying changes in illicit supply. These activities will improve states' abilities to monitor the epidemic by improving the timeliness and quality of surveillance data for both fatal and nonfatal opioid overdose as well as to leverage timely data to target effective responses. The Budget will improve multi-state opioid surveillance and response, enhance prescription drug monitoring programs, and improve prescribing practices, and increase awareness and knowledge among consumers about the risks of prescription opioids.

PREVENTING OPIOID OVERDOSES AND RELATED HARMS

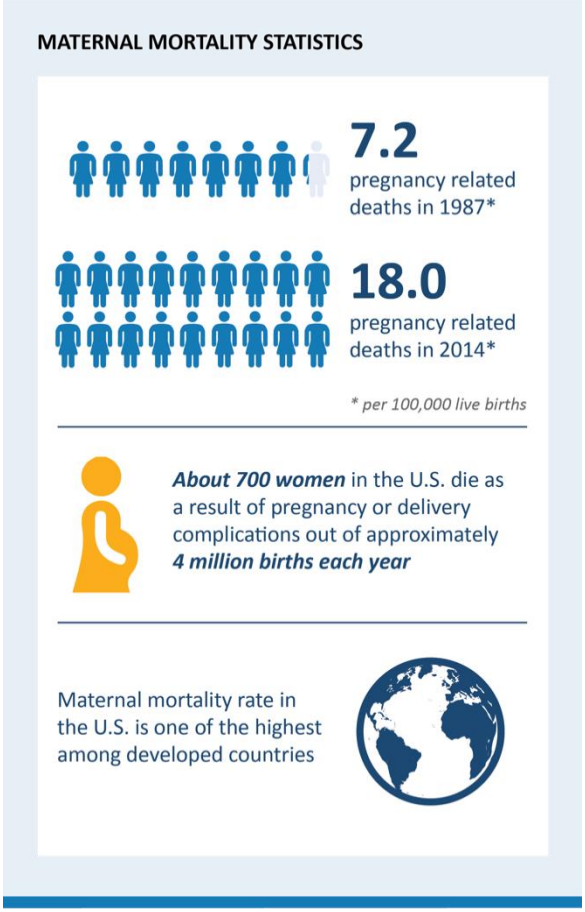
BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Birth defects affect 1 in 33 babies and are a leading cause of infant mortality in the United States. The FY 2020 Budget includes $112 million to prevent birth defects and developmental disabilities. CDC identifies causes of birth defects, finds opportunities to prevent them, and improves the health of those living with birth defects. CDC utilizes three essential strategies to prevent birth defects: surveillance and disease tracking; research to identify causes; and prevention research and programs. These efforts rapidly translate scientific findings into appropriate public health interventions.

Emerging Threats to Mothers and Babies

The FY 2020 Budget includes $10 million for the Emerging Threats to Mothers and Babies program. This program supports state, tribal, territorial, and local health departments in their efforts to capture emerging scientific information from surveillance systems and turn this data into relevant clinical guidance for obstetricians, gynecologists and pediatricians. This program will support the dissemination of information to the clinical community caring for mothers and their infants who are exposed

to emerging or known threats and continue to build clinical and public health partnerships to address emerging threats in the communities as they occur. These activities will support effective interventions to prevent future birth defects.



Neonatal Abstinence Syndrome

Neonatal abstinence syndrome is a growing problem in the United States. Neonatal abstinence syndrome occurs when newborn babies experience withdrawal after being exposed to drugs in the womb. The FY 2020 Budget provides $2 million to support CDC's continued work to advance our understanding of neonatal abstinence syndrome and translate these findings to improve the care of mothers and babies.

CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION

Six in ten Americans live with at least one chronic disease, like heart disease, cancer, stroke, or diabetes. Chronic diseases are responsible for 7 in 10 deaths each year, are the leading causes of death and disability in America, and are a leading driver of health care costs.

The FY 2020 Budget includes $951 million for chronic disease prevention and health promotion activities. CDC works to reduce the risk factors for chronic diseases. CDC funds states, tribes, cities, and territories to study how chronic diseases affect different populations in the United States, research effective interventions, and share information to help Americans understand risk factors for chronic diseases and how to prevent them.

The FY 2020 Budget proposes the America's Health Block Grant as a reform to state-based chronic disease programs. This $500 million block grant program will provide states the flexibility to support interventions that best address public health challenges specific to their state.

The Budget includes $337 million for cancer prevention and control, to continue to support cross-cutting activities for multiple types of cancer.

Maternal Mortality Review Committees

The Budget includes $12 million to support Maternal Mortality Review Committees to reduce maternal mortality. This funding will support state health departments strengthen data collection to understand the key factors leading to increasing maternal mortality. CDC will use this data to develop evidence-based approaches to reduce maternal deaths in the United States.

ENVIRONMENTAL HEALTH

Environmental hazards may be found in American's everyday environment, from air, water, or food. CDC's activities work to prevent illness, disability, and death from contacts between people and the environment.

The FY 2020 Budget includes $157 million to support CDC's environmental health activities. CDC will monitor health outcomes following environmental exposures, prepare for and respond to public health emergencies, including chemical, biological, radiological, and nuclear incidents, and support environmental health programs and interventions to protect and promote health.

OCCUPATIONAL SAFETY AND HEALTH

CDC's National Institute for Occupational Safety and Health is the lead research agency focused on worker safety and health to protect the nation's 161 million

workers. The FY 2020 Budget provides $190 million for occupational safety and health activities. CDC works cooperatively with employers and employees to adapt research findings into effective solutions that prevent injuries and illness. In addition to the discretionary resources provided for these activities, the Budget provides $55 million for the Energy Employee Occupational Injury Compensation Act program.

World Trade Center Health Program

The Budget includes $541 million in mandatory Federal share funding for the World Trade Center Health Program to provide medical monitoring and treatment to specific groups of individuals affected by the September 11, 2001 terrorist attacks on the United States. Those served by the program include responders at the World Trade Center and related sites in New York City, Pentagon, and Shanksville, PA, and survivors who were in the New York City disaster area. The program was established by the James Zadroga 9/11 Health and Compensation Act of 2010 and, in 2015, was reauthorized until 2090.

PUBLIC HEALTH PREPAREDNESS AND RESPONSE

CDC strengthens national preparedness for public health emergencies including natural, biological, chemical, radiological, and nuclear incidents. The Budget provides $825 million for these activities. State and local public health departments are key in preparing for, responding to, and recovering from public health emergencies. The Budget provides $675 million for the Public Health Emergency Preparedness cooperative agreements. CDC will continue to fund 62 awardees, including all 50 states, eight United States territories and freely-associated states, and four localities. The program provides critical resources for state, local, and territorial public health departments to build and strengthen their abilities to effectively respond to public health threats ranging from infectious diseases to natural disasters to radiological events. In FY 2020, CDC will continue to allocate funding to states and localities according to need and potential risk. CDC tracks recipient programmatic performance to inform future grant awards and ensure effective use of federal funds. State and local health departments use this funding to improve capabilities across the country so that communities can effectively manage public health emergencies.

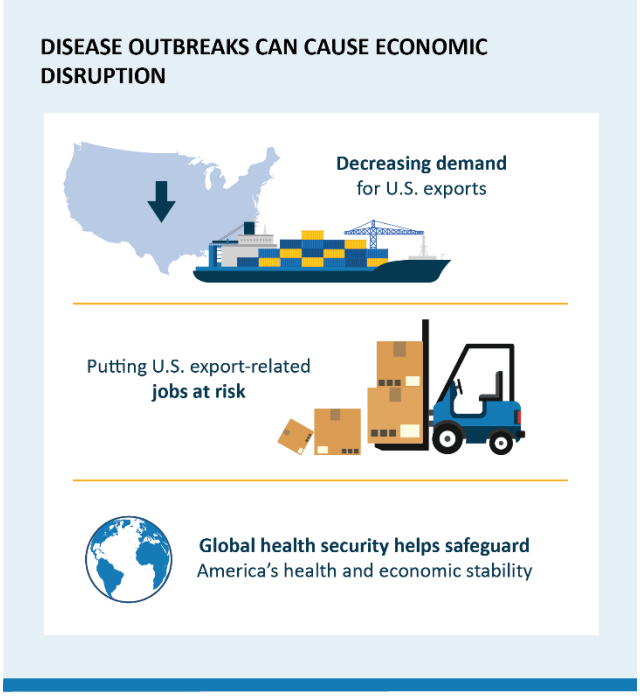
GLOBAL HEALTH

The most efficient and cost-effective way to protect Americans from health threats that begin overseas is to stop them before they spread to our shores. Because disease can travel from a rural village to any international or domestic major city in as little as 36 hours, disease threats anywhere in the world are a threat to America. CDC detects and controls disease outbreaks at their source, saving lives and reducing health care costs.

CDC has world experts in epidemiology, surveillance, informatics, laboratory systems, and other essential disciplines who work to prevent and respond to a variety of health threats across the globe. To support these activities, the Budget includes $457 million for CDC's global health efforts.

Global Health Security

The FY 2020 Budget includes $100 million for global health security. CDC's global health security activities enhance global capacity to prevent, detect, and rapidly respond to infectious disease threats. Investing in global health security protects Americans from emerging and re-emerging disease threats and prevents against future epidemics.



To accelerate progress toward a world safe and secure from infectious disease threats, the Budget continues to support CDC as the global leader in building disease

detection and response capabilities in other countries. This funding supports partnering with countries to achieve measurable improvements to their own capacity to respond to disease threats, activities preventing outbreaks, detecting threats early to save lives, and responding rapidly and effectively once outbreaks occur. CDC will leverage regional platforms that increase flexibility and efficiencies in addressing public health opportunities and challenges as they evolve and emerge globally.

This Budget also includes $7 million realigned from the HIV/AIDS, Viral Hepatitis, Sexually-Transmitted Infections, and Tuberculosis Prevention account to better align the operation of the Tuberculosis program. CDC will continue on-going global tuberculosis efforts in 25 high burden countries to find, cure, and prevent tuberculosis and help sustain partner countries' efforts to do the same.

INFECTIOUS DISEASES RAPID RESPONSE RESERVE FUND

The United States must be ready to respond to a pandemic, natural disaster, or chemical or radiological release at any moment. The FY 2020 Budget provides $50 million for the Infectious Diseases Rapid Response Reserve Fund for CDC that could be used to rapidly and effectively respond to emerging infectious disease outbreaks that threaten the health of Americans.

BUILDINGS AND FACILITIES

CDC's facilities support the dedicated personnel who work to protect Americans from health threats every day. Safe, secure, and fully operational buildings and facilities enable CDC to prevent new disease threats and address evolving public health needs.

The FY 2020 Budget includes $30 million to support repairs for and improvements to CDC's buildings and facilities. These investments enable the replacement, maintenance, and improvement of existing facilities essential for CDC's core mission.

AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

The Agency for Toxic Substances and Disease Registry (ATSDR) is a nonregulatory, congressionally-mandated public health agency which protects communities from harmful health effects of exposure to natural and man-made hazardous substances. ATSDR reduces morbidity and mortality related to exposure to natural and man-made toxic substances by responding to environmental health emergencies, investigating environmental health threats, and building capabilities of and providing actionable guidance to state and local health partners.

The FY 2020 Budget includes $62 million for ATSDR, with a priority on activities related to asthma, children's health, safe drinking water, and innovative laboratory methods.

National Institutes of Health

	dollars in millions			2020 +/- 2019
	2018 /1	2019 /2	2020	
Institutes/Centers				
National Cancer Institute	5,944	6,144	5,247	-897
National Heart, Lung, and Blood Institute	3,374	3,488	3,003	-486
National Institute of Dental and Craniofacial Research	447	462	397	-64
National Institute of Diabetes & Digestive & Kidney Diseases	2,113	2,180	1,896	-283
National Institute of Neurological Disorders and Stroke	2,145	2,274	2,026	-248
National Institute of Allergy and Infectious Diseases	5,268	5,523	4,754	-769
National Institute of General Medical Sciences	2,781	2,873	2,473	-400
Eunice K. Shriver Natl. Institute of Child Health & Human Development	1,457	1,506	1,297	-210
National Eye Institute	770	797	686	-111
Natl Institute of Environmental Health Sciences: Labor/HHS Appropriation	749	775	667	-108
National Institute of Environmental Health Sciences: Interior Appropriation	77	77	67	-11
National Institute on Aging	2,572	3,083	2,654	-429
National Institute of Arthritis & Musculoskeletal & Skin Diseases	585	605	521	-84
National Institute on Deafness and Communication Disorders	459	474	408	-66
National Institute of Mental Health	1,754	1,870	1,630	-240
National Institute on Drug Abuse	1,374	1,420	1,296	-123
National Institute on Alcohol Abuse and Alcoholism	508	526	452	-73
National Institute of Nursing Research	158	163	140	-23
National Human Genome Research Institute	557	576	495	-80
National Institute of Biomedical Imaging and Bioengineering	377	389	336	-53
National Institute on Minority Health and Health Disparities	304	315	271	-44
National Center for Complementary and Integrative Health	142	146	126	-20
National Center for Advancing Translational Sciences	761	806	694	-112
Fogarty International Center	76	78	67	-11
National Library of Medicine	428	442	380	-62
Office of the Director	1,804	1,917	1,769	-148
21st Century Cures Innovation Accounts	110	196	157	-39
Buildings and Facilities	129	200	200	--
National Institute for Research on Safety and Quality /3	--	--	256	+256
Total, Program Level	**37,224**	**39,306**	**34,368**	**-4,938**
Less Funds from Other Sources				
PHS Evaluation Funds	-923	-1,147	-741	-406
Current Law Mandatory Funding – Type 1 Diabetes	-150	-150	--	+150
Proposed Law Mandatory Funding – Type 1 Diabetes	--	--	-150	-150
Total, Discretionary Budget Authority	**36,151**	**38,010**	**33,477**	**-4,533**

	dollars in millions			2020
	2018 /1	2019 /2	2020	+/- 2019
Appropriations				
Labor/HHS Appropriation	36,074	37,933	33,410	-4,523
Interior Appropriation	77	77	67	-10
Full-Time Equivalents /4	17,532	18,101	18,339	+238

1/ Reflects the FY 2018 Final level including funding authorized by the 21st Century Cures Act and directed or permissive transfers. Funding level does not include supplemental hurricane appropriations ($50 million).
2/ FY 2019 reflects the annualized continuing resolution level for the NIEHS Interior Appropriation and the $5 million directed transfer to the HHS Office of the Inspector General.
3/ The FY 2020 Budget consolidates the highest priority activities of the Agency for Healthcare Research and Quality (AHRQ) within NIH as the National Institute for Research on Safety and Quality (NIRSQ). AHRQ's Enacted appropriation in FY 2018 and FY 2019 was $334 million and $338 million respectively. In addition, AHRQ received mandatory transfers from the Patient-Centered Outcomes Research Trust Fund (PCORTF) in FY 2018 and FY 2019 for total Program Levels of $433 million and $451 million, respectively. The PCORTF sunsets in FY 2019.
4/ Full-time equivalent levels include NIRSQ in FY 2020.

The National Institutes of Health's (NIH) mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

In pursuit of its mission, the National Institutes of Health (NIH) conducts and supports biomedical research that fosters fundamental creative discoveries, innovative research strategies, and their applications to improve human health.

As the nation's premier biomedical research agency, NIH plays a critical role in advancing basic and clinical biomedical research. NIH develops, maintains, and renews scientific, human, and physical resources to ensure the nation's capability to prevent disease and disability. The biomedical research enterprise depends not only upon NIH's support of cutting-edge science and technology, but also its wise investment of public resources to fund research in support of its mission to enhance the lives of all Americans.

NIH is a vital contributor to the U.S. economy. NIH-funded research drives economic growth in the pharmaceutical, biotechnology, and medical device industries.

The Fiscal Year (FY) 2020 Budget provides $34.4 billion for NIH. This total includes $492 million in resources available through the 21st Century Cures Act and $150 million in mandatory resources. To streamline federal research, the Budget also includes $256 million for the new National Institute for Research on Safety and Quality (NIRSQ) to continue key research activities currently administered by the Agency for Healthcare Research and Quality (AHRQ).

RESEARCH PRIORITIES IN FY 2020

Confronting the Opioid Crisis

More than two million Americans have an opioid use disorder[3], and millions more use opioids inappropriately by taking opioid medications longer or in higher doses than prescribed. The Budget includes $1.3 billion for opioids and pain research across NIH as part of the government-wide effort to combat the opioid epidemic. This total includes $500 million to continue the Helping to End Addiction Long-term (HEAL) Initiative and nearly $800 million to support ongoing research. Within NIH, NIRSQ will accelerate evidence on preventing and treating opioid abuse in primary care, especially older adults. NIH continues to develop long-lasting preventative and therapeutic solutions to the opioid crisis that can be implemented across the country, particularly in the areas hardest hit by the epidemic.

Helping to End Addiction Long-Term

To bring evidence-based solutions to the opioid crisis, and to provide safe and effective options for the more than 25 million Americans who suffer from daily

[3] https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report

chronic pain, NIH launched the HEAL Initiative in April 2018. Through HEAL, NIH is building on basic science discoveries to accelerate the development of novel medications and devices to treat all aspects of the opioid addiction cycle, including chronic use, withdrawal symptoms, craving, relapse, and overdose. In addition, HEAL funds studies on integrating prevention and treatment approaches into practice, including the HEALing Communities study, which will inform our understanding of how the implementation of promising and evidence-based strategies and treatments can decrease opioid use disorder and overdose deaths.

Long-lasting solutions to the opioid crisis require additional pharmacological and non-pharmacological options for pain management. As part of HEAL, NIH will continue working with experts from the biopharmaceutical industry and Federal partners to develop a data sharing collaborative, new biomarkers for pain, and a clinical trials network for testing new pain therapies.

Neonatal Abstinence Syndrome

To improve developmental outcomes for infants with Neonatal Abstinence Syndrome/Neonatal Opioid Withdrawal syndrome, NIH will determine the best approaches to identify and treat newborns exposed to opioids by expanding the Advancing Clinical Trials in Neonatal Opioid Withdrawal syndrome (ACT NOW) pilot studies. Results will inform clinical trials to identify evidence-based clinical practices, including assessment of drug-free treatment approaches and currently used medications.

Acute to Chronic Pain Signatures

The high prevalence of chronic pain in the United States, and the reliance on opioids for its management, has created an urgent need for safer, more effective pain control. Launched in 2018, the Acute to Chronic Pain Signatures program collects neuroimaging, sensory testing, and psychosocial data from patients with acute pain associated with a surgical procedure or acute musculoskeletal trauma. Through this study, NIH seeks to predict which patients will develop long-lasting chronic pain, and guide precision acute pain management approaches to prevent lasting pain.

Creating a National Research Resource to Advance Precision Medicine

Precision medicine represents a frontier of human health and disease, and considers individual differences in lifestyle, environment, and biology to prevent and treat diseases using strategies tailored to the individual. Initiated in 2016, the NIH *All of Us* Research Program, a key element of the Precision Medicine Initiative, is an historic effort to collect data from over one million people living in the United States to accelerate research and improve health. Unlike research studies focused on a specific diseases or populations, *All of Us* serves as a national research resource to support thousands of studies, spanning various health conditions.

National enrollment for *All of Us* launched in May 2018 and by mid-December 2018, more than 90,000 people completed all steps in the initial protocol. More than 75 percent of these participants are from communities

NATIONAL CANCER INSTITUTE - CHILDREN'S ONCOLOGY GROUP MATCH TRIAL

Cancer Research Includes 4 Broad Categories

Basic Research
seeks to understand the fundamental aspects of nature. It provides the foundation for advances against cancer.

Clinical Research
tests drugs, medical devices, or other interventions in human volunteers to improve all aspects of patient care.

Population-Based Research
explores the causes of cancer, cancer trends, and factors that affect the delivery and outcomes of cancer care in specific populations.

Translational Research
moves basic research findings into the clinic and clinical research findings into everyday care. In turn, results from clinical and population-based studies can guide basic research.

historically underrepresented in biomedical research, and more than 50 percent are from racial and ethnic minority groups. To encourage enrollment of diverse populations, NIH created a network of community engagement partners to promote outreach and build trust.

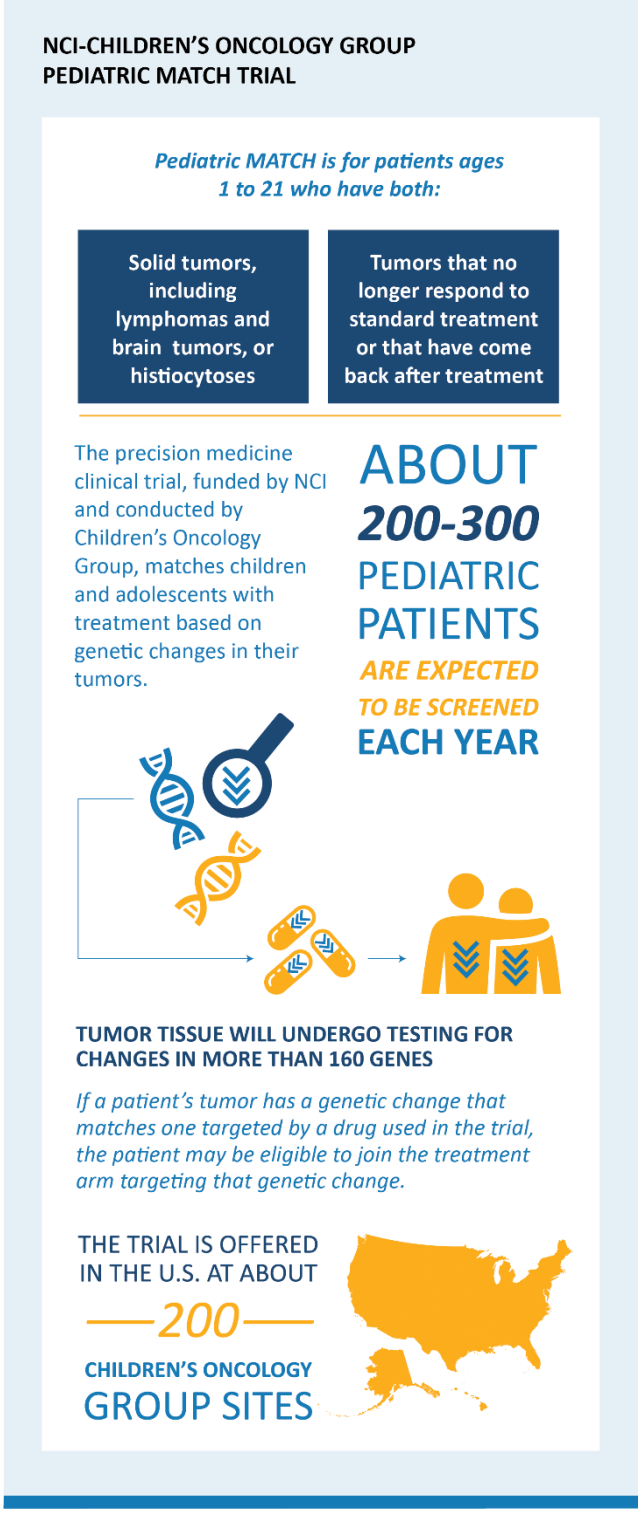
Genomic data from participants is a critical component of the program's research platform. In September 2018, NIH issued three Genome Center awards to support this effort. *All of Us* is planning a pilot program on the responsible return of genetic information to participants, including education and genetic counseling, as part of the program's commitment to give participants access to their own data.

Changing the Course of Childhood Cancer

The science of understanding pediatric cancer is especially challenging, and too many children and adolescents die from their disease. Many others endure lifelong adverse effects from their cancers or their treatment. Progress to treat some childhood cancers has been encouraging. However, for other cancers, advances in treatment have been limited.

NIH's current efforts to address pediatric cancer are notable and cross-cutting. For instance, the Children's Oncology Group, which is part of National Cancer Institute's (NCI's) National Clinical Trials Network, develops and coordinates pediatric cancer clinical trials that are available at more than 200 member institutions, including cancer centers throughout the United States and Canada. Additionally, the Pediatric MATCH precision medicine trial is a nationwide trial to explore whether targeted therapies can be effective for children and adolescents with solid tumors with specific gene mutations.

In FY 2020, NIH will invest $50 million to launch an initiative to accelerate and expand drug discovery and clinical trials, understand the biology of all pediatric cancers, and create a national data resource for pediatric cancer. This initiative will support research to develop new, more effective, and safer treatments for childhood cancers, and complement ongoing research within the NCI. Through this initiative, NCI will aggregate data from pediatric cancer cases and coordinate with others that maintain data sets to create a comprehensive, shared resource to support childhood cancer in all its forms. This knowledge, spanning from basic biology to clinical outcomes, provides a path to change the course of cancer in all children.



IDeA States Pediatric Clinical Trial Network

Infants and children living in rural and medically underserved states are less likely to be enrolled in clinical trials than children living in other states across

the nation. To address this gap, NIH created the Institutional Development Award (IDeA) States Pediatric Clinical Trials Network.
The goal of the IDeA program is to broaden geographic distribution of NIH funding, and as part of that program, the goals of the IDeA States Pediatric Clinical Trials Network include providing medically underserved and rural populations with access to cutting-edge clinical trials and applying findings from other relevant pediatric cohort studies to children in IDeA State locations. The IDeA States Pediatric Clinical Trials Network builds national pediatric research capacity by providing professional development opportunities for researchers as well as supporting investment in infrastructure.

In FY 2020, NIH will invest $15 million in the IDeA States Pediatric Clinical Trials Network to support studies such as a multi-site clinical trial, which will evaluate the dosing, safety, and efficacy of drugs that are commonly prescribed to children. The IDeA States Pediatric Clinical Trials Network is also partnering with ACT NOW pilot studies to develop best practices for treatment of Neonatal Opioid Withdrawal syndrome and advancing clinical trial protocols for a study that aims to decrease pediatric obesity rates in rural areas through the use of mobile health technology.

Supporting the Next Generation of Researchers
In August 2017, NIH launched the Next Generation Researchers Initiative. This initiative, which responds to the 21st Century Cures Act, addresses challenges faced by researchers trying to embark upon and sustain independent research careers. With dedicated funding of $100 million, NIH will continue to prioritize meritorious applications that request funding for early stage investigators seeking their first award and for investigators currently supported by NIH who are at risk of losing all research support. NIH Institutes and Centers will consider factors such as emerging areas of scientific inquiry, the distribution of the scientific portfolio, and the projected needs of the scientific workforce, including enhanced workforce diversity when making awards.

In response to an advisory committee recommendation and a recent report from the National Academy of Sciences, NIH is creating a new pathway for applications from early-stage investigators that does not require preliminary data and continues to provide a separate review of applications. NIH is also lengthening the window for early-stage eligibility to 11 years with additional flexibility due to significant life events.

Ending the HIV Epidemic: A Plan for America
HHS is proposing a once-in-a-generation opportunity to eliminate new HIV infections in our nation. Ending the HIV Epidemic: A Plan for America will work to reduce new infections by 75 percent in the next 5 years and by 90 percent in the next 10 years, averting more than 250,000 HIV infections in that span. NIH-funded research has supported development of the science and tools that make the ambitious goals of this initiative possible.

The FY 2020 Budget provides $6 million for NIH-sponsored Centers for AIDS Research to inform HHS partners on best practices, based on state-of-the-art biomedical research findings, and by collecting data on the effectiveness of approaches used in this initiative.

Working Toward a Universal Influenza Vaccine
NIH-supported research advances our understanding of how influenza (flu) strains emerge, evolve, infect, and cause disease. This research informs the design of new and improved therapies, diagnostics, and vaccines, including a universal influenza vaccine. Circulating and emerging influenza viruses present a public health threat and place substantial health and economic burdens on the United States and the world. Annual influenza vaccination is the most effective way to reduce influenza morbidity and mortality. However, traditional vaccine development relies heavily on predicting which strains will be in circulation each year. This approach is suboptimal for dealing with constantly evolving and newly emerging virus strains.

NIH invests both in ways to make seasonal flu vaccines longer lasting and more effective to protect the population, and supports efforts in rational design of a universal influenza vaccine, to protect against multiple influenza strains–including those that may pose a pandemic threat.

In FY 2018, NIH released a strategic plan to guide future basic, translational, and clinical research investments in areas essential to creating a safe and effective universal influenza vaccine. Along this path, NIH funds basic research to understand the transmission, natural history, and disease process of influenza. NIH supports research that characterizes how immunity occurs and how to tailor vaccination

responses to achieve immunity and extend protection duration.

Through cutting-edge vaccine technology, NIH modernizes vaccine development approaches to design a broadly protective flu vaccine for all ages. Several universal flu vaccine strategies are currently in testing in NIH-supported clinical trials. The Budget supports continued efforts to accelerate research progress toward developing a universal influenza vaccine, which would promote the protection of millions of people from infection and significantly mitigate the public health threat posed by influenza viruses.

Buildings and Facilities

Conducting cutting-edge biomedical research requires infrastructure and facilities that are conducive to leading-edge research and research support. The Budget includes $200 million to support NIH facilities projects, reduce the Backlog of Repair and Maintenance, and increase flexibility for Institutes and Centers to fund repair and improvement projects.

New Technologies to Revolutionize the Practice of Medicine

Rapid, early, and accurate identification of disease improves the chances of treatment success and is ultimately key to saving lives. NIH supports a diverse portfolio of research focused on developing cutting-edge diagnostic technologies, and NIH-funded technological advances that are pushing the boundaries of disease treatment and prevention. Examples include a miniature device that simultaneously detects and distinguishes between various tick-borne diseases, and another that captures mutated genetic material and proteins shed by brain tumors into the bloodstream for developing personalized treatments. Both devices use just a single drop of blood.

NIH invests in mobile health technology research that makes lifesaving health care more accessible. One application designed by NIH researchers includes a reusable glucose meter system built into a smartphone case, providing people with diabetes a mobile option for monitoring their glucose levels.

Leveraging Big Data and Artificial Intelligence

NIH has initiated a variety of programs to advance scientific discovery and cures by leveraging the incredible growth in the volume, speed of delivery, and complexity of large biomedical datasets. In June 2018, NIH released the Strategic Plan for Data Science. The plan articulates NIH's vision for making big data sustainable, interoperable, accessible and usable for the broader community by 1) optimizing data infrastructure, 2) modernizing data resources, 3) advancing data management, analytics, and tools, 4) promoting workforce development, and 5) enhancing policy stewardship and sustainability. NIH is now mapping out implementation activities, which will intensify over the next year, and include creating a new position—the NIH Chief Data Strategist—to collaborate closely with key stakeholders and lead implementation of the Plan.

NIH is focused on the promise of artificial intelligence and machine learning for catalyzing advances in basic and clinical research. NIH recognizes that there are many areas of biomedical research where novel computing, machine intelligence, and deep learning techniques have the potential to advance human health. NIH is committed to pushing those frontiers and is convening a new working group to further harness artificial intelligence and machine learning to advance biomedical research.

MAXIMIZING THE IMPACT OF NIH RESEARCH

Healthcare Research and Quality

To streamline HHS research activities, the Budget consolidates select activities of the Agency for Healthcare Research and Quality (AHRQ) into NIH as the National Institute for Research on Safety and Quality (NIRSQ). This new Institute within NIH will serve as a center of excellence for improving the quality and safety of health care. Within NIH, the Budget includes $256 million for NIRSQ. The Budget continues to emphasize NIRSQ's integral role in support of the Secretary's priority to move health care organizations from "volume" to "value" by focusing on improving outcomes, reducing cost and expanding choices for consumers. NIRSQ will achieve this by supporting health services research, addressing pressing health care issues through data and technology, and harnessing the power of predictive analytics to improve diagnostics.

Health Services Research and Data

Within NIRSQ, the Budget includes $58 million for Health Services Research, Data and Dissemination. Within the total, $43 million supports investigator-initiated research grants, which is a source for extramural researchers, to identify and pursue the

most innovative projects. This will allow NIRSQ to produce successful yet unexpected discoveries in the nation's most pressing health care issues such as the opioid epidemic and value-based research.

The Budget supports the Healthcare Cost and Utilization Project, which is the nation's most comprehensive source of hospital care data. This program helps federal, state, and local policymakers, and others make more informed decisions about health care delivery and based on the cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, state, and local levels.

Patient Safety

The Budget provides $65 million for the NIRSQ patient safety portfolio. Patient Safety activities will support lifesaving research and dissemination projects that prevent, mitigate, and decrease the number of patient safety risks and hazards. NIRSQ research in this area will provide the evidence base that CMS and other HHS agencies use to improve patient safety on a national scale. It will support the efforts of hospitals, long term care facilities, and others to improve care.
The Budget maintains key activities such as the national Combating Antibiotic-Resistant Bacteria enterprise and Patient Safety Learning Labs. These learning labs apply system engineering approaches to address both diagnostic and treatment errors in health care.

Medical Expenditure Panel Survey

The Medical Expenditure Panel Survey (MEPS) is a unique set of large-scale surveys of families and individuals, their medical providers, and employers across the United States. The Budget includes $72 million for MEPS activities in FY 2020, including improving its national estimates by expanding the capacity of individual states and groups of states through an expansion of MEPS. The survey expansion will increase the sample size by 1,000 households, a total of 2,300 persons, and redistribute the sample to states. As the only national comprehensive annual data on the use of medical care in the United States, the survey provides an important data source for research efforts aimed at improving health services.

Overview by Mechanism

	dollars in millions			
	2018 /1	2019 /2	2020	2020 +/- 2019
Mechanism				
Research Project Grants (dollars)	21,206	22,579	19,545	-3,035
[# of Non-Competing Grants]	*[25,858]*	*[27,492]*	*[28,760]*	*[+1,268]*
[# of New/Competing Grants]	*[11,461]*	*[11,675]*	*[7,894]*	*[-3,781]*
[# of Small Business Grants]	*[2,035]*	*[2,222]*	*[1,911]*	*[-311]*
[Total # of Grants]	*[39,354]*	*[41,389]*	*[38,565]*	*[-2,824]*
Research Centers	2,583	2,688	2,218	-470
Other Research	2,446	2,490	2,210	-280
Research Training	856	889	802	-87
Research and Development Contracts	3,073	3,133	2,795	-337
Intramural Research	3,996	4,130	3,634	-496
Research Management and Support	1,816	1,898	1,739	-159
Office of the Director (OD) /3	1,024	1,204	1,144	-60
NIH Common Fund (non-add)	*601*	*619*	*533*	*-86*
Office of Research Infrastructure Programs (non-add)	*289*	*289*	*249*	*-40*
OD Appropriation (non-add)	*1,914*	*2,119*	*1,926*	*-187*
Buildings and Facilities /4	147	218	214	-4
NIEHS Interior Appropriation (Superfund)	77	77	67	-10
Total, Program Level	**37,224**	**39,306**	**34,368**	**-4,938**
Less Funds from Other Sources				
PHS Evaluation Funds (NIGMS) /5	-923	-1,147	-741	+406
Current Law Mandatory Funding – Type 1 Diabetes (NIDDK) /6	-150	-150	--	+150
Proposed Law Mandatory Funding – Type 1 Diabetes (NIDDK) /6	--	--	-150	-150
Total, Discretionary Budget Authority	**36,151**	**38,010**	**33,477**	**-4,533**
Appropriations				
Labor/HHS Appropriation	36,074	37,933	33,410	-4,523
Interior Appropriation	77	77	67	-10
Full-time Equivalents /7	17,532	18,101	18,339	+238

1/ Reflects the FY 2018 Final level including funding authorized by the 21st Century Cures Act and directed and permissive transfers.
2/ Reflects the FY 2019 Enacted level including funding authorized by the 21st Century Cures Act for Labor/HHS appropriated funding, the FY 2019 continuing resolution level for NIEHS Superfund, and the $5 million directed transfer to the HHS Office of Inspector General.
3/ Number of grants and dollars for the Common Fund and Office of Research Infrastructure Programs components of OD are distributed by mechanism and the dollars are noted here as a non-add. OD appropriations are noted as a non-add because the remaining funds are accounted for under OD-Other.
4/ Includes Buildings and Facilities appropriation and funds for facilities repairs and improvements at the NCI Federally Funded Research and Development Center in Frederick, Maryland.
5/ Number of grants and dollars for Program Evaluation Financing are distributed by mechanism above. Therefore, the amount is deducted to provide subtotals only for the Labor/HHS Budget Authority.
6/ Number of grants and dollars for mandatory Type I Diabetes are distributed by mechanism above. Therefore, Type I Diabetes amount is deducted to provide subtotals only for the Labor/ HHS Budget Authority.
7/ Full-time equivalent levels include NIRSQ in FY 2020.

Substance Abuse and Mental Health Services Administration

	dollars in millions			2020 +/-
	2018	2019	2020	2019
Mental Health				
Community Mental Health Services Block Grant	723	723	723	--
PHS Evaluation Funds (non-add)	*21*	*21*	*21*	--
Programs of Regional and National Significance	439	460	430	-30
Prevention and Public Health Fund (non-add)	*12*	*12*	--	*-12*
Certified Community Behavioral Health Clinics	100	150	150	--
Children's Mental Health Services	125	125	125	--
Projects for Assistance in Transition from Homelessness	65	65	65	--
Protection and Advocacy for Individuals with Mental Illness	36	36	14	-22
Subtotal, Mental Health	**1,487**	**1,558**	**1,506**	**-52**
Substance Abuse Prevention				
Programs of Regional and National Significance	248	205	144	-61
Drug Free Communities	--	--	100	+100
Subtotal, Substance Abuse Prevention	**248**	**205**	**244**	**+39**
Substance Abuse Treatment				
Substance Abuse Prevention and Treatment Block Grant	1,858	1,858	1,858	--
PHS Evaluation Funds (non-add)	*79*	*79*	*79*	--
Formula Grants to States to Address Opioids	1,500	1,500	1,500	--
Programs of Regional and National Significance	399	461	430	-31
PHS Evaluation Funds (non-add)	*2*	*2*	--	*-2*
Subtotal, Substance Abuse Treatment	**3,757**	**3,819**	**3,788**	**-31**
Health Surveillance and Program Support				
Program Support	79	79	73	-6
Health Surveillance	47	47	34	-13
PHS Evaluation Funds (non-add)	*30*	*30*	*31*	*+1*
Public Awareness and Support	13	13	12	-1
Drug Abuse Warning Network	10	10	10	--
PHS Evaluation Funds (non-add)	--	--	*10*	*+10*
Performance and Quality Information Systems	10	10	10	--
Data Request and Publications, User Fees	2	2	2	--
Behavioral Health Workforce Data and Development, PHS Eval	1	1	1	--
Subtotal, Health Surveillance and Program Support	**162**	**162**	**141**	**-21**
SAMHSA Budget Totals				
TOTAL, Program Level	**5,654**	**5,744**	**5, 679**	**-65**
Less Funds from Other Sources:				
Prevention and Public Health Fund	*-12*	*-12*	--	*+12*
PHS Evaluation Funds	*-134*	*-134*	*-143*	*-9*
Data Request and Publications User Fees	*-2*	*-2*	*-2*	--
TOTAL, Discretionary Budget Authority	**5,507**	**5,597**	**5,535**	**-62**
Full-Time Equivalents	561	611	606	-5

The Substance Abuse and Mental Health Services Administration leads public health efforts to advance the behavioral health of the nation and reduces the impact of substance abuse and mental illness on America's communities.

The Fiscal Year (FY) 2020 President's Budget provides $5.5 billion for the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA funds programs, policies, information, data, contracts and grants, and leads the U.S. to act, on the knowledge that:

- Behavioral Health is essential to health;
- Prevention works;
- Treatment is effective; and
- People recover from mental and substance use disorders.

HHS has five priority areas to meet the behavioral health care needs of individuals, communities, and service providers:

- Combating the opioid crisis through the expansion of prevention, treatment, and recovery support services;
- Addressing serious mental illness and serious emotional disturbances;
- Advancing prevention, treatment, and recovery support services for substance use;
- Improving data collection, analysis, dissemination, and program and policy evaluation; and
- Strengthening health practitioner training and education.

SUBSTANCE ABUSE

An estimated 20 million Americans needed treatment for a serious substance abuse problem in 2017. Substance abuse complicates existing health issues, causes suffering well outside of the health care system, and increases health care costs. Deaths from drug overdose have risen over the past two decades, and are the leading cause of death from injury in the United States. From 2000 to 2017, nearly 700,000 people died from drug overdoses. The Budget provides $3.9 billion for substance abuse prevention and treatment activities.

Continuing the Fight against the Opioid Crisis

The opioid epidemic remains a public health emergency, as first declared by the Secretary in October of 2017. Opioids contribute to two-thirds of the 192 deaths every day from drug overdose. HHS requests $4.8 billion for programs across the Department that address the opioid crisis and serious mental illness; $1.9 billion of that is specifically for SAMHSA programs that address opioid misuse, abuse, and overdose. This funding will continue all existing opioid-related programs at the FY 2019 funding level including:

- $1.5 billion for the State Opioid Response program;
- $89 million to expand the availability of medication-assisted treatment, the most effective evidence-based treatment for opioid use disorder;
- $70 million for drug courts; and
- $48 million for training and equipping first responders on the use of opioid-overdose reversing drugs.

In addition to the ongoing efforts associated with fighting the opioids crisis, the Budget also funds a new $4 million program authorized by the SUPPORT for Patients and Communities Act (SUPPORT Act) signed into law in October of 2018. This program provides grants to accredited medical schools and teaching hospitals to develop curricula that satisfies the requirements to prescribe medication-assisted treatment.

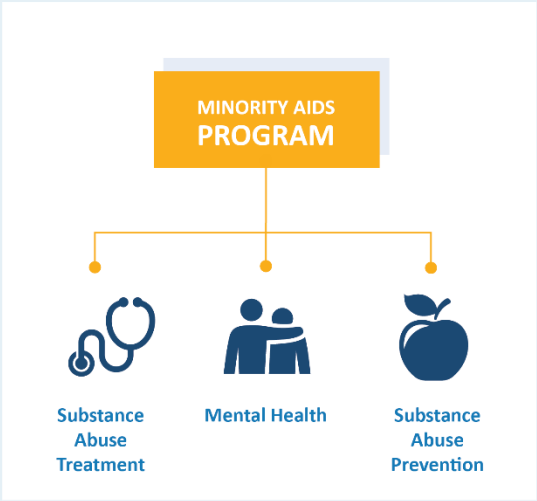
The Budget includes additional support services to help those in recovery succeed, including pregnant women and families struggling with addiction, and for states to enhance opioid abuse prevention strategies. SAMHSA will continue to direct $9 million for oversight, to ensure safe and effective operation of opioid treatment programs.

Substance Abuse Prevention and Treatment Block Grant

The Substance Abuse Prevention and Treatment Block Grant is the largest federal grant addressing substance use and provides one-third of all public funds spent for this purpose. This formula grant is a cornerstone of states' substance abuse financing in part due to its flexibility—it can fund services for hard-to-reach populations, payment systems and anti-fraud efforts, activities for which third party insurance does not reimburse, and other critical services. Approximately 2 million people receive care in facilities that receive public funding from this formula grant each year. The Budget provides $1.9 billion for this program.

FIGHTING HIV/AIDS AMONG VULNERABLE POPULATIONS

The Minority AIDS program enhances and expands the provision of effective, culturally competent, HIV/AIDS-related mental health and substance use disorder treatment services among vulnerable populations. This is achieved through grants to community-level domestic public and private non-profit entities, tribes, and tribal organizations.



Preventing Substance Abuse

Addressing substance abuse behaviors before they reach a crisis is more effective and less expensive than breaking the cycle of addiction. The Budget includes $244 million for substance abuse prevention efforts. This total includes demonstration programs to fight underage drinking and expand tribal behavioral health services, and to support state grants for the Strategic Prevention Framework. This amount also includes $100 million for the Drug Free Communities program to be directly appropriated to and administered by SAMHSA. SAMHSA has administered the program for several years on behalf of the Office of National Drug Control Policy.

The Budget maintains $5 million for federal drug-free workplace regulatory efforts and for states, tribes, and communities to receive technical assistance and training on best practices to prevent substance abuse.

Fighting HIV/AIDS

The Minority AIDS program enhances and expands the provision of effective, culturally, competent, HIV/AIDS-related mental health and substance use prevention and treatment services among vulnerable populations in an effort to reduce domestic HIV transmission and support those with HIV/AIDS. The program provides grants to community-level entities, tribes, and tribal organizations.

MENTAL HEALTH

In 2017, approximately 19 percent of American adults met the medical standard for a mental, behavioral, or emotional disorder that substantially interfered with major life activities. Of these 47 million people, approximately 11 million people—or 4.5 percent of all American adults—had a serious mental illness.[4]

The Budget provides $1.5 billion for mental health activities to meet the needs of those with the most serious mental health issues.

Continuing the Fight against Serious Mental Illness

The Budget includes $1 billion targeted specifically to programs that assist those with serious mental illness. This includes an increase of $10 million for a total of $15 million for the Assertive Community Treatment for Individuals with Serious Mental Illness program to help communities establish, maintain, or expand efforts to engage patients with serious mental illness through emergency and inpatient settings. The program reduces hospitalization of those with serious mental illness at the same cost and with higher patient satisfaction by coordinating care among a team of health care providers.

The Budget includes an increase of $10 million for a total of $14 million for Criminal and Juvenile Justice Programs. This program provides comprehensive treatment and recovery supports for people with co-occurring mental illness and addiction who are in the criminal justice system, including offenders re-entering the community. In a recent evaluation, participants reported mental health issues declined by 20 percent in the first six months of the program, alcohol and other drug use declined by 60 percent and employment rates increased from 36 percent to

[4] https://www.samhsa.gov/data/report/2017-nsduh-annual-national-report.

45 percent. In addition, nearly 74 percent of participants reported physical health improvements.

The Budget provides $14 million for Protection and Advocacy for Individuals with Mental Illness for legal-based advocacy services to protect the rights of individuals with mental illness who are at risk for abuse, neglect, and rights violations while residing in public or private care or treatment facilities.

Community Mental Health Services Block Grant

The Budget provides $723 million for the Community Mental Health Services Block Grant. This block grant is a flexible funding source that states use to address the needs of adults living with serious mental illness and children experiencing serious emotional disturbances. States will continue to spend at least 10 percent of the funds on early interventions for those experiencing a first episode of psychosis. States target local needs with this funding, prioritizing activities that insurance does not cover, such as payment infrastructure, physician training, and anti-fraud efforts.

Children's Mental Health Services

The Budget maintains the Children's Mental Health Services program at $125 million. This program helps states, tribes, and communities deliver evidence-based services and supports for children and youth with serious emotional disturbances. Grantees use these competitive grant awards to ensure effective collaboration between the juvenile justice, child welfare, and education systems. New findings by the National Institute of Mental Health[5] show that earlier intervention may prevent or lessen the further development of serious emotional disturbances and ultimately serious mental illness. The Budget proposes that up to 10 percent of the funds be available for a new demonstration targeting those at risk of developing serious mental illness.

Certified Community Behavioral Health Clinics

The Certified Community Behavioral Health Clinic (CCBHC) grant program provides funding for high quality behavioral health services at the local level. CCBHCs provide a comprehensive, coordinated range of behavioral health services certified to meet six key aspects of improved care. These include: Staffing, Organization Authority, Care Coordination, Scope of Services, Quality and other Reports, and Availability and Accessibility of Services.

CERTIFIED COMMUNITY BEHAVIORAL HEALTH CLINICS

The Certified Community Behavioral Health Clinic (CCBHC) grant program provides funding for high quality behavioral service at the local level. CCBHCs provide a comprehensive, coordinated range of behavioral health services certified to meet 6 key aspects of improved care.

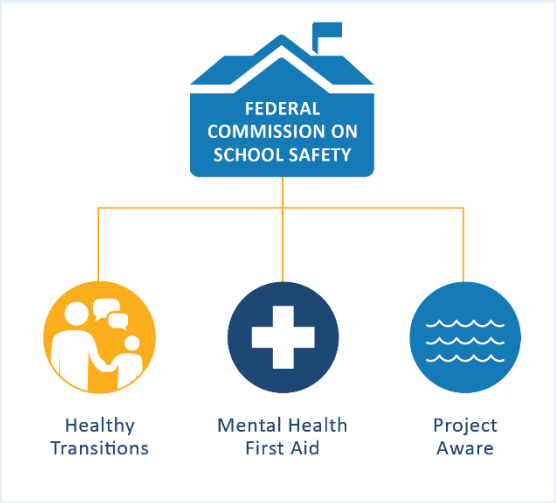
Mental Health Needs of Students

In response to the tragedy in Parkland, Florida, the President established a Federal Commission on School Safety. This commission heard testimony from members of the public, as well as key stakeholders, about the importance of developing a positive school climate and addressing the mental health needs of the nation's students. The Budget includes an increase of $15 million, for a total of $107 million, to expand access to school-based programs, including school safety programs such as Project AWARE, Healthy Transitions, and Mental Health First Aid. This increase in funding will target rural communities through telehealth models, behavioral health aides, and linkages to services. The program will also develop trainings within schools for school personnel to better recognize the signs and symptoms of mental illness in students.

[5] https://www.nimh.nih.gov/health/topics/schizophrenia/raise/.

ADDRESSING THE WORK OF THE FEDERAL SCHOOL SAFETY COMMISSION

Expanding access to school-based and school safety programs including:



Preventing Suicide

Suicide is a leading cause of death in the United States. Over 47,000 people in the United States died from suicide in 2017. This exceeds the rate of death from automobile accidents. The Budget provides $74 million for Suicide Prevention programs in SAMHSA. These programs include competitive grants to reduce suicide deaths and technical assistance to disseminate best practices to stakeholder and medical communities. Grantees increase awareness of suicide warning signs and knowledge of how to help those in need.

Other efforts implement the most effective evidence-based approaches to addressing suicide. This includes, for example, improving emergency room referral processes and clinical care practice standards, as well as assisting states in developing and implementing suicide prevention strategies.

Primary and Behavioral Healthcare Integration

The Budget does not include funding for the Primary and Behavioral Healthcare Integration program. States are free to use funds from the mental health and substance abuse block grants to support the integration of primary and behavioral health care systems.

HEALTH SURVEILLANCE AND PROGRAM SUPPORT

The Budget includes $141 million to monitor and provide program oversight to SAMHSA programs and to support nationwide Health Surveillance efforts. This funding will prioritize activities for which there is a unique federal role, such as the National Survey on Drug Use and Health. Within this funding, the Budget maintains $10 million for the Drug Abuse Warning Network (DAWN). DAWN is a national public health surveillance system that uses emergency room monitoring of mental and substance abuse crises to track non-fatal overdose rates for opioids and other trends in non-fatal substance abuse emergency department visits.

Centers for Medicare & Medicaid Services: Overview

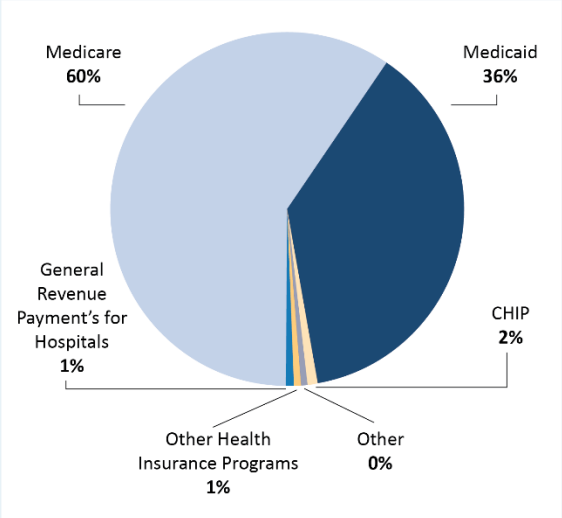
	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Current Law /1 /2				
Total Net Outlays, Current Law	999,437	1,104,397	1,171,660	+67,263
Proposed Law /1 /3				
Total Proposed Law	--	-6,301	-13,098	-6,797
Total Net Outlays, Proposed Law /4	999,437	1,098,096	1,158,562	+60,466

1/ Current law Medicare outlays net of offsetting receipts.
2/ Reflects other CMS health insurance programs.
3/ Reflects hospital payments that are proposed to be administered by CMS but financed outside of the Part A Trust Fund.
4/ Total net proposed law outlays equal current law outlays plus the impact of proposed legislation and offsetting receipts. Includes Trust Fund outlays for the Office of Medicare Hearings and Appeals for Fiscal Years 2018-2020.

The Centers for Medicare & Medicaid Services supports innovative approaches to improve health care quality, accessibility, and affordability.

The Centers for Medicare & Medicaid Services (CMS) funds Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Center for Medicare and Medicaid Innovation (CMMI), other health insurance programs, program integrity efforts, and operating costs. The Fiscal Year (FY) 2020 Budget estimate is $1.2 trillion in mandatory and discretionary outlays for CMS, a net increase of $60.5 billion above FY 2019. In total, the Budget proposes targeted savings of $954.1 billion in CMS mandatory programs over the next decade.

CMS FY 2020 NET FEDERAL OUTLAYS PROPOSED LAW $1.2 TRILLION



BUDGET REQUEST

The FY 2020 Budget request for CMS promotes all four of the Secretary's priorities to improve the health and well-being of the American people by (1) reducing prescription drug costs, (2) transforming the health care system to one that pays for quality and outcomes, (3) combating the opioid crisis, and (4) reforming America's health insurance system. As the Nation's largest administrator of health benefit programs, CMS is uniquely positioned to accelerate new initiatives that advance these priorities. In pursuing them, CMS is dedicated to putting patients first by empowering individuals with quality and cost information, and supporting Medicaid flexibilities that allow states to align their programs to their unique populations and improve health outcomes for Americans on Medicaid.

REDUCING PRESCRIPTION DRUG COSTS

The bipartisan effort began in 2018 when President Trump and Secretary Azar unveiled *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. The Blueprint is a package of comprehensive, cross-cutting drug pricing reforms built on four pillars: improved competition, better negotiation, incentives for lower

list prices, and lowering patient out-of-pocket costs. In FY 2018 and 2019, HHS made progress toward all of these goals. For example, CMS brought new negotiating tools from private insurance to both Medicare Part D and Medicare Advantage. CMMI also announced a potential proposal, the International Pricing Index Model, to leverage market forces in lowering the price of the most costly physician-administered drugs in Medicare Part B, which, due to a lack of negotiation, cost almost twice as much as they do in economically similar countries. CMS also proposed to require that drugs' list prices be disclosed in direct-to-consumer advertising, to help ensure consumers are aware of a drug's price before they talk to their doctor and facilitate increased price transparency.

The FY 2020 Budget legislative proposals complement administrative actions CMS has already taken to achieve the Blueprint's goals.

The Budget proposes a number of legislative changes to Medicare, including proposals to modernize the Medicare Part D prescription drug benefit, improve transparency and accuracy of payments for drugs under Medicare Part B, and better align the incentives of providers and health plans with those of beneficiaries and taxpayers.

The Budget also includes Medicaid proposals to lower prescription drug costs for states and taxpayers by ensuring manufacturers pay their fair share of Medicaid rebate covering all price increases for a drug, providing flexibility for states to develop innovative drug coverage and financing approaches, ensuring state Medicaid programs appropriately reimburse pharmacies for generic drugs, and ensuring drug companies pay appropriate rebates under the Medicaid Drug Rebate Program.

PROMOTING VALUE-BASED CARE

Delivery and payment reforms will transform our health system from one that pays for services and procedures to one that pays for quality and outcomes. The Budget increases transparency around price and quality by clarifying the Medicare coverage process through additional guidance and publicly releasing survey findings for all accredited facilities. The Budget creates a consolidated hospital quality program, reducing regulatory burden and aligning incentives similar to previous reform of the physician quality payment program.

The Budget includes innovative new CMMI models for both the Medicare and Medicaid Programs. In Medicare, models will encourage the adoption of high-value innovative technologies and discourage the use of low-value services. CMS will test interventions to improve maternal mortality and morbidity under Medicaid. By eliminating arbitrary thresholds to encourage participation in Advanced Alternative Payment Models, the Budget removes barriers that impede provider access to innovative payment programs.

COMBATING THE OPIOID CRISIS

The Budget includes several proposals to address Medicare and Medicaid beneficiaries impacted by the opioids crisis, while also implementing HHS's five-point strategy to combat the opioid epidemic by (1) improving access to prevention, treatment, and recovery support services;(2) collecting opioid epidemic data; (3) updating guidance for pain management; (4) targeting of overdose-reversing drugs; and (5) increasing support for research on pain and addiction. Proposals include allowing collaboration between CMS and the Drug Enforcement Administration (DEA) to revoke a provider's DEA Certification of Registration, after CMS revokes a provider's Medicare enrollment based on a pattern of abusive behavior, such as over-prescribing. The Budget also proposes to make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder.

In October 2018, the President signed the *Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*, the most comprehensive legislation to address a single drug crisis in history. This bold, bipartisan legislation addresses the opioid crisis by expanding access to substance abuse treatment, cracking down on shipments of illicit drugs, and providing more grant funding for prevention, treatment, and recovery.

Several FY 2019 Budget proposals to improve access to opioid use disorder treatment for Medicare and Medicaid beneficiaries were passed into law in the SUPPORT Act, including: a demonstration to expand

CMS EFFORTS TO COMBAT THE OPIOID EPIDEMIC

Over the past year, CMS has taken aggressive action to address the opioid epidemic's impact on Medicare and Medicaid beneficiaries, including:

- Improving provider education and outreach efforts, including the introduction of new tools and data sources to publicize ways to reduce overprescribing and support efforts that address the crisis.
- Working with states to support and improve opioid use prevention and treatment efforts, including medication-assisted and alternative treatments, through Section 1115 demonstration waivers, technical assistance, institution for Mental Disease facility exclusion waivers, and quality metrics.
- Publishing the CMS Opioids Roadmap outlining key prevention activities, opioid use disorder treatment, and data-driven policies and activities.
- Issuing new policies through Medicare rulemaking to advance several key opioid objectives, including: 1) requesting comment on a physician bundled pament for substance use disorder treatment; 2) finalizing a proposal to pay separately at average sales price plus 6 percent for non-opioid pain medications used for post-surgical pain management in ambulatory surgery centers; 3) removing pain-related questions from quality assessments that could incentivize opioid prescribing.
- Announcing the Integrated Care for Kids and Maternal Opioid Misuse models, focusing on delivering care to children and mothers with opioid use disorders.

access to comprehensive substance use disorder treatment for Medicare beneficiaries; requiring plan participation in a program to prevent prescription drug abuse in Part D; and a temporary requirement for states to cover Medication-Assisted Treatment under Medicaid. CMS is implementing these key changes, along with many other actions to improve treatment and access to care for Medicare and Medicaid beneficiaries included under the Act. The FY 2020 Budget builds on these initiatives.

HEALTH REFORM

The Budget includes a number of proposals to improve federal health programs so they work better for the people they serve. These reforms leverage competition within the private sector, allow patients to make choices that work for them, and give states the freedom to innovate.

In October 2018, HHS issued updated guidance for State Relief and Empowerment Waivers (Section 1332 Waivers), which loosened excessive restrictions that limited state flexibility and consumer choice in the individual market. This new guidance allows states to promote more affordable health insurance coverage options, while maintaining statutory requirements. The Budget proposes a number of legislative proposals, aligned with the core values of the Administration, to increase competition, put patients at the center of their own health care decisions, allow states to innovate, and deliver care in an affordable and sustainable way. These proposals include reforming medical liability to promote high-quality, evidence-based care and strengthening protections against governmental discrimination for individual and institutional health care entities that refuse to perform, pay for, or cover abortions.

The Budget also advances health care reforms that empower states and consumers to reform health care, expand options, and put the states in the driver's seat. The Budget supports market-based innovation and comprehensive Medicaid reform.

Empowering States and Consumers to Reform Health Care

The Fiscal Year (FY) 2020 Budget proposes bold, crosscutting reforms to our nation's safety net and federal health programs, so that they actually work for the people they serve. They aim to empower states to take charge of the health care system and create solutions that will be best suited for their citizens. These proposals also empower consumers to purchase coverage that best suits their health care needs. The goal of these proposals is more than a better-run health care system; it is more affordable, better-quality health care for all Americans.

These proposals align with the Administration's core values. First, they rely, to the extent possible, on competition within the private sector because that is a key way to drive down costs while improving quality. Second, these changes put patients at the center, free to make choices that work for them. Third, these reforms defer to states to innovate, rather than assuming the federal government knows best. Finally, these reforms aim to deliver care in an affordable, fiscally sustainable way, while maintaining a safety net for those in need.

These ideas are a departure from the way American health care has worked for too long. For the past half century, the federal government has been the dominant factor in both the financing and delivery of our health care.

Obamacare created a thicket of subsidies, regulations, and taxes designed to help those without employer insurance secure coverage on the individual market. It was supposed to not only expand this kind of private coverage, but also bring down costs. It has come up short on both of these objectives.

Using flexibilities under current law, this Administration has taken key steps to deregulate the health care system and introduce new options that expand choices and encourage competition. These steps include the expansion of access to short-term insurance policies and the ability to allow small businesses and sole proprietors to band together and form association health plans.

CMS also released four State Relief and Empowerment Waiver (also referred to as Section 1332 Waiver) concepts for states' use to promote more affordable, flexible health insurance coverage options. These concepts aim to spur innovative, state-initiated ideas to improve their health care markets. They are as follows:

- Account-Based Subsidies: a state directs public subsidies into a defined-contribution, consumer-directed account that an individual uses to pay for premiums or other health care expenses.
- State-Specific Premium Assistance: states design subsidy structures to meet the unique needs of their populations.
- Adjusted Plan Options: states provide financial assistance for different types of health insurance plans, increasing consumer choice.
- Risk Stabilization Strategies: states have flexibility to implement reinsurance programs or high-risk pools.

PREMIUMS ON EXCHANGES DROP FOR 2019

Average premiums have dropped for the first time since the implementation of the federally facilitated Exchanges in 2014, suggesting that the numerous actions taken by the Administration to stabilize the market are working. These actions include: implementing the market stabilization rule early in the Administration, granting states flexibility to set their essential health benefit benchmark, and using waiver authority to approve reinsurance programs in seven states.

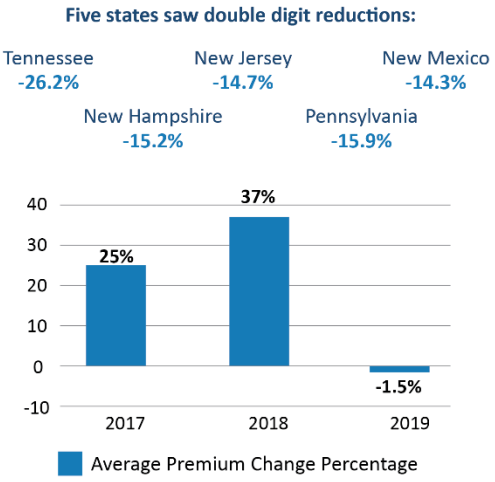
All told, the number of counties with only one insurer has dropped from 56 percent in 2018 to 39 percent in 2019, and only five states will have one insurer, cutting the 2018 number in half. Additionally, HHS has worked to provide consumers the choices they want in the market for affordable health coverage, including expanding access to short-term, limited duration insurance plans that may be up to 50-80 percent less expensive than other individual market plans.

This Budget includes legislative changes that build on what the Administration has already achieved to strengthen the federal government's major benefits programs by placing them on more sustainable financial footing. These proposals empower states and consumers to reform health care. States are more capable of tailoring health care programs to their unique markets, increasing options for patients and providers, and building financial stability and personal responsibility.

The Budget continues to support the Exchanges while the Administration works with Congress on broader health care reforms.

PREMIUMS ON EXCHANGES DROP FOR 2019

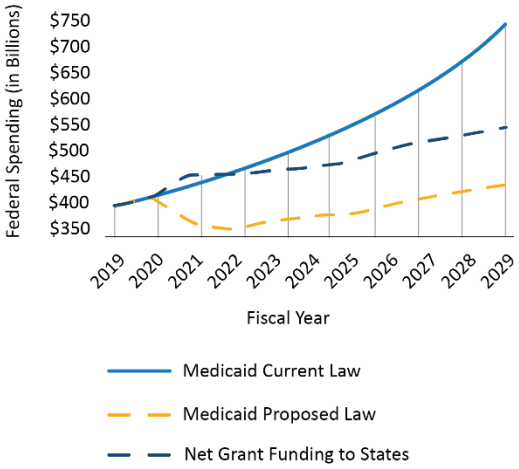
Average premiums for the second lowest cost silver plans for 2019 dropped 1.5 percent.



Source: Average Monthly Premiums for Second-Lowest Cost Silver Plan for States Using the HealthCare.gov Platform, 2016-2019

THE BUDGET SUPPORTS STATE REFORM, WHILE CURBING MEDICAID GROWTH

Recognizing that states are better positioned to address the unique needs of their populations, the Budget returns substantial control over health care from Washington, DC back to the states. The Budget replaces federal dollars currently spent on Obamacare's Medicaid expansion and premium tax credits with $1.2 trillion in Market-Based Health Care Grants for states over 10 years. Reforms to Medicaid will reduce overall Medicaid spending over the next ten years, putting the program on a more sustainable path.



Source: Based on estimates from the CMS Office of the Actuary.
Note: "Net Grant Funding to States" reflects the Market-Based Health Care Grants established in the Empower States and Consumers to Reform Health Care proposal in addition to federal Medicaid funding. Amounts do not include changes to premium tax credits.

2020 LEGISLATIVE PROPOSALS

Reforming the Health Care System

Empowering States and Consumers to Reform Health Care

The Administration is committed to empowering states and consumers to reform health care. The Budget supports a two-part approach to move away from Obamacare, starting with enactment of legislation modeled closely after the Graham-Cassidy-Heller-Johnson bill that include Market Based Health Care Grants. In Medicaid, this includes allowing states a choice between a per-capita cap or a block grant, and repealing Obamacare's Medicaid expansion, to modernize Medicaid financing and refocus the program on those it was originally intended to serve. The second part of the Budget proposal includes additional reforms to address unsustainable health care spending trends and builds upon the Graham-Cassidy-Heller-Johnson bill to make the system more efficient. This includes proposals to align the growth rates for the Market-Based Health Care Grant Program and Medicaid per capita cap and block grant with the Consumer Price Index for All Urban Consumers (CPI-U).

The Budget acknowledges the importance of ensuring protections for individuals with pre-existing conditions

and states would be required to include such plans in their applications for these grants. Specifically, states will be required to allocate at least 10 percent of their grant funding to ensure protections for high-cost individuals, including those with pre-existing conditions. [$267.0 billion in savings to HHS and $658.6 billion in government-wide net deficit reduction over 10 years].

Reform Graduate Medical Education Payments

Effective FY 2020, this proposal consolidates federal graduate medical education spending from Medicare, Medicaid, and the Children's Hospital Graduate Medical Education Program into a single grant program for teaching hospitals. Total funds available for distribution in FY 2020 would equal the sum of Medicare and Medicaid's 2017 payments for graduate medical education, plus 2017 spending on Children's Hospital Graduate Medical Education, adjusted for inflation. This amount would then grow at the CPI-U minus one percentage point each year. Payments would be distributed to hospitals based on the number of residents at a hospital (up to its existing cap) and the portion of the hospital's inpatient days accounted for by Medicare and Medicaid patients. The new grant program would be jointly operated by the Administrators of CMS and the Health Resources and Services Administration.

This grant program would be funded out of the general fund of the Treasury. The Secretary would have authority to modify the amounts distributed based on the proportion of residents training in priority specialties or programs (e.g., primary care, geriatrics) and based on other criteria identified by the Secretary, including addressing health care professional shortages and educational priorities. These changes modernize graduate medical education funding, making it better targeted, transparent, accountable, and more sustainable. [$47.9 billion in savings over 10 years]

Reform Medical Liability

The current medical liability system disproportionately benefits a relatively small group of plaintiffs and lawyers at the expense of adding to the cost of health care for every American and imposing a burden on health care providers. The current medical liability system does not work for patients or providers, nor does it promote high-quality, evidence-based care. The Budget proposes medical liability reforms that will save HHS programs $26.9 billion, and the federal government overall $31.5 billion, over 10 years. A significant portion of these savings is attributable to the estimated reduction in unnecessary services and curbing the practice of defensive medicine. These medical liability reforms will benefit all Americans by cutting unnecessary health care spending.

In addition to reducing health care costs, by providing a safe harbor based on clinical guidelines, physicians can focus on delivering effective patient care and evidence based medicine rather than on unsubstantiated lawsuits. If an inherently risky medical procedure does not work out as intended, physicians will be able to express sympathy to a grieving family without fear of giving rise to a lawsuit.

Specifically, the Budget proposes the following medical liability reforms:

- Capping awards for noneconomic damages at $250,000 indexed to inflation;
- Providing safe harbors for providers based on clinical standards;
- Authorizing the Secretary to provide guidance to states to create expert panels and administrative health care tribunals;
- Allowing evidence of a claimant's income from other sources such as workers' compensation and auto insurance to be introduced at trial;
- Providing for a 3 year statute of limitations;
- Allowing courts to modify attorney's fee arrangements;
- Establishing a fair share rule to replace the current rule of joint and several liability;
- Excluding provider expressions of regret or apology from evidence; and
- Requiring courts to honor a request by either party to pay damages in periodic payments for any award equaling or exceeding $50,000.

[$31.5 billion in government-wide net deficit reduction over 10 years]

Improving the Availability and Affordability of Private Health Insurance

Introduce New Minimum Required Contribution for Premium Tax Credits

This proposal introduces a new minimum required contribution percent for subsidized enrollees in health plans on the Exchanges. While the credits would continue to be calculated in the same way, an individual's premium tax credit would be reduced so that the individual is required to contribute a minimum

percentage of their income on any health plan, increasing personal responsibility. [$345 million in savings to Treasury in 2020 and 2021 prior to eliminating the tax credits; no HHS budget impact]

Provide Appropriation to Pay Cost-Sharing Reductions

This proposal provides a mandatory appropriation for Cost-Sharing Reduction payments through CY 2020. While these payments would end after 2020, the Administration requests funding while the requirement remains. [$479 million in costs in FY 2020 related to exempting this funding from sequestration]

Reduce the Grace Period for Exchange Premiums

This proposal reduces the grace period for individuals on Exchange plans to make premium payments from 90 days to 30 days. This proposal places more responsibility on individuals that fall behind on premiums thereby reducing the amount of time payments remain outstanding. [$78 million in savings to Treasury over 10 years; no HHS budget impact]

Other Health Care Reforms

Strengthen Protection against Governmental Discrimination for Health Care Entities that Refuse to Perform, Pay for, or Cover Abortion

This proposal would strengthen, clarify, and further codify the prohibition against government entities discriminating against individual and institutional health care entities that refuse to perform, refer for, participate in, pay for, or provide (or sponsor) coverage of abortion services, or facilitate or make arrangement for such activities, ensure that HHS has appropriate enforcement tools to address potential violations of that prohibition, and enable health care entities that are the victims of such discrimination to pursue civil actions for appropriate relief. [No budget impact]

Empowering States and Consumers to Reform Health Care

FY 2020 Empowering States and Consumers to Reform Health Care Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Empowering States and Consumers to Reform Health Care			
Subtotal, Non-Medicaid HHS Impact	2,190	475,830	1,118,565
Market-Based Health Care Grant Program (non-add)	*-*	*508,240*	*1,212,125*
Other HHS Impact (non-add)	*2,190*	*-32,410*	*-93,560*
Medicaid Impact (non-add)	*1,280*	*-429,058*	*-1,385,515*
Subtotal, HHS Impact (non-add)	*3,470*	*46,772*	*-266,950*
Subtotal, Non-HHS Impact (non-add)	*959*	*-153,251*	*-391,624*
Total, Government-wide Impact (non-add)	*4,429*	*-106,479*	*-658,574*
Reform Graduate Medical Education Payments			
General Fund Impact (HHS Impact)	15,290	87,380	185,280
Medicare Impact (non-add)	*-14,480*	*-89,640*	*-211,840*
Medicaid Impact (non-add)	*-1,600*	*-9,000*	*-21,300*
HRSA Impact (non-add) /1	*-*	*-*	*-*
Total, HHS-wide Impact (non-add)	*-790*	*-11,260*	*-47,860*
Reform Medical Liability			
Cost-Sharing Reductions Impact (HHS Impact)	-1	-1	-1
Medicare Impact (non-add)	*-69*	*-5,250*	*-26,895*
Medicaid Impact (non-add) /2	*-46*	*-46*	*-46*
Non-HHS Impact (non-add)	*-25*	*-1,540*	*-4,569*
Total, Government-wide Impact (non-add) /2/3	*-141*	*-6,836*	*-31,511*
Improving the Availability and Affordability of Private Health Insurance			
Introduce Minimum Required Contribution for Premium Tax Credits (Treasury Impact)	*-230*	*-345*	*-345*
Provide Appropriation to Pay Cost-Sharing Reductions (HHS Impact)	*479*	*479*	*479*
Reduce the Grace Period for Exchange Premiums (non-add) (Treasury Impact)	*-85*	*-78*	*-78*
Other Health Care Reform			
Improve and Expand Access to Health Savings Accounts (non-add) (Treasury Impact)	*0*	*11,588*	*28,530*
Prohibit Governmental Discrimination against Health Care Providers that Refuse to Cover Abortion (HHS Impact)	*-*	*-*	*-*
Total Outlays, Empowering States and Consumers to Reform Health Care Budget Proposals (HHS non-Medicaid Impact)	**17,958**	**563,688**	**1,304,323**

1/ Children's Hospital Graduate Medical Education is shown as $0 for FY 2020 and future years because this program is currently funded under a discretionary appropriation; in the FY 2020 Budget, HHS is no longer requesting funding for this program-specific appropriation. However, this proposal assumes that Children's teaching hospitals will continue to receive approximately the same amount of Graduate Medical Education funding from the General Fund as they do under current law in FY 2019 ($325 million).
2/ Savings reduced to account for the interaction with the proposal to Empower States and Consumers to Reform Health Care.
3/ Includes savings to programs overseen by the Department of the Treasury, the Department of Veterans Affairs, and the Office of Personnel Management.

Medicare

	dollars in millions			2020 +/-
	2018	2019	2020	2019
Current Law Outlays and Offsetting Receipts				
Benefits Spending (gross) /1	697,707	767,152	842,104	+74,952
Less: Premiums Paid Directly to Part D Plans /2	-10,484	-10,159	-12,884	-2,725
Subtotal, Benefits Net of Direct Part D Premiums Payments	**687,223**	**756,993**	**829,220**	**+72,227**
Related-Benefit Expenses /3	14,683	15,087	15,383	+296
Administration /4	9,614	9,952	8,912	-1,040
Total Outlays, Current Law	**711,520**	**782,032**	**853,515**	**+71,483**
Premiums and Offsetting Collections	-122,650	-130,885	-139,654	-8,769
Current Law Outlays, Net of Offsetting Receipts	**588,870**	**651,147**	**713,860**	**+62,714**
Proposed Law				
Medicare Proposals, Net of Offsetting Receipts	0	0	-23,257	-23,257
Medicare Trust Fund Administration /5	0	0	36	+36
Subtotal, Medicare Proposed Law	0	0	-23,221	-23,221
Total Net Outlays, Proposed Law	**588,870**	**651,147**	**690,640**	**+39,493**
Mandatory Total Net Outlays, Proposed Policy /6	**582,011**	**644,827**	**683,932**	**+39,105**

1/ Represents all spending on Medicare benefits by either the federal government or through other beneficiary premiums. Includes Medicare Health Information Technology Incentives.
2/ In Part D only, some beneficiary premiums are paid directly to plans and are netted out here because those payments are not paid out of the Trust Funds.
3/ Includes savings from investments in Social Security disability reviews and related benefit payments, including refundable payments made to providers and plans, transfers to Medicaid, and premiums to Medicare Advantage plans paid out of the Trust Funds from beneficiary Social Security withholdings.
4/ Includes CMS Program Management, the Health Care Fraud and Abuse Control Program (HCFAC), Quality Improvement Organizations, and other administration.
5/ A portion of this supports the State Health Insurance Assistance Programs through the Administration for Community Living (ACL). Please see the ACL chapter for more information.
6/ Removes total Medicare discretionary amount: FY 2018 -$6,859 million; FY 2019 -$6,320 million; and FY 2020 -$6,708 million.

Medicare provides health benefits to individuals who are aged 65 or older, disabled, or have end-stage renal disease. In Fiscal Year (FY) 2020, the Office of the Actuary has estimated that gross current law spending on Medicare benefits will total $842.1 billion and the program will provide health benefits to 62.7 million beneficiaries.

THE FOUR PARTS OF MEDICARE

Part A

Medicare Part A pays for health care services in inpatient hospitals and skilled nursing facilities, home health care related to a hospital stay, and hospice care. A 2.9 percent payroll tax, paid by both employees and employers, is the primary financing mechanism for Part A. Part A gross fee-for service spending will total an estimated $216.9 billion in Calendar Year (CY) 2020.

Individuals who have worked for 10 years (40 quarters) and paid Medicare taxes during that time generally receive Part A benefits without paying a premium, but most services require beneficiary coinsurance. In CY 2019, beneficiaries pay a $1,364 deductible for a hospital stay of 1–60 days, and a $170.50 daily coinsurance for days 21–100 in a skilled nursing facility.

Part B

Medicare Part B pays for physician, outpatient hospital, end-stage renal disease, laboratory, durable medical equipment, home health care unrelated to a hospital

stay, and other medical services. Part B coverage is voluntary and 91 percent of all Medicare beneficiaries are enrolled in Part B through both fee-for-service and Medicare Advantage. Beneficiary premiums finance approximately 25 percent of Part B costs with the remaining 75 percent covered by general revenues from the U.S. Treasury. Part B gross fee-for-service spending will total $220.3 billion in CY 2020.

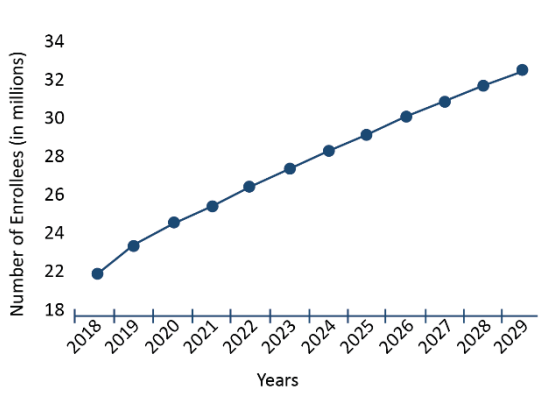
The standard monthly Part B premium is $135.50 in CY 2019, an increase of $1.50 from $134 in CY 2018. A statutory "hold harmless" provision applies each year to 70 percent of enrollees, limiting the annual rise in Part B premiums to no more than the Social Security cost of living increase. For these enrollees, any increase in Part B premiums must be lower than the increase in their Social Security benefits. Some beneficiaries also pay a higher Part B premium based on income: those with annual incomes above $85,000 (single) or $170,000 (married) will pay from $189.60 to $460.50 per month in CY 2019. The Part B deductible in CY 2019 is $185 for all beneficiaries, an increase of $2 from $183 in CY 2018.

Part C

Medicare Part C, the Medicare Advantage Program, pays plans a capitated monthly payment to provide all Part A and B services, and Part D services if offered by the plan. Plans can offer additional benefits or alternative cost-sharing arrangements that are at least as generous as the standard Parts A and B benefits under traditional Medicare. In addition to the regular Part B premium, beneficiaries who choose to participate in Part C may pay monthly plan premiums which vary based on the services offered by the plan and the efficiency of the plan.

In CY 2020, Medicare Advantage enrollment will total approximately 24 million beneficiaries, or 42 percent of all Medicare beneficiaries who are enrolled in both Parts A and B. Enrollment in Medicare Advantage is growing nearly 50 percent faster than enrollment in traditional Medicare. CMS data confirm that 99 percent of Medicare beneficiaries have access to at least one Medicare Advantage plan in CY 2019. Additionally, Medicare Advantage supplemental benefits have increased while premiums have remained stable. Part C gross fee-for-service spending will total $286.5 billion in FY 2020.

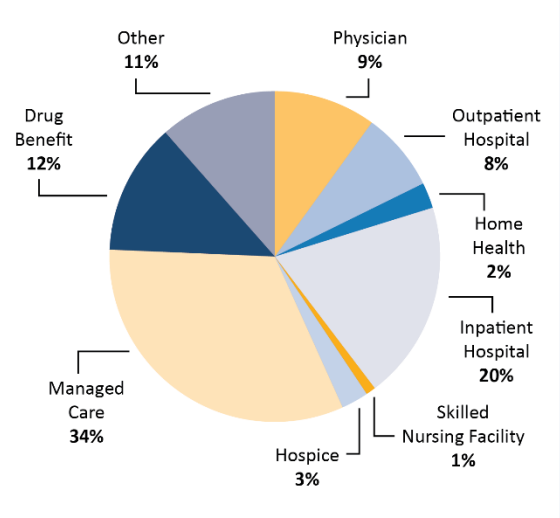
MEDICARE ADVANTAGE ENROLLMENT PROJECTED TO INCREASE BY 50 PERCENT FROM 2018-2029



Part D

Medicare Part D offers a standard prescription drug benefit with a CY 2019 deductible of $415 and base beneficiary premium of approximately $33. Enhanced and alternative benefits are also available with varying deductibles and premiums. Participating beneficiaries pay a portion of the cost of their prescription drugs. This portion varies based on whether the medication is generic or a brand name and the amount the beneficiary has already spent on medications that year. Low-income beneficiaries have varying degrees of cost-sharing, with co-payments ranging from $0 to $8.50 in 2019 and low or no monthly premiums. For CY 2020, CMS expects Medicare Part D enrollment to

MEDICARE BENEFITS BY SERVICE, 2020
CURRENT LAW ESTIMATE: $842.1 BILLION



increase by 3.1 percent to 48.2 million, including 13.4 million beneficiaries who receive the low-income subsidy. CMS estimates total gross spending for Part D to be $106.8 billion in FY 2020.

In CY 2019, of beneficiaries that have Part D coverage, approximately 54 percent are enrolled in a stand-alone Part D Prescription Drug Plan, 44 percent are enrolled in a Medicare Advantage Prescription Drug Plan, and 3 percent are enrolled in an employer plan. Of Medicare beneficiaries overall, approximately 77 percent of all Medicare beneficiaries receive prescription drug coverage through Medicare Part D or employer-sponsored retiree health plans, and a significant number through other creditable coverage, such as the Federal Employees Health Benefits Program.

Beneficiaries reach the Medicare Part D coverage gap, or "donut hole," once their total drug spending exceeds an initial coverage limit ($3,820 in total drug costs in CY 2019), and they stay in the coverage gap until they reach the threshold for qualified out-of-pocket spending ($5,100 in out-of-pocket costs CY 2019), at which point they are generally responsible for five percent of their drug costs. Until 2010, beneficiaries were responsible for 100 percent of their drug costs in the coverage gap, but a combination of manufacturer discounts and gradually increasing federal subsidies have closed the gap over time. The Bipartisan Budget Act of 2018 increased manufacturer discounts from 50 to 70 percent, and closed the brand drug coverage gap one year ahead of schedule -- in CY 2019 instead of CY 2020. In CY 2019, non-low income subsidy beneficiaries who reach the coverage gap will now pay just 25 percent of the cost of covered Part D brand drugs and biologics and will pay 37 percent of the costs for all generic drugs in the coverage gap. In CY 2020 and beyond, beneficiaries will pay 25 percent of the costs for all covered Part D drugs during both the coverage gap and initial coverage phases of the benefit. Low-income subsidy beneficiaries are statutorily excluded from the coverage gap discount program because Medicare pays for the majority of their cost-sharing.

MEDICARE QUALITY IMPROVEMENT ORGANIZATIONS

CMS contracts with Quality Improvement Organizations (QIOs) - experts in quality improvement - to ensure Medicare beneficiaries and their families receive high quality care and support CMS's aims of better health, better care and lower costs. The QIOs drive local change by partnering directly with Medicare providers, beneficiaries, families, and other organizations to support innovative approaches to improve quality, accessibility, and affordability, which translates into national quality improvement. The current five-year contract cycle, or 11th Scope of Work, began August 1, 2014. The 12th Scope of Work will begin in FY 2019.

There are two types of QIOs that work with providers and beneficiaries: Quality Innovation Network contractors and Beneficiary and Family Centered Care contractors. In the 11th Scope of Work, Quality Innovation Network contractors worked to reduce patient harms, such as infection reduction among nursing home residents, and provide staff training for hospital quality improvement. Beneficiary and Family Centered Care organizations perform the program's statutory case review work, including beneficiary complaints, concerns related to early discharge from health care settings, and patient and family engagement.

MEDICARE ENROLLMENT (IN MILLIONS)

	2018	*2019*	*2020*	Change 2020 +/- 2019
Aged 65 and over	50.7	52.4	54.1	**+1.7**
Disabled	8.8	8.7	8.6	**-0.1**
Total	**59.6**	**61.1**	**62.7**	**+1.6**

Source: CMS Office of the Actuary estimates

2020 LEGISLATIVE PROPOSALS

The FY 2020 Budget includes targeted Medicare proposals designed to improve value-based systems of care, exercise fiscal integrity, promote competition, reduce provider burdens, improve the appeals system, and address high drug prices. Together, this legislative package is expected to net savings to the Medicare Trust Funds of $811 billion over 10 years. A few Medicare proposals have general revenue or other impacts that would offset a portion of these savings government-wide. This package extends the solvency

of the Hospital Insurance Trust Fund by approximately 8 years, in part by ensuring Medicare payments are directly related to its health care financing role, financing certain payments to hospitals for graduate medical education and uncompensated care outside the Trust Fund and slowing their growth rate.

Improving Value-Based Systems of Care

Reprioritize Primary and Preventive Care in Medicare

Medicare's physician fee schedule does not adequately reimburse for primary care relative to specialty care due, at least in part, to challenges in reflecting clinician time and resources spent evaluating and coordinating ongoing patient care. Beginning in FY 2021, this proposal creates a risk-adjusted monthly Medicare Priority Care payment for providers who are eligible to bill for evaluation and management (E/M) services and who provide ongoing primary care to Medicare beneficiaries. The payment would be funded by a five percent annual reduction to the valuations of all non-E/M services and procedures under the Physician Fee Schedule. [No budget impact]

Expand Basis for Beneficiary Assignment for Accountable Care Organizations

In addition to physicians, Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists furnish primary care to Medicare beneficiaries, but Accountable Care Organizations (ACOs) cannot use non-physician primary care services to align beneficiaries to their ACO. Effective CY 2020, this proposal allows the Secretary to base beneficiary assignment on a broader set of primary care providers. This option broadens the scope of ACOs to better reflect the types of professionals that deliver primary care services to fee-for-service beneficiaries. [$80 million in savings over 10 years]

Create a Consolidated Hospital Quality Payment Program

Medicare requires inpatient hospitals to participate in four quality reporting programs: the Inpatient Quality Reporting Programs, the Hospital Value-Based Purchasing Program, the Hospital-Acquired Condition Reduction Program, and the Hospital Readmissions Reduction Program. This proposal establishes a new consolidated hospital quality payment program that combines and streamlines these four existing programs to drive quality improvement, lower health care costs, achieve transparency by publicly reporting performance information, and pay for value by making value-based incentive payment adjustments. Additionally, given the importance of monitoring patient safety, this proposal would require hospitals, as a Medicare Condition of Participation, to accurately report hospital acquired infections data to the CDC's National Health Safety Network. These streamlined requirements support CMS's Patients Over Paperwork and Meaningful Measures Initiatives. [No budget impact]

Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization

The Physician Self-Referral Law (commonly referred to as the Stark Law) has been identified by the Department and the regulated industry as a significant impediment to care coordination, participation in alternative payment models, and the establishment of novel financial arrangements that further the goals of a value-based system. Effective CY 2021, the Department, in consultation with the HHS Office of Inspector General, will establish a new exception to the physician self-referral law for arrangements that arise due to participation in advanced Alternative Payment Models and identify the types of arrangements and the minimum risk levels and level of participation in the model required for such exceptions. Effective CY 2021, this proposal addresses the problem by establishing a new process for physicians to self-report inadvertent, technical non-compliance violations of the law and excluding physician-owned distributors from the indirect compensation exception, if more than 40 percent of the physician-owned distributor's business is generated by physician-owners. [Budget impact not available]

Implement Value-Based Purchasing Program for Outpatient Hospitals and Ambulatory Surgical Centers

Medicare currently has value-based purchasing programs in place for inpatient hospital services and several other settings, but not for outpatient hospital services and ambulatory surgical centers. Beginning in CY 2021, CMS will implement a value-based purchasing program for hospital outpatient departments and ambulatory surgical centers, offering them incentives to improve quality and health outcomes. Under this proposal, two percent of payments would be linked to performance on quality and outcome measures. Total rewards and adjustments would be designed to be budget neutral. [No budget impact]

Redesign Outpatient Hospital and Ambulatory Surgical Center Payment Systems to Make Risk-Adjusted Payments

Under current law, Medicare bases payments for services furnished at outpatient hospital and ambulatory surgical centers on the setting of care rather than patient acuity. This proposal will risk-adjust payments to these facilities based on the severity of patients' diagnoses. These adjustments would be made in a budget neutral manner. This proposal will promote site neutrality in payments for similar services and similar patient characteristics at these facilities. [No budget impact]

Promoting Competition

Reform and Expand Durable Medical Equipment Competitive Bidding

Stakeholders raise two major concerns with the Medicare Durable Medical Equipment (DME) Competitive Bidding Program. First, DME suppliers can submit very low bids during the competition to win a Medicare contract and still get paid a higher price even though their low bid reduced prices for all other suppliers in the competition area. Second, current law requires that CMS use prices from urban DME competitions to inform fee schedule prices in rural areas, thereby undervaluing true costs in rural areas and threatening access to care. This proposal changes the way Medicare pays for DME under the competitive bidding program, from a single payment amount based on the maximum winning bid to the winning suppliers' own bid amounts. As a result, low bidders will be paid their low bid amount. The proposal also expands competitive bidding to additional geographic areas, including rural areas. In the event that fewer than two suppliers submit bids in a rural area, CMS will base prices on information from similar rural areas. Expanding competitive bidding will ensure prices for DME items and services in rural areas are based on competitions in those areas rather than on competitions in urban areas. [$7.1 billion in Medicare savings and $410 million in Medicaid savings over 10 years]

Support Coverage for Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes

Medicare DME coverage excludes non-durable alternatives to DME. This proposal allows Medicare coverage for innovative non-durable medical equipment alternatives to treat and manage diabetes. Payment for these alternative items would be subject to competitive bidding and capped at the payment rate for their DME counterpart. Allowing access to these alternatives makes it possible for beneficiaries to choose items and services that better suit their medical needs. [No budget impact]

Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts

Medicare beneficiaries in high-deductible health plans are currently prohibited from making tax-deductible contributions to their Health Savings Accounts (HSAs) or Medicare Savings Accounts (MSAs). This proposal allows beneficiaries enrolled in Medicare MSA Plans to contribute to their MSAs, subject to the annual HSA contribution limits determined by the Internal Revenue Service. Beneficiaries would also have a one-time opportunity to roll over the funds from their private HSAs to their Medicare MSAs and the ability to roll over funds from one MSA to another. Beneficiaries who elect this plan option would not be allowed to purchase Medigap or other supplemental insurance. Individuals who have an employer-sponsored, high-deductible health plan would also be allowed to make contributions to their HSAs, although Medicare would not cover any of the deductible. This proposal would give Medicare beneficiaries greater flexibility to take control of their health care using tools that are currently available in the private market. [$240 million in Medicare costs over 10 years]

Exercising Fiscal Stewardship

Modify Payments to Hospitals for Uncompensated Care

Medicare currently makes payments to hospitals for uncompensated care provided to non-Medicare beneficiaries. Effective FY 2021, this proposal establishes a new process to distribute uncompensated care payments to hospitals based on share of charity care and non-Medicare bad debt, as reported on Medicare cost reports. The total amount of available uncompensated care payments will be equal to FY 2019 funding levels, grown annually by the Consumer Price Index for all Urban Consumers. Uncompensated care payments will be funded from the general fund of the Treasury rather than the Medicare Trust Fund. Empirically justified Disproportionate Share Hospital payments will not be changed. This proposal more closely aligns Medicare

payment policy with private insurers, who do not typically cover uncompensated care. [$182.5 billion in Medicare savings over 10 years; this proposal would increase spending from general revenues by $84.5 billion over 10 years, for a net savings to the federal government of $98.0 billion over 10 years]

Pay On-Campus Hospital Outpatient Departments at the Physician Office Rate for Certain Services

Medicare generally pays on-campus hospital outpatient departments substantially more than physician offices for the same services. Effective CY 2020, this proposal makes site neutral payments between on-campus hospital outpatient departments and physician offices for certain services such as clinic visits, eliminating the disparity between what Medicare pays in these settings for the same services. [$131.4 billion in savings over 10 years]

Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care

Medicare payment for post-acute care service can differ substantially for similar beneficiaries depending on the setting, due to variation in supply and lack of evidence-based criteria regarding patient eligibility, the most appropriate setting, and level of care required. Under this proposal, skilled nursing facilities, home health agencies, and inpatient rehabilitation facilities will receive a lower annual Medicare payment update from FY 2020 to FY 2024 and, beginning in FY 2025, a unified post-acute care payment system would span all four post-acute care settings, with payments based on episodes of care and patient characteristics rather than the site of service. Payment rates would be budget neutral in FY 2025, risk adjusted, and set prospectively on an annual basis, with episode grouping and pricing based on the average cost for providing post-acute care services for a diagnosis, similar to the Diagnosis-Related Group methodology under the Inpatient Prospective Payment System (IPPS). This proposal would reduce costs, increase fairness, and give the Secretary the authority to adjust payments based on quality of care, geographic differences in labor and other costs, and other factors as deemed appropriate. [$101.2 billion in savings over 10 years]

Pay Site Neutral Rates to All Hospital-Owned Physician Offices Located Off-Campus

Medicare pays most off-campus hospital outpatient departments higher rates than the Physician Fee Schedule for the same services. These facility types include emergency departments, cancer hospitals, and grandfathered off-campus hospital outpatient departments billing under the Outpatient Prospective Payment System (OPPS) or under construction before November 2, 2015. This proposal requires all off-campus hospital outpatient departments to be paid under the Physician Fee Schedule effective CY 2020. This change will promote site neutrality by aligning payments to hospital outpatient departments with payments to physician offices, regardless of hospital ownership or facility type. [$28.7 billion in savings over 10 years]

Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria

Medicare pays a higher prospective payment rate to Long Term Care Hospitals (LTCHs) when admissions follow an acute care hospital stay with three or more days in an intensive care unit (ICU), or the LTCH provides at least 96-hours of mechanical ventilation services. Absent meeting these criteria, LTCHs receive a lower Medicare payment rate comparable to acute care hospitals under the IPPS. Effective FY 2020, this proposal raises the ICU stay threshold from three days to eight days to more accurately identify the chronically ill patients who typically receive the specialized care LTCHs provide. This change would promote site neutrality by basing payment on clinical characteristics and the needs of patients rather on location of care. [Savings of $10.0 billion over 10 years]

Reduce Medicare Coverage of Bad Debts

For most institutional provider types, Medicare currently reimburses 65 percent of bad debts resulting from beneficiaries' non-payment of deductibles and coinsurance. Effective FY 2020, this proposal reduces Medicare reimbursement of bad debt from 65 percent to 25 percent over three years. Rural hospitals with fewer than 50 beds, Critical Access Hospitals, Rural Health Clinics, and Federally Qualified Health Centers are exempt from the reduction. This proposal will more closely align Medicare policy with private payers, who do not typically reimburse for bad debt. [$38.5 billion in savings over 10 years]

Increase End-Stage Renal Disease (ESRD) Networks Funding to Match Consumer Price Index

Currently, ESRD Networks are funded by withholding 50 cents from each treatment payment under the ESRD Prospective Payment System, unchanged since 1989. This proposal updates the amount from 50 cents to

$1.50 and inflates that amount annually by the CPI-U to ensure funding is adequate for the networks to continue to carry out their work. [No budget impact]

Reducing Burden

Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models

Under the current structure of the Quality Payment Program, some clinicians who participate in advanced Alternative Payment Models may not be eligible for five percent incentive payments because they do not meet arbitrary thresholds. Effective CY 2020, the five percent bonus for clinicians in advanced Alternative Payment Models would be paid based on physician fee schedule revenues received through Models in which they participate rather than all Medicare physician fee schedule payments. This change directly rewards clinicians along a continuum based on their level of participation in advanced Alternative Payment Models, without subjecting clinicians to arbitrary participation threshold levels. [$280 million in savings over 10 years]

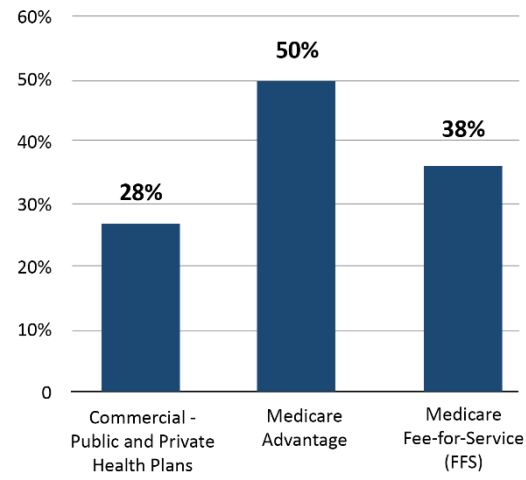
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment

Physicians must document a beneficiary's face-to-face encounter with a physician or a non-physician practitioner as a condition for Medicare payment for a DME order. This proposal allows CMS flexibility in the enforcement of the face-to-face requirement, eliminating this overly burdensome requirement for most Medicare providers and beneficiaries. [No budget impact]

Improve Safety and Quality of Care by Publicly Reporting Medicare Survey and Certification Reports Conducted by Accreditation Organizations

Accreditation organizations currently do not make their survey reports and accompanying Plans of Corrections publicly available, and the Secretary is prohibited from disclosing accreditation surveys that are *not* home health agencies surveys or related to an enforcement action. This proposal would provide CMS with the authority to publish surveys for all accredited facilities, including hospitals, hospices, ambulatory surgical centers, outpatient physical therapy and speech-language pathology services, and rural health clinics. This change will increase transparency and accelerate value. [No budget impact]

MEDICARE EXCEEDS COMMERCIAL ALTERNATIVE PAYMENT MODELS (APM) PARTICIPATION IN 2017



Source: APM Health Care Payment Learning and Action Network (https://hcp-lan.org/2018-apm-measurement/2018-infographic).

Remove the Redundant Requirement that Physicians Certify that All Critical Access Hospital Patients are Expected to be Discharged within 96 Hours of Admission

Under current law, physicians must certify that all patients at critical access hospitals (CAH) are reasonably expected to be discharged or transferred within 96 hours of admission. The CAH is still eligible for Medicare payment if an individual patient's stay exceeds 96 hours, so long as the CAH maintains an annual average length of stay of 96 hours or less, which is a Medicare Condition of Participation. This proposal removes the 96-hour physician certification requirement, thereby eliminating the burden of this unnecessary requirement. [No budget impact]

Remove Timeframe for Initial Surveys for End-Stage Renal Disease Facilities under the Bipartisan Budget Act of 2018

The Bipartisan Budget Act of 2018 established a time frame by which compliance surveys should be initiated for new dialysis facilities seeking their initial certification, but did not specify whether the requirement applied to facilities participating in Medicare through accreditation. The proposal clarifies that the time frame is only applicable to surveys conducted by state survey agencies on behalf of CMS. Therefore, the statutory time frame would not be applicable to any End-Stage Renal Disease treatment

facility choosing to be accredited by a CMS-approved accreditation organization, clarifying the current ambiguity over whether state survey agencies are required to survey these providers. [No budget impact]

Simplify and Eliminate Reporting Burdens for Clinicians Participating in the Merit-based Incentive Payment System

The Merit-based Incentive Payment System (MIPS) is burdensome and overly complex, consisting of physician and other clinical level measures that are often not meaningful to clinicians who report them and do not help improve patient care. Effective CY 2022, this proposal alters the MIPS program by adopting a uniform set of broader claims calculated measures and simplifying beneficiary surveys to assess performance at the group practice level instead of the individual clinician level during the performance period to reduce burden and provide meaningful and comparable results to clinicians and patients. This proposal would use the budget-neutral payment adjustments under the current statute to fund the incentive pool during the corresponding payment year and would retain the $500 million in annual additional performance bonus payments for top performers. [No budget impact]

QUALITY PAYMENT PROGRAM – YEAR ONE PERFORMANCE RESULTS

Snapshot of Payment Adjustments for MIPS Eligible Clinicians in 2019

93% of MIPS eligible clinicians received a positive payment adjustment for their performance in 2017

- 71% earned a positive adjustment and an adjustment for exceptional performance
- 22% earned a positive payment adjustment only

95% overall avoided a negative payment adjustment for their performance in 2017

- 2% received a neutral adjustment (no increase or decrease)
- 5% received a negative payment adjustment

Encourage Meaningful Measures for the End-Stage Renal Disease Quality Incentive Program

Current law is prescriptive about which measures to include in the ESRD Quality Incentive Program. Effective upon enactment, this proposal provides the Secretary with broad authority to add and remove measures to the ESRD Quality Incentive Program through rulemaking. CMS will submit all new measures to the designated pre-rulemaking entity as currently specified in statute. This change will align the ESRD Quality Incentive Program with CMS's Meaningful Measures initiative, which seeks greater flexibility and less burden regarding the quality measures Medicare uses in its value-based payment systems. [No budget impact]

BURDEN REDUCTION IMPACT: PATIENTS OVER PAPERWORK

Burden reduction for health providers increases efficiencies and improves the patient care experience. Across rules finalized in 2017 and 2018, CMS projects an estimated savings of nearly: $5.2 billion and a reduction of 53 million burden hours through 2021 – the equivalent of saving more than 6,000 years of burden hours over the next 4 years.

Total Projected Savings in 2018-2021 from Rules Finalized in 2017 and 2018

Provider Types	Savings	
	Dollars (millions)	Hours (thousands)
Accountable Care Organizations	$4	45
Ambulatory Surgical Centers	$1,400	915
Clinicians	$15	17,500
End Stage Renal Disease	$56	633
Home Health	$496	8,400
Hospice	$269	1,000
Hospitals	$1,200	14,000
Long Term Care	$497	6,600
Rural/Federally Qualified Health Centers	$100	950

Improve the Medicare Appeals System

The Budget includes the following proposals to improve the Medicare appeals process across all four levels: two at CMS, the Office of Medicare Hearings and Appeals, and the Departmental Appeals Board:

Change the Medicare Appeal Council's Standard of Review

Currently, when a party files a request for review of an Administrative Law Judge decision, the Medicare Appeal Council must review the decision de novo, from the beginning. This proposal changes the Council's standard of review from a *de-novo* to an *appellate-level* standard of review. Changing the Departmental Appeals Board's standard of review will increase adjudication capacity by up to 30 percent and further distinguish the Council's role as an administrative appellate body. [No budget impact]

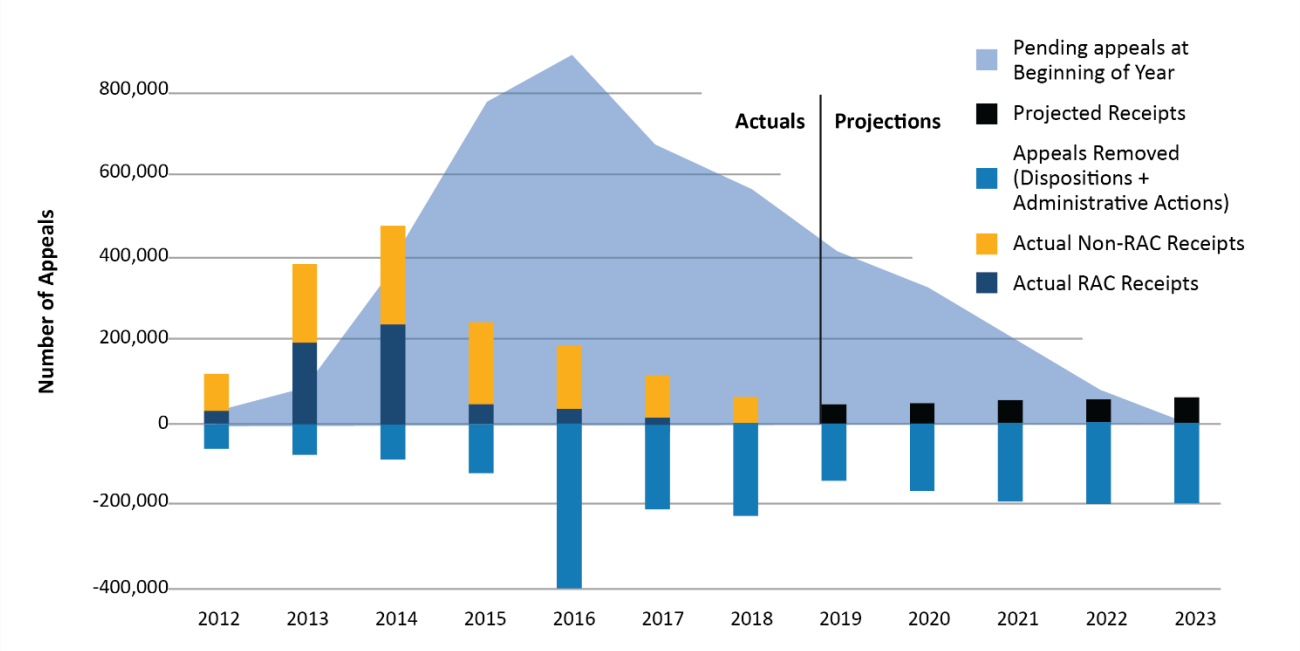
Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals

Currently, there are no administrative fees charged for filing a Medicare appeal, which has in some cases resulted in appellant's often filing non-meritorious appeals. This proposal establishes a post-adjudication user fee for all unfavorable Medicare appeals, other than beneficiary appeals, at the Office of Medicare Hearings and Appeals (the 3rd level of appeals) and the Departmental Appeals Board, the 4th level of appeals. The user fee will support a portion of the administrative costs required to adjudicate appeals and encourage those appellants who frequently file to more carefully asses their appeals before filing. [No budget impact]

Expedite Procedures for Claims with No Material Fact in Dispute

Appellants have an option to bypass the Administrative Law Judge (ALJ) hearing at the third level of Medicare appeals by requesting expedited access to judicial review if specific conditions are met. This proposal allows the Office of Medicare Hearings and Appeals to issue decisions on the record without holding a hearing if there is no material fact in dispute. These cases include appeals, for example, in which Medicare does not cover the cost of a particular drug or the ALJ cannot find in favor of an appellant due to binding limits on authority. This proposal increases the efficiency of the Medicare appeals system and results in faster adjudications of pending appeals at the ALJ level of appeal. [No budget impact]

RISE AND PROJECTED FALL OF MEDICARE APPEALS BACKLOG AT OMHA FY2012-2023



Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review

The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal increases the minimum amount in controversy required for adjudication of an appeal by an Administrative Law Judge to the Federal District Court amount in controversy requirement, which is $1,630 in calendar year 2019 and updated annually. This adjustment will allow the amount at issue to better align with the amount spent to adjudicate the claim. Appeals not reaching the minimum amount in controversy will be adjudicated by a Medicare magistrate. [No budget impact]

Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold

The Social Security Act requires a hearing by an Administrative Law Judge for a Medicare appeal even in situations where the amount-in-controversy is below the cost of adjudicating the claim. This proposal allows the Office of Medicare Hearings and Appeals to use Medicare magistrates for appealed claims below the Federal District Court amount in controversy threshold, which is $1,630 in calendar year 2019 and updated annually. This policy enables Administrative Law Judges to focus on more complex and higher amount in controversy appeals, while ensuring that all appealed claims are adjudicated. [No budget impact]

Limit Appeals When No Documentation is Submitted

Currently, appellants may pursue Medicare appeals when they have not submitted any documentation. This proposal limits the right for non-beneficiary appellants to appeal a redetermination of a claim that was denied because no documentation was submitted to support the items or services billed. This proposal does not apply to beneficiary appeals. Limiting the right to appeal when no documentation is submitted will incentivize providers and suppliers to submit documentation at the beginning of the appeals process so decisions can be made at the lowest, least costly level of appeal. [No budget impact]

Remand Appeals to the Redetermination Level with the Introduction of New Evidence

The status quo allows new evidence to be submitted at the second level of appeals or above, decreasing the efficiency of the Medicare appeals system and contributing to the backlog of pending appeals at Levels 3 and 4. This proposal permits the remand of an appeal to the first level of appeal when new documentary evidence is submitted into the administrative record at the second level of appeal or above. Exceptions may be made if evidence was provided to the lower level adjudicator but erroneously omitted from the record, or if an adjudicator denies an appeal on a new and different basis than earlier determinations. This proposal incentivizes appellants to include all evidence early in the appeals process and ensures the same record is reviewed and considered at subsequent levels of appeal. [No budget impact]

Require a Good-Faith Attestation on All Appeals

Currently, there are no statutory requirements that appellants consider the merits of their appeal before filing. This proposal requires all appellants to include in their initial appeal filing an attestation that they are submitting their appeal under a good-faith belief that they are entitled to receive Medicare reimbursement. This proposal also authorizes the Secretary to sanction or impose civil monetary penalties on appellants who submit attestations that are found to be unreasonable or made in bad faith. Requiring appellants to provide a good-faith attestation will reduce non-meritorious appeals and indiscriminate filing of appeals by high volume appellants. [No budget impact]

Medicare Legislative Proposals Discussed in Other Chapters

Medicare Drug Pricing Legislative Proposals

For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. To address this issue, in May 2018, President Trump and Secretary Azar released the *American Patients First* Blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs. The FY 2020 Medicare legislative proposals work to achieve the Blueprint's goals through proposals to modernize the Medicare Part D prescription drug benefit, improve transparency and accuracy of payments for drugs under Medicare Part B, and better align the incentives of providers and health plans with those of beneficiaries and taxpayers. Please see the Lowering the Cost of Prescription Drugs chapter for proposal

descriptions. [$67.2 billion in Medicare savings over 10 years]

Reduce Fraud, Waste, Abuse, and Improper Payments in Medicare

The Budget includes a number of Medicare program integrity proposals that strengthen the Department's and states' ability to fight fraud, waste, and abuse in the Medicare program and to reduce improper payments. See the Program Integrity chapter for proposal descriptions. [$6.4 billion in Medicare savings over 10 years]

Legislative Proposals for Medicare-Medicaid Enrollees

The Budget includes four proposals to improve the quality and efficiency of care for Medicare-Medicaid, dually-eligible beneficiaries. See the Medicaid chapter for proposal descriptions. [$210 million in Medicare savings over 10 years, attributed to the proposal to *Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries*]

Reform Graduate Medical Education Payments

Funding for Graduate Medical Education (GME) comes from multiple fragmented funding streams, and HHS's GME financing system does not target training to the types of physicians needed in the United States. The Budget includes a proposal to consolidate and better target federal spending for GME. See the Empowering States and Consumers to Reform Health Care chapter for a proposal description. [$211.8 billion in Medicare savings over 10 years]

Reform Medical Liability

The Budget includes a set of proposals to reform medical liability to reduce medical malpractice costs and the practice of defensive medicine (see the Empowering States and Consumers to Reform Health Care chapter for proposal descriptions). [$26.9 billion in net Medicare savings over 10 years]

2020 ADMINISTRATIVE PROPOSALS

The Budget includes seven Medicare administrative proposals that the Department plans to implement in FY 2020 and save an estimated $6 billion over ten years. These proposals do not require Congressional action. These proposals support the Administration's priorities of improving value-based systems of care, promoting competition, and exercising fiscal stewardship.

Improving Value-Based Systems of Care

Encourage Adoption of High-Value Innovative Technologies through Bundled Payment Demonstrations

It is currently not cost effective for providers to invest in some innovative technologies that could potentially save Medicare dollars over an episode of care. Under this proposal, the Center for Medicare & Medicaid Innovation would use existing authorities to identify bundled payment arrangements for certain high value devices. For example, these devices include technologies that could significantly reduce time and costs in a post-acute care setting but providers otherwise consider them impractical solely in the scope of Medicare payments to facilities. The proposal would require the device manufacturer to bear some or all of the risk. [No budget impact]

Improve Clarity and Transparency around Medicare Coverage Process

Some stakeholders find the process and standards for the Medicare coverage determination process lack clarity. This proposal requires CMS to issue additional guidance around the Medicare coverage process, including sub-regulatory guidance on the evidence standards that CMS utilizes in assessing coverage and the process to appeal coverage determinations, in an effort to improve clarity around Medicare coverage. [No budget impact]

Promoting Competition

Strengthen the Parallel Review Process to Streamline Medicare Coverage

The Parallel Review program is a collaborative effort between the Food and Drug Administration (FDA) and CMS that is intended to reduce the time between FDA approval of a drug or device and Medicare coverage of that item. This proposal strengthens the existing parallel review process to improve device manufacturer participation and increase transparency. [No budget impact]

Improve Medicare Beneficiary Access to Breakthrough Devices

There is currently no expedited pathway for Medicare beneficiaries to access innovative devices that have received FDA breakthrough designation. This proposal provides Medicare coverage of devices approved through the Breakthrough Device Program for

beneficiaries participating in clinical trials for up to four years from the date of FDA approval.
[No budget impact]

Add Additional Items to Durable Medical Equipment Competitive Bidding Program

The DME Competitive Bidding Program applies market-based competitive principles in setting prices for applicable items and services in Medicare. This proposal adds ventilators and orthotics to the next round of the competitive bidding program with implementation of prices beginning in 2021. This reform will ensure appropriate prices for these items and services, which will save money for taxpayers especially Medicare beneficiaries. [$6.1 billion in Medicare savings over 10 years]

Exercising Fiscal Stewardship

Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters

Encounter data is a more accurate source of risk-adjustment data in Medicare Advantage, reflecting services rendered versus patient diagnoses that insurance companies submit. This proposal phases-in the use of encounter data for Medicare Advantage payment risk adjustments. In payment year 2020, CMS is proposing to calculate risk scores by adding 50 percent of the risk score using encounter data and fee-for-service diagnoses to 50 percent of the risk score using plan-reported Risk Adjustment Processing System and fee-for-service diagnoses. CMS would increase the weighting of encounter data-based risk scores over subsequent years by moving to a risk score incorporating 75 percent of the encounter data/fee-for-service-based risk score in payment year 2021 and a risk score of 100 percent encounter data/fee-for-service-based risk score in payment year 2022. Using encounter data for risk-adjustment removes incentives for plans to inaccurately increase the severity of health conditions of their beneficiaries, improves Medicare payment accuracy, and reduces potential improper payments. [No budget impact]

Publicly Report Drugs with Significant Wastage Using Part B Claims Data

There may be a financial incentive for manufacturers to produce and providers to purchase drugs in larger packaged dosages than typically needed, because CMS pays for these discarded drugs and biologics up to the amount included in a package or vial, in addition to the amount administered to the beneficiary. Since January 1, 2017, providers and suppliers have been required to flag discarded drugs and biologicals for CMS on their Part B claims. This proposal requires CMS to make public which Part B drugs have the highest reported drug wastage using data gathered from these claims. Publicly reporting this information will allow for a better understanding of which drugs would benefit from different packaging to reduce wastage. [No budget impact]

FY 2020 Medicare Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Medicare Legislative Proposals			
Improving Value-Based Systems of Care			
Reprioritize Primary and Preventive Care in Medicare	--	--	--
Expand Basis for Beneficiary Assignment for Accountable Care Organizations	--	-30	-80
Create a Consolidated Hospital Quality Payment Program	--	--	--
Reform Physician Self-Referral Law to Better Support and Align with Alternative Payment Models and to Address Overutilization	*	*	*
Implement Value-Based Purchasing Program for Outpatient Hospitals and Ambulatory Surgical Centers	--	--	--
Redesign Outpatient Hospital and Ambulatory Surgical Center Payment Systems to Make Risk-Adjusted Payments	--	--	--
Promoting Competition			
Reform and Expand Durable Medical Equipment Competitive Bidding	--	-2,470	-7,110
Support Coverage for Innovative Alternatives to Durable Medical Equipment for Treatment and Management of Diabetes	--	--	--
Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts	--	50	240
Exercising Fiscal Stewardship			
Modify Payments to Hospitals for Uncompensated Care /1	--	-66,780	-182,460
Pay On-Campus Hospital Outpatient Departments at the Physician Office Rate for Certain Services	-4,670	-45,980	-131,400
Address Excessive Payment for Post-Acute Care Providers by Establishing a Unified Payment System Based on Patients' Clinical Needs Rather than Site of Care	-1,210	-27,230	-101,150
Pay Site Neutral Rates to All Hospital-Owned Physician Offices Located Off-Campus	-1,100	-10,510	-28,660
Authorize Long-Term Care Hospital Site Neutral Exceptions Criteria	-530	-4,190	-10,000
Reduce Medicare Coverage of Bad Debts	-410	-12,910	-38,510
Increase ESRD Networks Funding to Match Consumer Price Index	--	--	--
Reducing Burden			
Eliminate Arbitrary Thresholds and Other Burdens to Encourage Participation in Advanced Alternative Payment Models	-350	-620	-280
Eliminate the Unnecessary Requirement of a Face-to-Face Provider Visit for Durable Medical Equipment	--	--	--
Improve Safety and Quality of Care by Publicly Reporting Medicare Survey and Certification Reports Conducted by Accreditation Organizations	--	--	--

FY 2020 Medicare Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Remove the Redundant Requirement that Physicians Certify that All Critical Access Hospital Patients are Expected to be Discharged within 96 Hours of Admission	--	--	--
Remove Timeframe for Initial Surveys for End Stage Renal Disease Facilities under the Bipartisan Budget Act of 2018	--	--	--
Simplify and Eliminate Reporting Burdens for Clinicians Participating in the Merit-based Incentive Payment System	--	--	--
Encourage Meaningful Measures for the End-Stage Renal Disease (ESRD) Quality Incentive Program	--	--	--
Improve the Medicare Appeals System			
Change the Medicare Appeal Council's Standard of Review	--	--	--
Establish a Post-Adjudication User Fee for Level 3 and Level 4 Unfavorable Medicare Appeals	--	--	--
Expedite Procedures for Claims with No Material Fact in Dispute	--	--	--
Increase Minimum Amount in Controversy for Administrative Law Judge Adjudication of Claims to Equal Amount Required for Judicial Review	--	--	--
Establish Magistrate Adjudication for Claims with Amount in Controversy Below New Administrative Law Judge Amount in Controversy Threshold	--	--	--
Limit Appeals When No Documentation is Submitted	--	--	--
Remand Appeals to the Redetermination Level with the Introduction of New Evidence	--	--	--
Require a Good-Faith Attestation on All Appeals	--	--	--
Medicare Interactions			
Drug Pricing Legislative Proposals	-230	-19,470	-67,160
Reduce Fraud, Waste, Abuse, and Improper Payments in Medicare	-450	-2,760	-6,460
Legislative Proposals for Medicare-Medicaid Enrollees	-20	-90	-210
Reform Graduate Medical Education Payments /2	-14,480	-89,640	-211,840
Rebase National Medicare & You Education Program User Fee /3	40	310	680
Reform Medical Liability	-70	-5,250	-26,895
Subtotal Outlays, Medicare Legislative Proposals	**-23,480**	**-287,570**	**-811,295**
Medicare Administrative Proposals			
Improving Value-Based Systems of Care			
Encourage Adoption of High-Value Innovative Technologies through Bundled Payment Demonstrations	*	*	*
Improve Clarity and Transparency around Medicare Coverage Process	--	--	--
Promoting Competition			
Strengthen the Parallel Review Process to Streamline Medicare Coverage	--	--	--
Improve Medicare Beneficiary Access to Breakthrough Devices	--	--	--

FY 2020 Medicare Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Add Additional Items to Durable Medical Equipment Competitive Bidding Program	--	-1,930	-6,080
Exercising Fiscal Stewardship			
Eliminate Excessive Payment in Medicare Advantage by Using Claims Data from Patient Encounters	**--**	**--**	**--**
Publicly Report Drugs with Significant Wastage Using Part B Claims Data	--	--	--
Reduce Fraud, Waste, and Abuse in Medicare	-15	-140	-370
Subtotal, Medicare Administrative Proposals	**-15**	**-2,070**	**-6,450**
TOTAL, Medicare FY 2020 Budget Proposals	**-23,495**	**-289,640**	**-817,745**

*Budget impact unavailable as of the publication date of the FY 2020 President's Budget.

1/ Memorandum A: Give Medicare Beneficiaries with High Deductible Plans the Option to Make Tax Deductible Contributions to Health Savings Accounts or Medical Savings Accounts (non-add):

Medicare Impact	--	50	240
General Revenue Treasury Impact	--	4,396	12,357
Total Impact	--	4,446	12,597

2/ Memorandum B: Modify Medicare Payments to Hospitals for Uncompensated Care (non-add):

Medicare Impact	--	-66,780	-182,460
General Revenue Impact (CMS)	--	34,920	84,450
Total Impact	--	-31,860	-98,010

3/ The proposal to Rebase National Medicare & You Education Program User Fee has a projected net positive revenue impact for the Medicare Trust Funds of $371 million over 10 years, comprised of $1.05 billion in additional user fees offset by $680 million in projected benefit spending. See proposal description in CMS Program Management chapter.

Program Integrity

	dollars in millions			2020 +/-
	2018	2019	2020	2019
Health Care Fraud and Abuse Control Program				
Discretionary	745	765	792	+27
Mandatory /1	$1,298	$1,330	$1,410	+80
Subtotal, Health Care Fraud and Abuse Control Program	**$2,043**	**$2,095**	**$2,202**	**+107**
Medicaid Integrity Program /1 /2	$80	$82	$90	+8
Total, Budget Authority	**$2,123**	**$2,177**	**$2,292**	**+115**

1/ The FY 2018 and FY 2019 mandatory base includes sequester reductions.
2/ Additional information on the Medicaid Integrity Program is included in the States Grants and Demonstrations chapter.

The Fiscal Year (FY) 2020 Budget strengthens the integrity and sustainability of Medicare and Medicaid by investing in the prevention of fraud, waste, and abuse, protecting beneficiaries, and eliminating wasteful spending. Two programs, the Health Care Fraud and Abuse Control (HCFAC) Program Account and the Medicaid Integrity Program, comprise the largest portion of the federal government investment in health care program integrity. The FY 2020 Budget provides $2.3 billion in total mandatory and discretionary investments for the HCFAC and Medicaid Integrity Programs.

HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM

The HCFAC Program, established in 1996, serves as the primary federal program that addresses health care fraud and abuse through a coordinated effort between HHS and the Department of Justice (DOJ). It provides both discretionary and mandatory funding to address the full spectrum of health care fraud and abuse interventions, from prevention, detection, and reducing improper payments to investigations and prosecution.

Discretionary Health Care Fraud and Abuse Control

The Budget requests $792 million in discretionary HCFAC funding, $27 million above the FY 2019 enacted level. This includes $317 million in base discretionary funds plus a discretionary cap adjustment of $475 million, consistent with the Budget Control Act of 2011.

Of the $792 million, CMS receives $614 million, DOJ receives $98 million, and the HHS Office of Inspector General (OIG) receives $80 million.

CMS has shifted recent investments in HCFAC away from the "pay-and-chase" model to front-end prevention efforts. The program supports new and expanded efforts to reduce Medicare and Medicaid improper payment rates. For example, CMS will improve Medicaid data systems to better track fraud and abuse, expand Medicare fee-for-service targeted education and medical review, and strengthen oversight of Medicare Advantage. Activities balance fraud and abuse protections while limiting burden on providers.

Mandatory Health Care Fraud and Abuse Control

The Medicare Part A Trust Fund provides $1.4 billion in mandatory HCFAC resources for FY 2020, allocated to the Medicare Integrity Program and other HCFAC partners. This funding supports efforts across HHS, OIG, DOJ, and the Federal Bureau of Investigation to combat health care fraud, waste, and abuse.

Return on Investment

Program integrity efforts are proven cost-effective investments for federal spending. Medicare Integrity Program prevention and detection efforts have consistently yielded a return of over $10 billion in savings annually.

The three-year rolling average return-on-investment for HCFAC law enforcement activities is $4 gained for every $1 spent. In FY 2017 alone, these activities returned $2.3 billion to the federal government, including $1.4 billion returned to the Medicare Trust Funds and $407 million in federal Medicaid recoveries returned to the Treasury.

MEDICAID INTEGRITY PROGRAM

Using HCFAC as a model, the Deficit Reduction Act of 2005 established the Medicaid Integrity Program as the nation's first program integrity effort focused on Medicaid. The mandatory appropriation for the Medicaid Integrity Program adjusts annually for inflation and will total $90 million in FY 2020.

States are primarily responsible for combating fraud, waste, and abuse in the Medicaid program, and the Medicaid Integrity Program plays an important role supporting these efforts. Funded activities include reviews, audits, education activities, and technical support to states. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded by the HCFAC Program.

In FY 2018, CMS released a new program integrity strategy for Medicaid to address new program integrity challenges associated with the rapid increase in Medicaid spending in the last decade due in part to Medicaid expansion. The new initiatives in this strategy include the following:

- New audits targeting improper claims for federal matching funds, managed care medical loss ratios, and rate setting. These audits address issues identified, in part, by the OIG and Government Accountability Office.
- New audits of state beneficiary eligibility determinations previously found to be high risk by the OIG. These audits will examine how states determine eligibility for groups that qualify for enhanced federal match.
- Optimizing state-provided claims and provider data to both improve Medicaid eligibility and payment data and maximize their use for program integrity purposes.

Also included under the Medicaid Integrity Program, the Medicaid Financial Management and Oversight Project provides funding specialists, including accountants and financial analysts, who work with states to improve CMS's financial oversight of Medicaid and the Children's Health Insurance Program (CHIP). In 2018, these funding specialists partnered with states to avert or remove $1.5 billion in payments that states could not justify.

2020 LEGISLATIVE PROPOSALS

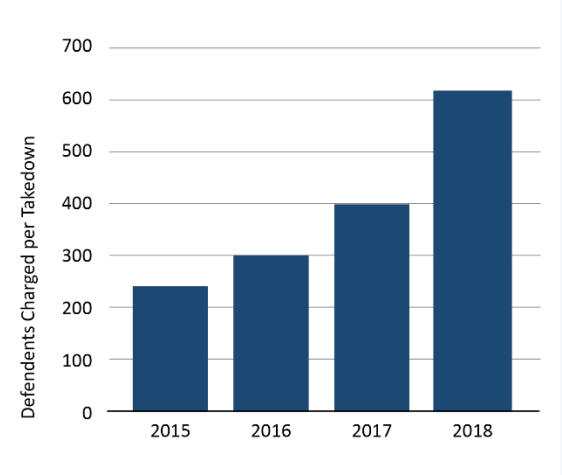
The FY 2020 Budget includes a comprehensive package of program integrity legislative proposals, saving $19.6 billion over ten years, that strengthen fiscal stewardship in Medicare and Medicaid by: addressing opioid-related fraud and abuse; improving payment accuracy; enhancing provider and program oversight; and supporting law enforcement.

Addressing Opioids

Prevent Abusive Prescribing by Establishing HHS Reciprocity with the Drug Enforcement Administration to Terminate Provider Prescribing Authority

CMS and the Drug Enforcement Administration (DEA) rely on provider data to detect and prevent abusive prescribing of controlled substances, but data reciprocity agreements do not exist between the two organizations.

HHS AND DOJ NATIONAL HEALTH CARE FRAUD AND OPIOID TAKEDOWNS



As evidenced by the chart above, coordinated efforts between DOJ and HHS result in increasing law enforcement takedowns of defendants committing opioid fraud. Under this proposal, CMS must report all Medicare revocation actions or preclusion list placements to the DEA that are based totally or in part on a pattern of abusive prescribing of controlled substances. In turn, the DEA could use this data to consider revocation of a DEA registration. [Budget impact not available]

Improving Payment Accuracy

Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation

Medicare cannot hold a practitioner financially accountable for improperly documenting ordered items or services. This proposal allows the Secretary to assess an administrative penalty on providers for ordering high-risk, high-cost items or services without proper documentation, such as diagnosis or encounter data. CMS would levy an administrative penalty of $50 for Part B items/services and $100 for Part A services. [No budget impact]

Expand Prior Authorization to Additional Medicare Fee-for-Service Items at High Risk of Fraud, Waste and Abuse

While prior authorization can be an effective tool for health care payers to support payment accuracy and reduce unnecessary utilization, current law restricts Medicare's ability to use this tool on all but a few fee-for-service items and services. This proposal extends the narrow existing authority to all Medicare fee-for-service items and services, specifically those that are at high risk for fraud and abuse. By allowing prior authorization on additional items and services, CMS can reduce Medicare improper payments. [$6.3 billion in savings over 10 years]

Require Prior Authorization When Physicians Order Certain Services Excessively Relative to Their Peers

The Medicare Payment Advisory Commission and the Government Accountability Office, have found that certain in-office ancillary services are prone to inappropriate physician self-referral and overutilization. Effective CY 2021, this proposal establishes a prior authorization program for high utilization practitioners of radiation therapy, therapy services, advanced imaging, and anatomic pathology services. Patients would be attributed to the physician who provided the plurality of their evaluation and management (E/M) services during the given year. CMS will re-evaluate annually to determine which physicians would be subject to prior authorization in the coming calendar year. [Budget impact not available]

Improve Efficiency and Strengthen Program Integrity Efforts in Medicare Parts C and D

Despite their success in Fee-for-Service, Recovery Audit Contractors have found Medicare Parts C and D to be an unattractive business model because of differing payment structures, a narrow scope of payment error, and unlimited appeal timeframes. To more efficiently use program integrity resources, this proposal removes the requirement for CMS to expand the Recovery Audit Program to the Medicare Parts C and D. The proposal also requires plan sponsors to report Part C and D fraud and abuse incidents and corrective actions. Given that the functions of the Part C and D Recovery Audit Programs are currently being performed through other program integrity mechanisms, this proposal creates programmatic and administrative efficiencies while strengthening fraud and abuse reporting. [No budget impact].

Pass Treasury Collection Fees for CMS Overpayment Collections onto the Debtor

CMS currently absorbs all fees charged by the Department of the Treasury for the collection of most CMS overpayments. The proposal gives the Secretary authority to pass Treasury fees for CMS overpayment collections on to the debtor for certain programs. Specifically, CMS would increase the amount of the collection to account for Treasury's recovery fee and ensure the Medicare Trust Funds are fully repaid. [$200 million in savings over ten years]

Implement Targeted Risk-Adjustment Pre-Payment Review in Medicare Advantage

The Medicare Advantage improper payment rate was 8.10 percent in FY 2018 and overpayments were estimated at over $9 billion. To improve Medicare Advantage payment accuracy, beginning in Calendar Year 2021, this proposal would confirm diagnoses submitted by Medicare Advantage Organizations for risk-adjustment with the medical record prior to CMS making risk-adjusted payments. The Secretary would be authorized to determine the threshold at which plans would be required to submit medical record documentation in support of the risk-adjustment and exclude certain types of plans. Confirming diagnoses before making risk-adjusted payments would improve payment accuracy in Medicare Advantage. [No budget impact]

Strengthen CMS's Ability to Recoup Medicaid Improper Payments

States are responsible for making correct beneficiary eligibility determinations to prevent misuse of taxpayer dollars. However, recent audits identified instances of states enrolling individuals in Medicaid who do not meet eligibility requirements, resulting in in

overpayments to States. Current law and regulations restrict CMS's ability to recover these overpayments from states. This proposal gives CMS authority to collect overpayments from States that spend federal resources on ineligible or misclassified beneficiaries. Specifically, it would permit HHS to issue disallowances outside of the current improper payment rate measurement process and allow HHS and OIG to extrapolate findings on beneficiary eligibility to ensure federal recovery of incorrect eligibility determinations. Additionally, it strengthens CMS' ability to issue disallowances for beneficiary eligibility errors by eliminating the current three percent threshold for states' eligibility-related improper payments. In place of the current three-percent disregard, HHS would issue rulemaking specifying criteria for disallowances, including limiting disallowances to instances of monetary loss such as cases where ineligible individuals receive benefits. [$4.4 billion in savings over 10 years]

Enhancing Provider and Program Oversight

Prevent Fraud by Applying Penalties on Providers and Suppliers who Fail to Update Enrollment Records

Medicare requires providers and suppliers to update enrollment records to remain in compliance with program requirements. This proposal provides CMS with the authority to implement civil monetary penalties for failure to report changes to information provided during enrollment or revalidation. Because outdated enrollment records can result in inaccurate information and make Medicare more susceptible to fraud, this proposal provides an additional incentive for providers and suppliers to update their enrollment records. [$32 million in collections over 10 years]

Ensure Providers that Violate Medicare's Safety Requirements and Have Harmed Patients Cannot Quickly Re-enter the Program

The reasonable assurance period currently allows providers and suppliers who have been terminated from participation in Medicare for noncompliance with Federal requirements to reenter the program after a just a preliminary showing of compliance. This is allowed even under circumstances that conflict with Medicare's minimum reenrollment requirements and puts beneficiaries at an increased risk of harm. This proposal allows the Secretary to enforce an exception to Medicare's reasonable assurance period in cases of patient harm or neglect by removing providers from the program for a one-to-three year period. [No budget impact]

Require Reporting on Clearinghouses and Billing Agents when Medicare Providers and Suppliers Enroll in the Program

Providers and suppliers employ clearinghouses and billing agents to process their claims with CMS, yet CMS has no method for tracking these entities and their affiliations, which leaves the program vulnerable to fraud and abuse. This proposal requires providers and suppliers to report clearinghouses and billing agents that act on behalf of Medicare providers and suppliers. This proposal would allow CMS to obtain organizational information from clearinghouses and billing agents in support of CMS and law enforcement's efforts to track and address fraud and abuse. [No budget impact]

Require Providers and Suppliers to Produce Part B Records to Support Part D Investigations or Audits

Currently, CMS lacks specific statutory authority to require records from Part B providers and suppliers in connection with an investigation or audit of drugs paid under Part D of the Medicare program. The proposal allows CMS to demand Part B records and information in support of Part D investigations and audits. Access to Part B records and information would allow CMS to complete more comprehensive Part D abusive prescribing investigations. [No budget impact]

Create Authority to Revoke or Deny Medicare Billing Privileges Based on Medical Board or Independent Review Organizations

The Secretary does not have authority to take administrative action against a provider based on a medical board's administrative action or Independent Review Organization determination, outside of a medical license suspension. The proposal allows the Secretary to take administrative action against physicians who have a prior medical board action(s) or an Independent Review Organization determination demonstrating that improper practitioner conduct led to patient harm. Examples of permissible administrative actions include revocation from Medicare or denial of billing privileges. [No budget impact]

Provide Flexibility for Enrolling Out-of-State Providers in Medicaid

Providers who render services to Medicaid beneficiaries who are visiting from another state face duplicative paperwork in order to receive payment from that state's Medicaid program. This proposal will

allow providers to receive payment for treating a Medicaid beneficiary from another state without enrolling in the home state of that Medicaid beneficiary as long as the provider is already enrolled in either Medicare fee-for-service or any state Medicaid program including, but not limited to, emergency and urgent care services. This proposal will improve the efficiency of provider payments while also improving beneficiary access to needed services. [$9 million in costs over 10 years]

Streamline the Medicaid Terminations Process

States do not always remove bad actors from their Medicaid programs as quickly as is necessary to avoid continued fraud, waste, and abuse. This proposal enhances the existing Medicaid provider terminations statute in three ways. First, it defines appeals periods such that state Medicaid agencies will report terminations after the first level of appeal rather than waiting until all appeals have been exhausted. Second, it establishes reporting requirements for rescissions and reinstatements of terminated Medicaid providers. Third, it requires that states check the centralized Termination Notification Database before enrolling providers. [No budget impact]

Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments

The OIG has reported that Medicaid personal care services claims are at a high risk for fraud and has recommended CMS better screen such claims prior to payment. The Budget proposes requiring states to implement claims edits that will enable states to screen and automatically deny unusual personal care services claims, such as: claims for duplicative services; for services provided by personal care service attendants not meeting state qualification requirements; and for services rendered to individuals no longer eligible for Medicaid. [$8.7 billion in savings over 10 years]

Consolidate Provider Enrollment Screening for Medicaid and CHIP

To protect Medicaid against ineligible and fraudulent providers, states are required to screen providers enrolling in Medicaid or CHIP according to their risk for fraud, waste, and abuse; however, providers enrolling in multiple state Medicaid or CHIP programs and managed care plans often face unnecessary and duplicative screening by states, federal programs, and managed care plans. This proposal requires providers receiving federal funding and enrolling in Medicaid or CHIP to undergo centralized CMS screening. State Medicaid and CHIP Agencies will retain flexibility to apply additional screening requirements but not to duplicate CMS screening. [No budget impact]

Extend Flexibility in Annual Open Payments Reporting Deadline

Many covered entities find the Open Payments reporting deadline burdensome with a limited time for review and corrections before publication. The proposal removes the statutory June 30th publication date for Open Payments data and provides the Secretary discretion to establish an alternative annual publication date that does not extend beyond October 1. This approach provides more time for impacted parties to review Open Payments data before it is released, ensuring reduced provider burden and improved accuracy of the Open Payments data. [No budget impact]

Require Physician Owned Distributors to Report in Open Payments

Currently, Physician Owned Distributors often sell or distribute implantable medical devices to other entities with whom they have a financial interest but are not required to report in the Open Payments Program, making it difficult for patients to recognize potential conflicts of interests. Effective calendar year 2020, this proposal requires that all Physician Owned Distributors report and identify themselves in the Open Payments program. This approach promotes increased transparency in response to a primary criticism of Physician Owned Distributors, that ownership may affect physicians' clinical decision-making, influencing them to perform unnecessary surgeries or choose a medical device in which they have a financial interest over one more appropriate for the patient. [No budget impact]

Supporting Law Enforcement and Fraud Reduction

Expand Medicaid Fraud Control Unit Review to Additional Care Settings

Medicaid Fraud Control Units receive cases of abuse and neglect in non-institutional settings that they cannot pursue due to legal restrictions. The current limitation on federal matching was established in 1978, at a time when Medicaid services were typically provided in institutional settings, and does not reflect the shift in delivery and payment for health services to home and community based settings. The Budget proposes to allow Medicaid Fraud Control Units to receive federal matching funds for the investigation or

prosecution of abuse and neglect of a beneficiary in non-institutional settings, such as home-based care. [Budget impact not available]

Clarify Authority for the Healthcare Fraud Prevention Partnership

Currently, the Healthcare Fraud Prevention Partnership operates under the authority established by the HCFAC Program, which limits allowable fraud and abuse activities to data sharing. This proposal establishes explicit authority for the Partnership and expands the scope of allowable activities beyond data sharing. The new authorities would allow the Partnership to address the full spectrum of fraud and abuse in the health care sector, including efforts to examine large public health issues that have fraud, waste, and abuse implications, such as addressing opioid misuse. [No budget impact]

2020 ADMINISTRATIVE PROPOSALS

The Budget includes seven program integrity administrative proposals that the Department plans to implement in FY 2020, saving $568 million over the next ten years. These proposals do not require Congressional action. Each proposal supports the Administration's program integrity priorities of improving payment accuracy and oversight.

Improving Payment Accuracy

Address Excessive Billing for Durable Medical Equipment that Require Refills on Serial Claims

CMS estimates that almost 36 percent of Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) payments were improperly paid in FY 2018. By leveraging Medicare demonstration authority, this proposal tests whether using a benefits manager for serial durable medical equipment claims results in lower improper payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring that beneficiaries were receiving the correct quantity of supplies or services for the appropriate period. [No budget impact]

Address Overutilization and Billing of Durable Medical Equipment, Prosthetics and Orthotics by Expanding Prior Authorization

As noted above, CMS estimates that almost 36 percent of Medicare DMEPOS payments were improperly paid in FY 2018. This proposal subjects additional DMEPOS item and services to prior authorization as a condition of Medicare payment. Prior authorization would be applied to items with a high risk for improper payments, leading to improved payment accuracy. [$300 million in savings over 10 years]

Address Improper Payments of Chiropractic Services through Targeted Medical Review

Recent legislation requires Medicare prior authorization for certain chiropractic services rendered by providers with aberrant billing patterns in an effort to reduce improper payments. . However, CMS has determined that implementing the prior authorization program as specified in the legislation would cost more to administer than it would save. Under this proposal, CMS would use Innovation Center authority to test whether more targeted medical review could effectively address improper payments in chiropractic services. [No budget impact]

Reduce Utilization of Low-Value Health Services through Prior Authorization Demonstrations

CMS and other health care payers use prior authorization as a tool to reduce or eliminate unnecessary utilization of health care services. To address over-utilization in Medicare of low-value health services, CMS will explore options within their current authority to test prior authorization of low-value services. When implementing this proposal, CMS will consider patient access and other quality concerns, in an effort to reduce burden on patients while ensuring appropriate provisions of health care. [No budget impact]

Expand Medicare Advantage Risk Adjustment Data Validation Audits

Risk Adjustment Data Validation (RADV) contract audits support CMS program integrity and oversight in Medicare Advantage and perform as the primary corrective action for Medicare Advantage improper payments. This proposal expands the number of contract-level RADV audits. The number of RADV audits would increase annually, until the current level doubles in CY 2023. [No budget impact]

Incentivize States to Address Medicaid Improper Payments Related to Beneficiary Eligibility

Current regulations restrict CMS's ability to issue disallowances related to beneficiary eligibility. This proposal will revise the regulations relating to Medicaid improper payment rate measurement, empowering CMS to issue disallowances to states with a beneficiary eligibility improper payment rate above the statutory

three percent threshold. [$190 million in savings over 10 years]

Enhancing Provider and Program Oversight

Allow Revocation and Denial of Provider Enrollment Based on Affiliation with a Sanctioned Entity

Providers and suppliers that abuse the Medicare program evade revocation from the program by "reinventing" themselves under a new business's corporate umbrella. This proposal expands the current authority to revoke or deny an individual's and entity's Medicare enrollment if they are affiliated with a sanctioned entity. This change will stop these abusive enrollment practices by allowing the Secretary to take administrative actions against entities that have owners, managing employees, officers, and/or directors that previously affiliated with sanctioned Medicare entities. [$70 million in savings to Medicare and $8 million in savings to Medicaid over ten years]

Establish Unique Identifiers for Personal Care Service Attendants

Most states do not currently assign unique identifiers to personal care service attendants, making it difficult to track their activities or to verify claims in ways that adequately address concerns about fraud, waste, and abuse in personal care services. HHS will reduce fraud and abuse among personal care service attendants by requiring states to assign unique identifiers to personal care service attendants that will be listed on claims along with dates that attendants performed services in question. [No budget impact]

Program Integrity

FY 2020 Program Integrity Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Legislative Proposals			
Address Opioids			
Prevent Abusive Prescribing by Establishing HHS Reciprocity with the Drug Enforcement Agency to Terminate Provider Prescribing Authority	*	*	*
Improving Payment Accuracy			
Medicare			
Assess a Penalty on Physicians and Practitioners who Order Services or Supplies without Proper Documentation	-	-	-
Expand Prior Authorization to Additional Medicare Fee-for-Service Items at High Risk of Fraud, Waste and Abuse	-430	-2,660	-6,260
Require Prior Authorization When Physicians Order Certain Services Excessively Relative to Their Peers	*	*	*
Improve Efficiency and Strengthen Program Integrity Efforts in Medicare Parts C and D	-	-	-
Pass Treasury Collection Fees for CMS Overpayment Collections onto the Debtor	-20	-100	-200
Implement Targeted Risk-Adjustment Pre-Payment Review in Medicare Advantage	-	-	-
Medicaid			
Strengthen CMS's Ability to Recoup Medicaid Improper Payments	-	-1,480	-4,420
Enhancing Provider and Program Oversight			
Medicare			
Prevent Fraud by Applying Penalties on Providers and Suppliers who Fail to Update Enrollment Records /1	-2	-13	-32
Ensure Providers that Violate Medicare's Safety Requirements and Have Harmed Patients Cannot Quickly Re-enter the Program	-	-	-
Require Reporting on Clearinghouses and Billing Agents when Medicare Providers and Suppliers Enroll in the Program	-	-	-
Require Providers and Suppliers to Produce Part B Records to Support Part D Investigations or Audits	-	-	-
Create Authority to Revoke or Deny Medicare Billing Privileges Based on Medical Board or Independent Review Organizations	-	-	-
Medicaid			
Provide Flexibility for Enrolling Out-of-State Providers in Medicaid	-	4	9
Streamline the Medicaid Terminations Process	-	-	-
Implement Prepayment Controls to Prevent Inappropriate Personal Care Services Payments	-700	-3,830	-8,670
Consolidate Provider Enrollment Screening for Medicaid and CHIP	-	-	-
Crosscutting			
Extend Flexibility in Annual Open Payments Reporting Deadline	-	-	-
Require Physician Owned Distributors to Report in Open Payments	-	-	-

FY 2020 Program Integrity Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Supporting Law Enforcement and Fraud Reduction			
Medicaid			
Expand Medicaid Fraud Control Unit Review to Additional Care Settings	*	*	*
Crosscutting			
Clarify Authority for the Healthcare Fraud Prevention Partnership	-	-	-
Subtotal Outlays, Program Integrity Legislative Proposals	**-1,152**	**-8,079**	**-19,573**
Subtotal, Medicare Impact	-452	-2,773	-6,492
Subtotal, Medicaid Impact	-700	5,306	-13,081
Administrative Proposals			
Improving Payment Accuracy			
Medicare			
Address Excessive Billing for Durable Medical Equipment that Requires Refills on Serial Claims	-	-	-
Address Overutilization and Billing of Durable Medical Equipment, Prosthetics and Orthotics by Expanding Prior Authorization	-15	-120	-300
Address Improper Payments of Chiropractic Services through Targeted Medical Review	-	-	-
Reduce Utilization of Low-Value Health Services through Prior Authorization Demonstrations	-	-	-
Expand Medicare Advantage Risk Adjustment Data Validation Audits	-	-	-
Medicaid			
Incentivize States to Address Medicaid Improper Payments Related to Beneficiary Eligibility	-	-60	-190
Enhancing Provider and Program Oversight			
Crosscutting			
Allow Revocation and Denial of Provider Enrollment Based on Affiliation with a Sanctioned Entity	-	-23	-78
Medicare Impact (non-add)	-	*-20*	*-70*
Medicaid Impact (non-add)	-	*-3*	*-8*
Medicaid			
Establish Unique Identifiers for Personal Care Service Attendants	-	-	-
Subtotal Outlays, Program Integrity Administrative Proposals	**-15**	**-203**	**-568**
Subtotal, Medicare Impact	-15	-140	-370
Subtotal Medicaid Impact	-	-63	-198

*Budget impact unavailable as of the publication date of the FY 2020 President's Budget.
1/ This proposal reflects new revenue collections to the Medicare Part A Trust Fund.

Medicaid

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Current Law				
Benefits /1	371,903	396,820	403,549	+6,639
State Administration	17,254	21,861	22,528	+667
Total Net Outlays, Current Law	**389,157**	**418,681**	**425,986**	**+7,305**
Proposed Law				
Legislative Proposals	-	-	-7,835	-7,835
Total Net Outlays, Proposed Law	**389,157**	**418,681**	**418,151**	**-530**

1/ Includes outlays from the Vaccines for Children Program, administered by the Centers for Disease Control and Prevention. Also reflects administrative proposal outlay impacts assumed in the baseline.

Medicaid provides medical assistance to millions of low-income and disabled Americans. In Fiscal Year (FY) 2018, more than one in five individuals were enrolled in Medicaid for at least one month in the United States. In FY 2019, over 76 million people on average in any given month are expected to receive health care coverage through Medicaid. CMS predicts that enrollment will increase in the future due to factors such as population growth.

HOW MEDICAID WORKS

States design, implement, and administer their own Medicaid programs based on guidelines established by the federal government. The federal government matches state expenditures based on the Federal Medical Assistance Percentage, which can be no lower than 50 percent. In FY 2019, the federal share of Medicaid outlays will be approximately $418.7 billion. Without reforms, CMS's Office of the Actuary estimates total federal and state Medicaid benefit spending will be $1.1 trillion by FY 2029, comprising 3.2 percent of U.S. gross domestic product.

Currently, states must cover individuals who meet certain minimum categorical and financial eligibility standards. Medicaid beneficiaries include children; pregnant women; adults in families with dependent children; and the aged, blind, and/or disabled. Individuals must meet certain minimum income eligibility criteria that vary by category. States have the flexibility to extend coverage to higher income groups, including medically needy individuals, through waivers and amended state plans. Medically needy individuals do not meet the income standards of the above mentioned categorical eligibility groups but incur large medical expenses and would otherwise qualify for Medicaid.

Under Medicaid, states must cover certain medical services and are provided the flexibility to offer additional benefits to beneficiaries. Medicaid covers most of the costs of providing long-term care services for beneficiaries. Medicare and private health insurance often furnish limited coverage.

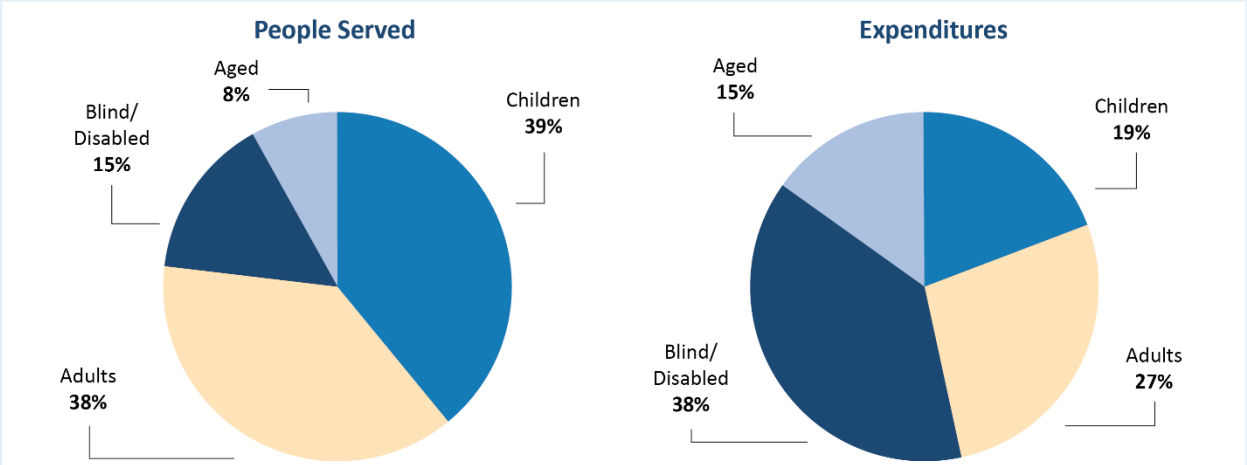
RECENT PROGRAM DEVELOPMENTS

Empowering Individuals through Community Engagement

Millions of able-bodied, working-age adults became eligible for Medicaid through the Obamacare Medicaid expansion. While medical coverage is important, public assistance programs trap many individuals in dependency. In addition to ensuring access to health care for Americans, the Trump Administration also prioritizes helping individuals obtain economic self-sufficiency.

In January 2018, the Administration announced its intention to break the cycle of poverty and dependence through approval of Section 1115 community engagement demonstrations. The demonstrations promote work or community engagement activities (e.g., volunteering, educational activities, or job training) for working-age, able-bodied adults to promote improved health and well-being. Since then, CMS approved community engagement demonstrations in eight states.

PERCENTAGE OF MEDICAID BENEFICIARIES VS. FEDERAL MEDICAL ASSISTANCE EXPENDITURES BY ELIGIBILITY GROUP



Source: CMS Office of the Actuary
Estimates of expenditures by eligibility group in FY 2017 are projected based on prior year data and may change as more data becomes available. Totals and components exclude administrative costs, Disproportionate Share Hospital expenditures, territorial enrollees and expenditures, and financial adjustments. Percentages may not add to 100% due to rounding.

CMS remains committed to supporting states in their efforts to develop new and innovative solutions to improve their Medicaid programs and to provide individuals on Medicaid with better health, the ability to experience the dignity of a job and personal responsibility, and move individuals forward on the path to independence and greater well-being.

Designing Innovative Service Delivery Systems in Mental Health

In November 2018, as required by the 21st Century Cures Act of 2016, CMS published a State Medicaid Director letter discussing strategies under existing authorities for states to implement innovative service delivery system reforms for adults with serious mental illness, and children with serious emotional disturbance. Examples of these innovations include improving availability of behavioral health screenings and mental health and substance use disorder services in schools to identify and engage children with serious emotional disturbance sooner.

The letter explained a demonstration opportunity for states to receive federal financial support for treating Medicaid beneficiaries with these conditions during short-term acute care stays in psychiatric hospitals or in residential treatment facilities that qualify as an Institution for Mental Diseases.[6]

2020 LEGISLATIVE PROPOSALS[7]

The FY 2020 Budget provides additional flexibility and reduces administrative burden for states; puts Medicaid on a path to fiscal stability by restructuring Medicaid financing and reducing waste; and refocuses Medicaid on populations the program was originally intended to serve—low-income families, the elderly, people with disabilities, children, and pregnant women. In total, the Budget includes net savings to Medicaid of $1,482.7 billion over 10 years. Of this total, the Budget includes $1,385.5 billion in savings to Medicaid related to the Empowering States and Consumers to Reform Health Care proposal (see related chapter for more information).

[6] For more information, please see the State Medicaid Director letter: https://www.medicaid.gov/federal-policy guidance/downloads/smd18011.pdf

[7] Except where otherwise noted, estimates reflect gross savings to Medicaid. In some cases, savings will be reduced when enacted in conjunction with the Empower States and Consumers to Reform Health Care proposal.

Increasing Medicaid Flexibility for States and Reducing Burden

Allow States to Extend Medicaid Coverage for Pregnant Women with Substance Use Disorders to One Year Postpartum

Substance use is strongly associated with significant adverse health impacts for both mothers and infants. Opioid use during pregnancy and incidents of neonatal abstinence syndrome have increased dramatically in recent years. This proposal would make it easier for states to provide full Medicaid benefits for one-year postpartum for pregnant women diagnosed with a substance use disorder. [$245 million over 10 years]

Increase the Limit on Medicaid Copayments for Non-Emergency Use of the Emergency Department

State flexibility to charge copayments above the nominal statutory amounts for non-emergency use of the emergency department is limited to waiver requests, a burdensome and time-consuming process. The Budget proposes to provide states the option to use state plan authority to increase these copayments to encourage personal financial responsibility and proper use of health care resources. [$1.6 billion in savings over 10 years]

Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers

States are required to submit unnecessary paperwork to renew managed care waivers in place for years. This proposal reduces burdensome federal reviews by allowing states to grandfather managed care authorities in waivers and demonstration programs under their state plans if there are no substantive changes and it has been renewed at least once. [No budget impact]

Increase Flexibility in the Duration of Section 1915(b) Managed Care Waivers

Medicaid managed care is widespread in states, yet states must submit paperwork for re-approval of Medicaid managed care waivers every five years for programs involving dual-eligible individuals and every two years for Section 1915(b) waivers for all other Medicaid eligibility groups. This proposal eliminates the current five-year time limit for Section 1915(b) waivers to give the Secretary the flexibility to determine the appropriate approval timeframe for all Medicaid managed care enrolled populations. [No budget impact]

Modify the Medicaid Fair Hearing Requirement to Eliminate Duplicative Appeals

States may be forced to adjudicate duplicative appeals at the state Medicaid agency when another entity has already adjudicated the same case. This proposal reduces the burden on states by allowing them to meet the Medicaid fair hearing requirements for cases that have already been adjudicated by Exchange Appeal Entities or by the U.S. Department of Health and Human Services (HHS). Specifically, the requirement that state Medicaid agencies must provide the opportunity for a fair hearing would change to permit state Medicaid agencies to substitute a fair hearing before another state agency or HHS. [No budget impact]

Focusing Medicaid Eligibility on the Most Needy

Strengthen Work Requirements to Promote Self-Sufficiency

The Budget improves consistency between work requirements in federally funded public assistance programs, including Medicaid and Temporary Assistance for Needy Families (TANF), by requiring that able-bodied, working-age individuals find employment, train for work, or volunteer (community service) in order to receive welfare benefits. This would enhance service coordination for program participants, improve the financial well-being of those receiving assistance, and ensure federally funded public assistance programs are reserved for the most vulnerable populations. [$130.4 billion in savings over 10 years]

Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations

Asset tests once allowed states to prioritize receipt of Medicaid for lower-income individuals by screening for assets and resources, such as savings accounts or vehicles. However, Obamacare's Modified Adjusted Gross Income (MAGI) eligibility rules eliminated asset tests for most children and able-bodied adults, leaving asset tests only for aged, blind, and disabled Medicaid beneficiaries. This proposal provides states the option to apply asset tests to populations determined financially eligible by the MAGI standard, such as able-bodied adults, so states can refocus Medicaid on the truly needy. This proposal also provides states with the option to apply asset tests just to individuals eligible through the MAGI standard who are receiving long-term care. [$2.1 billion in savings over 10 years]

Reduce the Maximum Allowable Home Equity for Medicaid Eligibility

Some states have set home equity limits so high that individuals with the means to pay for their own long-term care qualify for Medicaid payment for that care, transferring what should be an individual or family responsibility to the taxpayers. This proposal removes states' authority to substitute a higher home equity limit than the statutory minimum. This approach focuses long-term care coverage on lower-income individuals without significant assets that could be liquidated to cover their long-term care. [$6.7 billion in savings over 10 years]

Require Documentation of Satisfactory Immigration Status before Receipt of Medicaid Benefits

Currently, states must enroll individuals that claim they have, but cannot immediately provide, documentation of citizenship or satisfactory immigration status. After a reasonable opportunity period, the individuals must submit evidence of citizenship or satisfactory immigration status. This proposal requires individuals to prove Medicaid eligibility before they receive coverage. States may still elect to provide coverage during a reasonable opportunity period, but this proposal prohibits federal payments for medical assistance during this period. [$2.3 billion in savings over 10 years]

Reducing Wasteful Spending in Medicaid

Address Inappropriate Financing of Medicaid State Share by Public Providers

In recent years, some units of government, including states and localities, have acquired ownership of privately operated medical facilities. These newly public health care providers generate state and local Medicaid matching payments, while being held harmless for these donations by states through increased Medicaid supplemental payments. This proposal will prohibit units of government from exploiting this financing mechanism. Closing this loophole will prevent states from inappropriately generating state share, to restrain Medicaid spending and improve equity in Medicaid funding between states. [Budget impact not available]

Prohibit Medicaid Payments to Public Providers in Excess of Costs

Medicaid payments for health care services are limited to what Medicare would have paid for the same service (referred to as the Upper Payment Limit), which in some cases may exceed a public provider's actual cost of providing care to Medicaid patients. This proposal limits Medicaid reimbursement for health care providers operated by a unit of government to an amount not exceeding the actual cost of providing those services. This will prevent states from using supplemental payments to public providers to circumvent Medicaid matching requirements. [Budget impact not available]

Clarify Medicaid Treatment of Third Party Payments for Disproportionate Share Hospital Allotments

Medicaid regulations require states to include all third party payments for Medicaid beneficiaries when calculating uncompensated care costs under the Medicaid Disproportionate Share Hospital (DSH) limits. Some providers continue to receive duplicate uncompensated care payments from other payers, such as private insurance or Medicare. This proposal would codify existing regulations to remove ambiguity for states and hospitals. This will strengthen CMS's ability to enforce existing federal regulations and prevent states from paying hospitals twice for the same care episode. [No budget impact]

Continue Medicaid Disproportionate Share Hospital Allotment Reductions

Current law reduces Medicaid DSH allotments between FY 2020 and FY 2025 to account for decreases in uncompensated care. The Budget continues Medicaid DSH allotment reductions for FY 2026 through FY 2029, since the new Market-Based Health Care Block Grants proposed in the Budget provide states with resources to maintain coverage for those previously covered by Obamacare. [$25.9 billion in savings over 10 years]

Rescind Remaining Balances from the Medicaid Improvement Fund

The Medicaid Extenders Act of 2019 (P.L. 116-3) rescinded $25 million from the Medicaid Improvement Fund, authorized for Medicaid administrative activities beginning in FY 2021. This proposal rescinds the remaining $6 million balance from the fund. [$6 million in savings over 10 years]

LEGISLATIVE PROPOSALS FOR MEDICARE-MEDICAID ENROLLEES

Reducing Wasteful Spending for Medicare-Medicaid Enrollees

Allow CMS Flexibility to Determine the Frequency of Program of All-Inclusive Care for the Elderly Program Reviews

Current law requires a comprehensive review of a new Program of All-inclusive Care for the Elderly (PACE) organization's operations annually during the three-year trial period, including an on-site visit, and reviews as appropriate after the trial period. This proposal provides flexibility to conduct one comprehensive review of a new PACE organization only during the first year of the three-year trial period, barring no significant noncompliance issues in the first year audit. It allows for continuing reviews in any year after the first year of the trial period. These flexibilities would decrease the large administrative and financial burden on PACE organizations, CMS, and state administering agencies that participate in the PACE program reviews. [No budget impact]

Allow for Federal/State Coordinated Review of Dual Eligible Special Needs Plan Marketing Materials

Marketing materials provided by Dual Eligible Special Needs Plans to beneficiaries go through separate state and CMS review processes. This proposal allows for joint state and CMS review, while enhancing their ability to provide a uniform message to beneficiaries. Providing CMS with the ability to coordinate reviews with states based on a single submission of these marketing materials can improve the quality of products available to beneficiaries, while reducing the burden on health plans, states, and CMS. [No budget impact]

Improve Appeals Notifications for Dually Eligible Individuals in Integrated Health Plans

Medicare and Medicaid have different appeals processes in statute, resulting in different requirements related to timeframes and limits, amounts in controversy, and levels of appeals. This proposal provides HHS with the authority to streamline the appeals notification requirements for health plans that integrate payment and services for Medicare-Medicaid enrollees. It improves communications to beneficiaries so they do not receive conflicting instructions based on differing Medicare and Medicaid requirements. It also improves care coordination for a population with complex and high-cost medical needs. [No budget impact]

Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries

The Social Security Act requires that CMS maintain a Special Enrollment Period (SEP) for full-benefit dually eligible beneficiaries who would like to make changes to their Medicare Advantage and Medicare prescription drug coverage outside of the annual enrollment period. This SEP has created unintended consequences, including aggressive targeting of dually eligible beneficiaries by enrollment agents, and decreased incentives for plans to invest in care coordination for this population. This proposal narrows the continuous SEP by allowing CMS to apply the same annual election process for both dually eligible and non-dually eligible beneficiaries, while preserving the ability for full-benefit dually eligible beneficiaries to use a SEP to opt into integrated care programs or change plans following auto-assignment into a Part D plan. This proposal protects full-benefit dually eligible beneficiaries from aggressive marketing targeted to low-income beneficiaries who currently have a continuous SEP, improves incentives to invest in care coordination for high-cost, often vulnerable beneficiaries, and reduces the administrative burden on health plans from beneficiary fluctuations between plans. [No budget impact to Medicaid, $210 million in savings to Medicare over 10 years]

MEDICAID INTERACTIONS

Medicaid Drug Pricing Legislative Proposals

Although pharmacy coverage is an optional benefit under federal Medicaid law, all states currently provide coverage for outpatient prescription drugs to all categorically eligible individuals and most other enrollees within their state Medicaid programs. For years, American patients have suffered under a drug-pricing system that provides generous incentives for innovation, while too often failing to deliver important medications at an affordable cost. To address this issue, in May 2018, President Trump and Secretary Azar released the *American Patients First* Blueprint, a comprehensive plan to bring down prescription drug prices and out-of-pocket costs. The FY 2020 Medicaid legislative proposals work to achieve the Blueprint's goals by strengthening negotiation

and accountability to lower the costs of prescription drugs for states and the federal government. Please see the Lowering the Cost of Prescription Drugs chapter for proposal descriptions.

Empowering States and Consumers to Reform Health Care

Medicaid costs to states and the federal government are growing at an unsustainable rate and states do not have the flexibility they need to address the underlying drivers of these trends. The Budget supports the comprehensive Medicaid reform in the 2017 Graham-Cassidy-Heller-Johnson legislation, including allowing states a choice between a per-capita cap or a block grant, and repealing Obamacare's Medicaid expansion. Medicaid financing reform will empower states to design individual, state-based solutions that prioritize Medicaid dollars for traditional Medicaid populations and support innovation (see the Empowering States and Consumers to Reform Health Care chapter for a proposal description). [$1.4 trillion in Medicaid savings over 10 years]

Reform Graduate Medical Education Payments

Current funding for Graduate Medical Education (GME) comes from multiple fragmented funding streams, and HHS's GME financing system ineffectively targets training to certain types of physicians that are necessary for the Nation. The Budget includes a proposal to consolidate and better target federal spending for GME (see the Empowering States and Consumers to Reform Health Care chapter for a proposal description). [$21.3 billion in Medicaid savings over 10 years]

Reform Medical Liability

The Budget includes a set of proposals to reform medical liability to reduce medical malpractice costs and the practice of defensive medicine (see Empowering States and Consumers to Reform Health Care chapter for proposal descriptions). [$46 million in net Medicaid savings over 10 years[8]]

Reduce Fraud, Waste, Abuse, and Improper Payments in Medicaid

The Budget includes a number of Medicaid program integrity proposals that strengthen the Department's and states' ability to fight fraud, waste, and abuse in the Medicaid program and to reduce improper payments (see the Program Integrity chapter for descriptions of these proposals). [$13.1 billion in Medicaid savings over 10 years]

2020 ADMINISTRATIVE PROPOSALS

The Budget includes seven Medicaid administrative proposals that the Department plans to implement in FY 2020 and save an estimated $53.4 billion over 10 years. These proposals support the Administration's priorities for Medicaid and do not require Congressional action.

Focusing Medicaid Eligibility on the Most Needy

Test Interventions to Improve Maternal Mortality and Morbidity

Maternal morbidity and mortality in the United States have been rising significantly in recent decades. Under the Center for Medicare and Medicaid Innovation authority, this proposal aims to explore a potential service delivery model to test interventions to improve maternal mortality and morbidity. [No budget impact]

Tighten Medicaid Child Support Enforcement Requirements

Not all state Medicaid agencies collect the information that state child support agencies need or share that information in a timely manner, impairing the ability of child support agencies to enforce child support requirements. Under this proposal, CMS and the Administration for Children and Families will issue joint guidance to State Medicaid Agencies and Child Support enforcement agencies outlining successful processes for cross-agency coordination, including collecting information from custodial parents, sharing data, and transmitting relevant information to child support agencies in a timely manner. As more custodial parents provide information aiding child support enforcement, it will ensure more children receive required support and will promote parents as the primary source of economic support for their children. [No budget impact]

Allow States the Flexibility to Conduct More Frequent Eligibility Redeterminations

Current regulations prohibit states from conducting Medicaid eligibility redeterminations more than once every 12 months for individuals eligible based on MAGI

[8] Savings accounts for the interaction with the Empowering States and Consumers to Reform Health Care proposal.

financial eligibility. The Budget commits to using regulatory authority to allow states the option to conduct more frequent eligibility redeterminations for MAGI populations to ensure that Medicaid is focused on the most needy. [$45.6 billion in savings over 10 years]

Reducing Wasteful Spending in Medicaid

Require Minimum Standards in Medicaid State Drug Utilization Review Programs

The Medicaid statute requires that each state develop a Drug Utilization Review program targeted in part at reducing clinical abuse and misuse, including of opioids. CMS currently does not set minimum requirements for these programs, and there is substantial variation in how states approach this issue. Under this proposal, HHS will set minimum standards for Drug Utilization Review programs, notably, to help increase oversight of opioid prescriptions and dispensing in Medicaid. [$245 million in savings over 10 years]

Reduce the Federal Match Rate for Medicaid Eligibility Workers

Medicaid regulations and related subregulatory guidance implementing Obamacare increased the federal match rate for Medicaid eligibility workers to 75 percent by linking these costs to state system operation. This proposal would phase down this match rate to 50 percent by FY 2024. This will return federal reimbursement to historical levels and incentivize states to administer their Medicaid programs in a more efficient and fiscally responsible way. [$7.4 billion in savings over 10 years]

Improve Transparency of Medicaid Supplemental Payments

CMS does not currently have comprehensive provider-level data on Medicaid supplemental payments and how they are financed by states. To improve the transparency and oversight of Medicaid supplemental payments, the Budget commits to issuing a regulation requiring more complete and timely provider-level data on supplemental payments, including the financing of such payments. This approach will provide CMS more data to assess whether state payments to Medicaid providers are economical, efficient, and fall within the Upper Payment Limit. [No budget impact]

Increasing Medicaid Flexibility for States and Reducing Burden

Make Medicaid Non-Emergency Medical Transportation Optional

Under current regulations, states must provide Non-Emergency Medical Transportation (NEMT) to all Medicaid beneficiaries. States have requested additional flexibility from this requirement due to challenges containing NEMT costs and addressing program integrity concerns. The Budget commits to using regulatory authority to change the provision of this benefit from mandatory to optional to provide greater flexibility to states. [No budget impact]

Medicaid

FY 2020 Medicaid Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Medicaid Legislative Proposals			
Increasing Medicaid Flexibility for States and Reducing Burden			
Allow States to Extend Coverage for Pregnant Women with Substance Use Disorders to One Year Postpartum	25	120	245
Increase the Limit on Medicaid Copayments for Non-Emergency Use of the Emergency Department	-60	-570	-1,550
Provide a Pathway to Make Permanent Established Medicaid Managed Care Waivers	-	-	-
Increase Flexibility in the Duration of Section 1915(b) Managed Care Waivers	-	-	-
Modify the Medicaid Fair Hearing Requirement to Eliminate Duplicative Appeals	-	-	-
Focusing Medicaid Eligibility on the Most Needy			
Strengthen Work Requirements to Promote Self-Sufficiency	-8,300	55,600	-130,400
Allow States to Apply Asset Tests to Modified Adjusted Gross Income Standard Populations	-50	-790	-2,110
Reduce the Maximum Allowable Home Equity for Medicaid Eligibility	-	-2,520	-6,650
Require Documentation of Satisfactory Immigration Status Before Receiving Medicaid Benefits	-190	-1,010	-2,310
Reducing Wasteful Spending in Medicaid			
Address Inappropriate Financing of Medicaid State Share by Public Providers	*	*	*
Prohibit Medicaid Payments to Public Providers in Excess of Costs	*	*	*
Clarify Medicaid Treatment of Third Party Payments for Disproportionate Share Hospital Allotments	-	-	-
Continue Medicaid Disproportionate Share Hospital (DSH) Allotment Reductions	-	-	-25,920
Rescind Remaining Balances from the Medicaid Improvement Fund	-	-6	-6
Reducing Wasteful Spending for Medicare-Medicaid Enrollees (Medicaid Impact)			
Allow CMS Flexibility to Determine the Frequency of Program of All-Inclusive Care for the Elderly Program Reviews	-	-	-
Allow for Federal/State Coordinated Review of Dual Eligible Special Needs Plan Marketing Materials	-	-	-
Improve Appeals Notifications for Dually Eligible Individuals in Integrated Health Plans	-	-	-
Clarify the Part D Special Enrollment Period for Dually Eligible Beneficiaries	-	-	-
Medicaid Interactions			
Drug Pricing Legislative Proposals (Medicaid Impact) /1	-151	-903	-2,087
Empower States and Consumers to Reform Health Care (Medicaid Impact) /2	1,280	-429,058	-1,385,515

FY 2020 Medicaid Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029
Reform Graduate Medical Education Payments (Medicaid Impact) /2	-1,600	-9,000	-21,300
Reform Medical Liability (Medicaid Impact) /2 /3	-46	-46	-46
Reduce Fraud, Waste, Abuse, and Improper Payments (Medicaid Impact) /4	-700	-5,306	-13,081
Reform and Expand Durable Medical Equipment Competitive Bidding (Medicaid Impact) /5	-	-145	-410
Extend Special Immigrant Visa Program (Medicaid Impact) /6	8	74	142
Extend Reduced Pension for Certain Veterans and Survivors covered by Medicaid plans (Medicaid Impact) /7	-	-	571
Subtotal Gross Outlays, Medicaid Legislative Proposals	**-9,785**	**-504,761**	**-1,590,427**
Net Effect of All Medicaid Interactions /8	**1,950**	**37,910**	**107,740**
Subtotal Net Outlays, Medicaid Legislative Proposals	**-7,835**	**-466,851**	**-1,482,687**
Medicaid Administrative Proposals			
Focusing Medicaid Eligibility on the Most Needy			
Test Interventions to Improve Maternal Mortality and Morbidity	-	-	-
Tighten Medicaid Child Support Enforcement Requirements	-	-	-
Allow States the Flexibility to Conduct More Frequent Eligibility Redeterminations	-1,300	-17,600	-45,600
Reducing Wasteful Spending in Medicaid			
Require Minimum Standards in Medicaid State Drug Utilization Review Programs	-20	-105	-245
Reduce the Federal Match Rate for Medicaid Eligibility Workers	-	-2,116	-7,406
Improve Transparency of Medicaid Supplemental Payments	-	-	-
Program Integrity Administrative Proposals (Medicaid Impact)	0	-63	-198
Increasing Flexibility for States and Reducing Burden			
Make Medicaid Non-Emergency Medical Transportation Optional	-	-	-
Subtotal, Medicaid Administrative Proposals /9	**-1,320**	**-19,884**	**-53,449**
TOTAL, Medicaid FY 2020 Budget Proposals	**-9,155**	**-486,735**	**-1,536,137**

* Budget impact unavailable as of the publication date of the FY 2020 President's Budget.
1/ See Lowering the Cost of Prescription Drugs chapter for descriptions of these proposals.
2/ See Empowering States and Consumers to Reform Health Care chapter for descriptions of these proposals.
3/ Savings reduced to account for the interaction with the "Empowering States and Consumers to Reform Health Care" proposal.
4/ See Program Integrity chapter for descriptions of these proposals.
5/ See Medicare chapter for description of this proposal.
6/ This proposal is included in the Department of State's FY 2020 Budget Request.

FY 2020 Medicaid Budget Proposals

	dollars in millions		
	2020	2020 -2024	2020 -2029

7/ This proposal is included in the Department of Veterans Affairs' FY 2020 Budget Request.
8/ The gross Medicaid savings from all proposals in this package would be reduced when enacted in conjunction with the Empower States and Consumers to Reform Health Care proposal. As such, due to this interaction, the net Medicaid savings proposed in the Budget is a subset of gross savings and is non-additive.
9/ These administrative actions are assumed to take effect in FY 2020 under current law.

Children's Health Insurance Program

	dollars in millions			2020 +/- 2019
	2018	2019	2020	
Current Law				
Children's Health Insurance Program (CHIP)	17,282	18,434	16,882	-1,552
Child Enrollment Contingency Fund	0	200	0	-200
Total Outlays, Current Law	**17,282**	**18,634**	**16,882**	**-1,752**
Proposed Law				
CHIP Legislative Proposals	0	0	0	0
Total Outlays, Proposed Law	**17,282**	**18,634**	**16,882**	**-1,752**

The Balanced Budget Act of 1997 established the Children's Health Insurance Program (CHIP), administered at the federal level by CMS, to provide coverage for children whose families have incomes too high to qualify for Medicaid but too low to afford private health insurance. Every state, the District of Columbia, and all five territories have approved CHIP state plans.

HOW CHIP WORKS

CHIP is a partnership between the federal government and states and territories to help provide low-income children under age 19 with health insurance coverage and access to health care. Congress appropriates a capped funding amount for CHIP annually, which CMS then allocates to states and territories with an approved CHIP plan based on a formula set in law. Since Fiscal Year (FY) 2009, the amount of funding Congress appropriated for CHIP has exceeded the amount CMS can award to states and territories under the statutory formula.

States, including the 50 states, District of Columbia, and territories, have flexibility in designing their programs. They can implement CHIP by expanding Medicaid, creating a separate program, or combining both approaches. As of December 2018, there were 14 Medicaid expansion programs, 2 separate programs, and 40 combination programs among the states, the District of Columbia, and the territories.

States use a Modified Adjusted Gross Income standard to determine eligibility for coverage under a state's CHIP program. The statute permits states to offer continuous eligibility for 12 months, regardless of changes in family income, and to enroll children who are eligible for family coverage under a state employee health plan into CHIP.

States with an approved CHIP plan are eligible to receive an enhanced federal matching rate, which ranges from 65 to 85 percent. From FY 2016 through FY 2019, each state's enhanced Federal matching rate increased by up to 23 percentage-points to cover between 88 and 100 percent of total costs for child health care services and program administration, drawn from a capped allotment.

CHIP has several financing mechanisms to address potential state funding shortfalls. The Child Enrollment Contingency Fund supports states that predict a funding shortfall due to higher than expected enrollment. HHS invests the Contingency Fund in interest-bearing securities of the United States. Since its establishment in FY 2009, only three states have qualified for a Contingency Fund payment, totaling $309 million. States are not required to spend Contingency Fund resources on CHIP activities.

In addition, HHS recoups unused state allotment funding to redistribute to states facing a funding shortfall if their current allotment is insufficient to meet program demand. Since 2012, CMS has redistributed $1.7 billion to 30 states and territories. However, existing shortfall funding is limited and may not be sufficient to address future needs.
The Children's Health Insurance Program Reauthorization Act of 2009 established a CHIP Performance Bonus Fund for FYs 2009 through 2013 to provide payments to states that met five out of eight specific enrollment and retention activities. CMS's authority to make payments from the Performance

Bonus Fund expired after FY 2013, leaving some funds unused.

In FY 2018, the CMS Office of the Actuary estimated that 9.8 million individuals received health insurance funded through CHIP allotments at some point during the year. CHIP enrollment throughout the year averaged approximately 7.0 million individuals.

RECENT PROGRAM DEVELOPMENTS

In 2018, Congress passed and the President signed the HEALTHY KIDS Act (P.L. 115-120) and the Bipartisan Budget Act of 2018 (P.L. 115-123), which both extended CHIP funding, and authorized the Child Enrollment Contingency Fund for 10 years through FY 2027. This 10-year extension is the longest period of CHIP funding and stability since its creation in 1997, which enables continued coverage of over 9 million children currently enrolled in CHIP.

The HEALTHY KIDS Act and Bipartisan Budget Act of 2018 also extended CHIP Express Lane Eligibility, the qualifying state option, and the expansion allotment adjustment. The Express Lane Eligibility option permits states to enroll children in Medicaid or CHIP based on findings, such as income, household size, or other eligibility factors, from other federal programs. Under the qualifying state option, certain states that significantly expanded Medicaid eligibility for children prior to the enactment of CHIP in 1997 may use CHIP allotment funding to finance the cost of children covered under Medicaid with incomes above 133 percent of the Federal Poverty Level. Qualifying states may elect to use their CHIP allotment funding to fund the difference between the CHIP Enhanced Federal matching rate and the Medicaid matching rate. The expansion allotment adjustment permits states with planned CHIP benefit or eligibility expansions to children to request increases to their allotments in even fiscal years.

Financing

The 23-percentage point increase in the CHIP enhanced federal matching rate phases down to 11.5 percentage points in FY 2020. CHIP returns to the traditional enhanced federal matching rate for FYs 2021 to 2027.

Payments from the Contingency Fund are currently authorized through FY 2027 for states that face a funding shortfall based on greater than expected enrollment.

Eligibility and Coverage

States must maintain the same eligibility levels for all children covered under Medicaid and CHIP that were in place as of March 30, 2010, through September 30, 2019. For FYs 2020-2027, this requirement only applies to children in families with incomes up to 300 percent of the Federal Poverty Level.

Outreach and Enrollment

The Outreach and Enrollment Program provides grants and funds a national outreach and enrollment campaign to children who are eligible for, but not enrolled in, Medicaid and CHIP. Funding for the Outreach and Enrollment Program totals $168 million for FYs 2018 through 2027.

Improving Quality

CHIP funds activities to improve child health quality in Medicaid and CHIP and to strengthen the quality of, and access to, children's health care. States use a variety of health care delivery and measurement approaches for both providers and patients. Funding for child health quality activities totals $150 million for FYs 2018 to 2027. Beginning in FY 2024, states will be required to report on pediatric quality measures in the Child Core Set, which are currently optional.

2020 LEGISLATIVE PROPOSALS

Strengthen the CHIP Safety Net for States

The Budget proposes to bolster the safety net available to states experiencing funding shortfalls, while eliminating funding streams that do not support children's health. Beginning in FY 2021, the Budget would allow CMS to transfer unused annual appropriations to a Shortfall Fund that would be available for redistribution to states facing funding shortfalls. This would permit CMS to streamline funding mechanisms for states, make it easier for states to access needed funding when facing CHIP funding shortfalls, and ensure that shortfall funding is available to states and territories that need it for years to come. In addition, this proposal repeals the CHIP Performance Bonus Fund because CMS has not had the authority to make Performance Bonus payments since FY 2013. This proposal also repeals the Child Enrollment Contingency Fund because few states can

meet the restrictive eligibility criteria to qualify for a Contingency Fund payment when facing a funding shortfall. [No budget impact]

Children's Health Insurance Program

FY 2020 CHIP Proposals

	dollars in millions		
	2020	2020-2024	2020-2029
CHIP Proposals			
Strengthen the CHIP Safety Net	--	--	--
Total Outlays, CHIP Proposals	--	--	--

State Grants and Demonstrations

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Current Law Budget Authority				
Medicaid Integrity Program/1	80	82	90	+8
Money Follows the Person Evaluations/2	--	112	--	-112
Money Follows the Person Evaluations/2	--	1	--	-1
Demonstration Project to Increase Substance Use Provider Capacity under the Medicaid Program	--	55	--	-55
Children's Health Insurance Program (CHIP) Outreach and Enrollment Grants	120	--	--	--
Total Current Law Budget Authority	**200**	**250**	**90**	**-160**
Current Law Outlays/3				
Medicaid Integrity Program/1	82	81	86	+5
Money Follows the Person Demonstration/2	381	360	470	+110
Money Follows the Person Evaluations	--	1	1	--
Demonstration Project to Increase Substance Use Provider Capacity under the Medicaid Program	--	16	24	+8
Demonstration Programs to Improve Community Mental Health Services	1	3	3	--
Children's Health Insurance Program (CHIP) Outreach and Enrollment Grants/4	17	14	25	+11
Incentives for Prevention of Chronic Diseases in Medicaid/5	--	--	1	+1
Total Current Law Outlays	**481**	**475**	**610**	**136**

1/ Budget authority is adjusted annually by Consumer Price Index for All Urban Consumers. Outlays include some spending from prior year budget authority. Also described in the Program Integrity chapter.
2/ The Medicaid Extenders Act of 2019 (P.L. 116-3) amends the Deficit Reduction Act to provide $112 million in FY 2019 for states with approved Money Follows the Person demonstrations to continue providing home and community-based long-term care services to individuals transitioning from institutions to community-based settings until FY 2021.
3/ The following programs/laws were excluded from the Current Law Outlays table because outlays were less than $1 million: Ticket to Work and Work Incentives Improvement Act, Federal Reimbursement of Emergency Health Services Furnished to Undocumented Aliens, and the Medicaid Emergency Psychiatric Demonstration.
4/ See the CHIP chapter for additional information about this program.
5/ Outlays are from prior year budget authority.

CMS State Grants and Demonstrations funds diverse activities including: strengthening Medicaid program integrity, increasing the treatment capacity of providers participating under a State plan or waiver to provide substance use disorder treatment or recovery services, funding outreach activities to enroll children into Medicaid and the Children's Health Insurance Program (CHIP), and providing grants to states to prevent chronic diseases.

MEDICAID INTEGRITY PROGRAM

The Medicaid Integrity Program was established by the Deficit Reduction Act of 2005, which appropriated $75 million annually. Congress later increased appropriations for inflation beginning in Fiscal Year (FY) 2011. While states have the primary responsibility for combating Medicaid fraud, waste, and abuse, the Medicaid Integrity Program plays an important role supporting state efforts by providing technical support to states and contracting with eligible entities to carry out activities such as agency reviews, audits, identification of overpayments, and education

activities. The Medicaid Integrity Program works in coordination with Medicaid program integrity activities funded by the Health Care Fraud and Abuse Control program.

Please refer to the Program Integrity chapter for additional information.

DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE DISORDER PROVIDER CAPACITY UNDER THE MEDICAID PROGRAM

The President recently signed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), which includes Medicaid provisions to address the opioids crisis.

The SUPPORT Act includes a $55 million Medicaid demonstration project over 4.5 years. CMS will oversee efforts to increase substance use provider capacity, by providing an enhanced Medicaid match rate for select states. CMS may select at least 10 states to receive planning grants to assess their behavioral treatment and provider needs to improve provider networks treating substance use disorders. CMS may choose up to five (provided they meet specified criteria) of the 10 states to award planning grants to receive the enhanced federal match rate and implement the activities under this demonstration:

- Supporting ongoing analysis of state behavioral health treatment needs;
- Supporting recruitment training and providing technical assistance for providers offering substance use disorder treatment or recovery services;
- Improving reimbursement for and expanding the amount or treatment capacity of participating providers authorized to dispense Food and Drug Administration-approved drugs; and
- Improving reimbursement for and expanding the amount or treatment capacity of providers to address the treatment needs for certain populations enrolled under the State plan or waiver.

CHIP OUTREACH AND ENROLLMENT GRANTS

Through grants and a national campaign, the Outreach and Enrollment Program improves outreach to, and enrollment of, children who are eligible for, but unenrolled in, Medicaid and CHIP, including American Indian or Alaska Native children. Funding supports family education about the availability affordable health coverage under Medicaid and CHIP, identifying children likely to be eligible for these programs, and assisting families with the application and renewal process. A total of $168 million is available for outreach and enrollment grants through FY 2027. The Bipartisan Budget Act of 2018 requires that 10 percent of the funding from FYs 2024 to 2027 is set aside for evaluations and technical assistance.

Please refer to the CHIP chapter for additional information.

MONEY FOLLOWS THE PERSON DEMONSTRATION

This demonstration, recently extended through FY 2021 by the Medicaid Extenders Act of 2019, helps states support individuals to achieve independence. States are continuing to operate this demonstration with available funding, and have demonstrated positive outcomes. States that are awarded competitive grants receive an enhanced Medicaid matching rate to help eligible individuals transition from a qualified institutional setting to a qualified home or community-based setting. The Medicaid Extenders Act of 2019 (P.L. 116-3) also provides $112 million in FY 2019 to states with approved Money Follows the Person demonstration projects to continue providing home and community-based long-term care services to individuals transitioning from institutions to community-based settings.

Center for Medicare and Medicaid Innovation

	dollars in millions			2020 +/-
	2018	2019	2020	2019
Innovation Center Obligations /1	$931.2	$1,021.7	$1,400.0	+378.3
1/ FY 2018 numbers are actuals. FY 2019 and 2020 are estimates.				

The Center for Medicare and Medicaid Innovation (Innovation Center) tests innovative payment and service delivery models with the potential to preserve or enhance the quality of care and reduce Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) spending. The Innovation Center operates under this statutory mandate in support of CMS's goal of fostering an affordable, accessible health care system that puts patients first. Under current law, in Fiscal Year (FY) 2020, the Innovation Center will receive its second $10 billion, ten-year appropriation.

INNOVATION CENTER MISSION AND VISION

To increase the transparency, responsiveness, and effectiveness of the Innovation Center's work, CMS issued a Request for Information (RFI) in 2017. The RFI specifically asked for feedback on a new direction for the Innovation Center, to promote patient-centered care; test market-driven reforms to empower beneficiaries as consumers; improve price transparency; and increase choices and competition to drive quality, reduce costs, and improve outcomes.

CMS received over 1,000 responses to the RFI from a wide variety of individuals and organizations, health systems, physician groups, consumers, and private businesses. The responses provided valuable insight about possibilities for improving existing Innovation Center models, as well as ideas for transformative new models that empower beneficiaries with more choices and better health outcomes.

Based on these responses and other input from stakeholders, the Innovation Center reexamined its portfolio and began developing new models that put patients first, reduce unnecessary burden, increase efficiencies, and improve the patient experience.

VALUE-BASED TRANSFORMATION

Paying for value (outcomes and health vs. procedures and sickness) is a central premise of the Innovation Center's work. The Innovation Center is developing and testing models that complement HHS's "four Ps" of driving toward value: Patients as Consumers, Providers as Accountable Patient Navigators, Paying for Outcomes, and Prevention of Disease Before It Occurs.

Patients as Consumers

Getting better value from our health system and paying for value requires empowering patients to be engaged and informed consumers. To achieve this, the Innovation Center is interested in integrating interoperability and promotion of patients' timely and secure access to their health information into its models and will pursue opportunities to do so. CMS is considering models with elements that allow patients to make the right choices for themselves and their health by improving their access to information about pricing and alternative therapies.

Providers as Accountable Patient Navigators

In the shift toward value, empowered patients will still need physicians to help them navigate the health care system, and HHS needs to give those physicians the right incentives to guide patients in making choices that will lead to good outcomes. In developing models, the Innovation Center is pursuing opportunities for larger, more sophisticated physician practices that are ready to take significant risk for total patient outcomes to do so. At the same time, the Innovation Center is seeking to provide flexibility for smaller practices to ensure they are able to participate, while helping them move toward value-based payments. CMS is also considering models that empower providers in high-cost specialty areas that are in need of patient-centered reforms.

Paying for Outcomes

The U.S. health care payment system is overly complex and often does not create sufficient incentives for higher-quality, lower-cost care. The Innovation Center closely monitors and evaluates its models to ensure that the incentives are driving better outcomes and not

just more volume. An Alternative Payment Model (APM) is a payment approach that creates added incentives to provide high-quality and cost-efficient care. APMs can apply to a specific clinical condition, a care episode, or a population. Payment for value, as measured through outcomes, is the central premise of every model the Innovation Center tests.

Prevention of Disease Before it Occurs

The best way to improve health and lower costs is to prevent disease before it occurs. The Innovation Center supports this goal by developing models that help to break down the silos between medical care, nutrition, transportation, housing, and other social supports in an effort to consider an individual's health holistically and prevent disease. For example, the Accountable Health Communities Model addresses a critical gap between clinical care and community services in the current health care delivery system by testing whether systematically identifying and addressing the health-related social needs of Medicare and Medicaid beneficiaries reduces health care costs and utilization.

INNOVATION CENTER MODELS

To date, the Innovation Center has launched 38 models, including Accountable Care Organization (ACO) models; episode-based payment initiatives; primary care transformation; initiatives focused on the Medicaid, CHIP, and dually eligible populations; initiatives to accelerate the development and testing of new payment and service delivery models; and initiatives to speed the adoption of best practices. The Innovation Center also implements demonstrations established through statute.

Model Evaluations and Results to Date

The Innovation Center uses independent evaluators to routinely and rigorously assess the impact of each model on quality and expenditures. The evaluations include advanced statistical methods and carefully selected comparison groups to ensure that models deemed to be successful represent true opportunities for high-value investments of taxpayer dollars.
The Innovation Center recently reviewed and synthesized evaluation results across multiple models to identify best practices for future model design in three key areas: primary care, episode-based payments, and state-based models. Findings from these models revealed that: (1) the Innovation Center's primary care initiatives improved practices' efforts to become Patient-Centered Medical Homes or advanced primary care practices; (2) episode payment models led to reductions in utilization and gross Medicare expenditures for many episode types, with limited impact on quality or functional status outcomes; and (3) state-based model tests leveraged CMS investments in infrastructure and technical assistance, which then encouraged health care providers to gain experiences and resources needed to enable them to take on higher risk.

Expanded Models

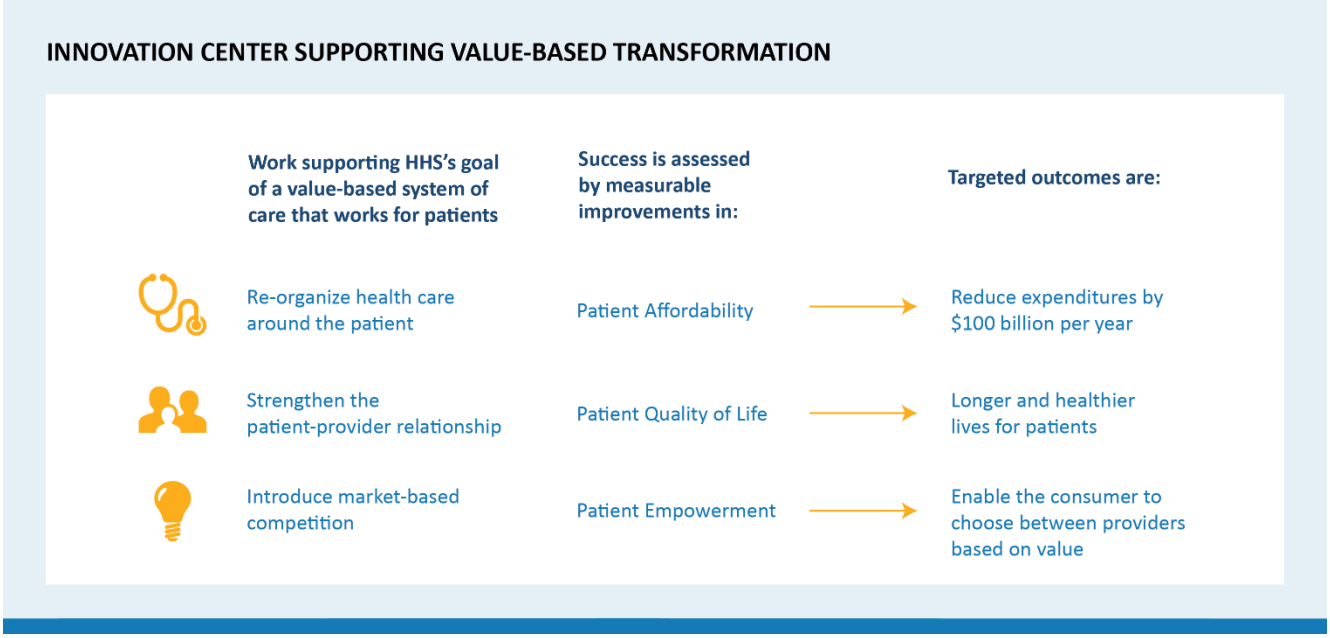
The statute provides the Secretary authority to expand the duration and scope of a model being tested through rulemaking, including nationwide implementation. To exercise this authority, the Secretary, working with the Chief Actuary at CMS, must determine that expansion would either reduce spending without reducing quality of care or improve quality of care without increasing spending. To date, the Pioneer ACO Model, which supported experienced providers to coordinate care for patients across care settings, and the Medicare Diabetes Prevention Program, which helped prevent the onset of type 2 diabetes among pre-diabetic Medicare beneficiaries, were certified for expansion using this authority. Congress may also choose to codify successful models.

NEW INITIATIVES

Since January 2018, the Innovation Center has launched a number of bold, new models designed to provide better care at a lower cost and aligned with the "four Ps" of value-based transformation.

Emergency Triage, Treat, and Transport (ET3) Model

The ET3 model removes existing barriers to beneficiaries receiving the right care, in the right place, at the right time, in order to reduce expenditures and enhance quality of care. It tests new Medicare payments and care delivery options for ambulance suppliers and providers who partner with qualified



health care practitioners to deliver treatment in place or with alternative destination sites, such as urgent care or behavioral health clinics. The model will begin January 1, 2020 and run for five years.

Medicare Advantage Value Based Insurance Design (MA VBID) Model

The existing MA VBID model tests the impact of allowing MA organizations to develop plan benefit designs that are targeted to specific groups of enrollees based on chronic conditions. The Bipartisan Budget Act of 2018 updated the MA VBID model to allow plans in all 50 states and territories to apply beginning in 2020, and extended participation to more Medicare Advantage plan types, including all Special Needs Plans. In January 2019, the Innovation Center announced the addition of new flexibilities for health plans to the MA VBID model, including targeted supplemental benefits based on beneficiaries' socioeconomic status, health conditions, or both; expanding the scope of rewards and incentives programs; greater use of telehealth; requirements for wellness and health care planning (advanced care planning); and an integrated hospice benefit. These new additions will be available beginning in plan year 2020, and in 2021 for the integrated hospice benefit. The model will run for another five years, through 2024.

Part D Payment Modernization Model

To address the high costs of prescription drugs, CMS will test the impact of modernized program design and incentives in Part D. This model tests whether increased plan sponsor liability for Part D catastrophic spending, coupled with greater programmatic flexibilities and formulary management tools, including a Part D rewards and incentives program, will reduce expenditures and improve quality of care for Medicare beneficiaries. CMS is currently accepting applications from Part D sponsors to participate in this model, which is scheduled to begin in plan year 2020. Participants with drug costs below the spending target benchmark will be eligible for performance based payments, while participants with drug costs exceeding the benchmark will be penalized.

Integrated Care for Kids Model (InCK)

By integrating behavioral and physical health care, the InCK model aims to support states and local providers as they address the needs of pediatric Medicaid and CHIP beneficiaries with significant health needs. The InCK model tests whether the combination of a local service delivery model that coordinates integrated behavioral, physical, and complementary child health services, and a state-specific payment model that supports the coordination of those integrated services, reduces health care expenditures and improves the quality of care for this population. The model aims to prevent opioid misuse and improve outcomes for children affected by family opioid misuse and will run between January 1, 2020 and December 31, 2026.

Maternal Opioid Misuse (MOM) Model

The MOM model aims to improve quality of care for pregnant and postpartum Medicaid beneficiaries with opioid use disorder through state delivery system innovations. It tests sustainable coverage and payment

strategies supporting the coordination of clinical care and the integration of services essential for health, wellbeing, and recovery; expands access, service-delivery capacity, and infrastructure based on state-specific needs; and improves quality of care and reduces costs for mothers and infants. This model will run from January 1, 2020 through December 31, 2024.

Bundled Payments for Care Improvement (BPCI)-Advanced Model

BPCI Advanced aims to align incentives for participating health care providers to reduce expenditures and improve quality of care for Medicare beneficiaries. It is an episode payment model that builds on the original BPCI models to test bundled payments for 32 clinical episodes that would typically include care furnished in acute and post-acute settings. These episodes were selected based on opportunities for cost savings and quality improvement, sufficient volume for evaluation, and a goal to include a variety of clinical services, specialties, and beneficiary types. The model qualifies as an Advanced APM under the Quality Payment Program. The model runs from October 1, 2018 through December 31, 2023.

INNOVATION CENTER DEMONSTRATIONS DISCUSSED IN OTHER CHAPTERS

The Budget also proposes new models to test innovations in program integrity, incentives for adopting high-value technology and devices, and strategies to reduce maternal mortality. Please see the Medicare, Medicaid, and Program Integrity chapters for proposal descriptions.

Program Management

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Discretionary Administration				
Program Operations	2,815	2,824	2,390	-435
Federal Administration	733	733	748	+15
Survey and Certification	397	397	442	+45
Research /3	20	20	--	-20
Subtotal, Discretionary Budget Authority	**3,965**	**3,975**	**3,579**	**-395**
Mandatory Administration /1				
Medicare Improvements for Patients and Providers Act	3	3	3	--
Protecting Access to Medicare Act (2014)	6	9	10	--
Improving Medicare Post-Acute Care Transformation (2014)	17	17	6	-11
Medicare Access and CHIP Reauthorization Act	152	108	20	-88
21st Century Cures Act	11	--	--	--
SUPPORT Act	--	3	--	-3
Bipartisan Budget Act	13	12	--	-12
Subtotal, Mandatory Administration	**202**	**152**	**39**	**-113**
Reimbursable Administration				
Medicare and Medicaid Reimbursable Administration /2	372	551	594	+43
Exchange-Related Reimbursable Administration /1	1,700	1,853	1,842	-11
Risk Corridor Collections	22	--	--	--
Subtotal, Reimbursable Administration	**2,094**	**2,404**	**2,436**	**+32**
Total Program Management Program Level, Current Law	**6,260**	**6,531**	**6,055**	**-476**
Proposed Law				
Survey and Certification Revisit and Complaint Investigation Fee /4	--	--	--	--
Rebase National Medicare & You Education Program User Fee /4	--	--	--	--
Program Management Implementation Funds (mandatory)	--	--	200	+200
Subtotal, Proposed Law	**--**	**--**	**200**	**+200**
Total Program Management Program Level, Proposed Law	**6,260**	**6,531**	**6,255**	**-276**

1/ Includes user fees charged to issuers in Federally-facilitated Exchanges, State-based Exchanges on the Federal platform, and Risk Adjustment.
2/ Includes the following user fees: Clinical Laboratory Improvement Amendments of 1988, sale of research data, coordination of benefits for the Medicare prescription drug program, MA/prescription drug program, recovery audit contractors, and provider enrollment fees.
3/ Research funding is being requested as part of the Program Operations funding in FY 2020.
4/ Collections from the proposed user fee would begin in FY 2021.

The Fiscal Year (FY) 2020 discretionary Budget requests $3.6 billion for CMS Program Management which will enable CMS to continue to effectively administer Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The FY 2020 Budget reflects CMS's priorities to: empower States and provide them with greater flexibility; modernize programs to address the changing needs of the people CMS serves; leverage innovation and technology to drive better care for Americans, and strengthen the integrity and sustainability of Medicare and Medicaid by investing in activities to prevent fraud, waste, and abuse.

PROGRAM OPERATIONS

The Budget requests $2.4 billion for Program Operations and funds essential payment, information technology, and outreach activities for Medicare, Medicaid, CHIP, and private insurance programs. Priority activities for FY 2020 include:

Medicare Contractor Operations

Approximately 36 percent, or $866 million, of the FY 2020 Program Operations request supports ongoing Medicare contractor operations. This includes processing 1.3 billion Medicare Part A and B claims, enrolling providers in the Medicare program, reimbursing providers, processing 2.3 million first-level appeals, responding to provider inquiries, educating providers about the program, and administering the participating physicians/supplier program.

Medicare Appeals

The Budget includes $86 million to timely process approximately 264,000 second level appeals. CMS actively supports the Department's effort to improve the Medicare appeals process and address the pending backlog of appeals at the Administrative Law Judge and Departmental Appeals Board levels. The Budget funds initiatives to decrease the number of new appeals entering the system and address pending appeals in the backlog.

Information Technology Systems and Support

The Budget includes $440 million for information technology systems, including cybersecurity, allowing the agency to protect the valuable consumer health data of millions of Americans from outside threats. The Budget will continue an initiative, started in FY 2018, that enables seniors to access and navigate the Medicare program more seamlessly, provides new personalized tools to improve the customer experience, and helps beneficiaries make health care decisions that are best for them.

Medicaid and CHIP Operations

The Budget requests $103 million for administrative activities to improve Medicaid and CHIP program operations. This includes the modernization of data systems and continued development of a scorecard for state Medicaid and CHIP programs to track the extent to which states achieve tangible results that improve the lives of beneficiaries.

Exchanges

The Budget expands the use of Exchange user fees to cover all Federal administrative expenses associated with operating the Exchanges. The program level for Exchanges totals $1.3 billion, all of which will be funded by Exchange user fees with the exception of $6 million from the Health Care Fraud and Abuse Control appropriation. Expanding the use of user fees for Federal administrative expenses will make the Exchanges more financially self-sustaining.

THE MEDICAID AND CHIP (MAC) SCORECARD

The MAC Scorecard is a searchable, web based reporting platform displaying data on:

- *Medicaid health outcomes*
- *Quality of care*
- *Access to care*
- *Federal and state administrative performance and efficiency*

This initiative reflects the Administration's commitment to transparency and accountability in welfare programs. CMS successfully completed MAC Scorecard 1.0 in June 2018 and will add additional quality and program integrity measures in subsequent versions with the goal of releasing an annual MAC Scorecard every fall that aligns with the annual Child and Adult Core Set measures publishing cycle.

Medicare Quality Improvement and Value-Based Transformation

The Budget includes $175 million to support Medicare quality improvement and value-based activities previously funded by the Quality Improvement Organization mandatory appropriation to support increasing patient safety, making communities healthier, better coordinating post-hospital care, and improving clinical quality. This is the second-year of a five-year transition of quality improvement and value-based transformation support activities from the mandatory Quality Improvement appropriation to CMS Program Management.

FEDERAL ADMINISTRATION

The FY 2020 Budget requests $748 million for CMS Federal administrative costs. At this level CMS will have staff to support core Medicare, Medicaid, and CHIP operations. The request includes $15 million for personnel costs, previously funded by the Quality Improvement Organization mandatory appropriation, to support Medicare quality improvement and value-based transformation initiatives. This is the second-year of a five-year transition of personnel costs from the mandatory Quality Improvement Organization Improvement appropriation to CMS Program Management.

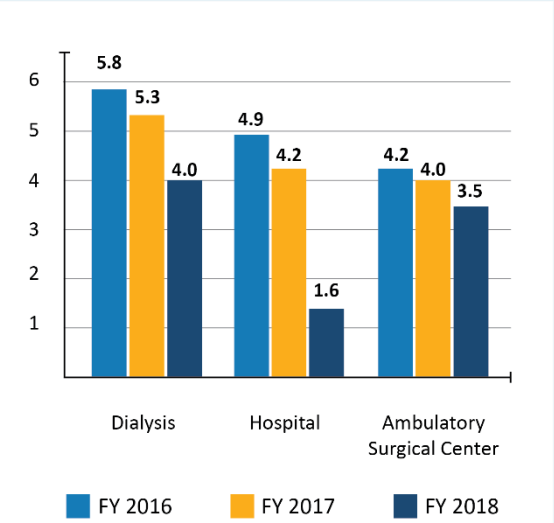
SURVEY AND CERTIFICATION

The FY 2020 Budget requests $442 million for Survey and Certification, a $45 million increase. The increased funding will enable CMS to maintain non-statutory survey frequency levels. The volume and cost of surveys have increased due to the growing number of participating facilities, higher levels of complaints, and increasing costs to conduct surveys.

Approximately 90 percent of the request will go directly to State survey agencies to perform health and safety oversight of Medicare certified providers. CMS expects states to complete over 21,000 initial surveys and re-certifications and over 60,000 visits in response to complaints in FY 2020. Surveys include mandated Federal inspections of long-term care facilities (i.e., nursing homes), home health agencies, hospices, and federal inspections of other key facilities. All facilities participating in the Medicare and Medicaid programs must undergo inspection when entering the program and on a regular basis thereafter.

The Budget proposes to levy a fee on Medicare-certified health care facilities to cover a portion of the costs of substantiated complaint surveys as well as revisit surveys that occur as a result of deficiencies found during an initial certification, recertification, or substantiated complaint visit. The fees would be set through rulemaking. This authority would enable CMS to more regularly revisit poor performing facilities, while creating an incentive for facilities to correct deficiencies and ensure quality of care. Indian Health Service facilities would be exempt from these fees. The Budget assumes collections beginning in FY 2021.

NATIONAL AVERAGE NUMBER OF DEFICIENCIES PER SURVEY



The Budget requests two-year budget authority for the Survey and Certification program. This approach increases administrative flexibility, enhances oversight and quality of care, and ensures that funds are available early enough in the state fiscal year to enable more effective planning, staffing, and funding of survey agencies to accomplish federally mandated survey workloads. This approach is particularly important since many states operate on fiscal years that are different from the Federal fiscal year. This proposal will further facilitate CMS's existing ability to reallocate funding between states when appropriate.

NATIONAL MEDICARE EDUCATION PROGRAM

The budget funds the National Medicare Education Program at $385 million, including $265 million in budget authority. CMS is committed to ensuring that beneficiaries have access to the educational materials and tools they need to find accurate and up-to-date information on their coverage options and covered benefits. The Budget requests $273 million, including $184 million in budget authority, to support the 1-800-MEDICARE call center, which provides beneficiaries with access to customer service representatives trained to answer questions about the Medicare program. The request will support an estimated 23 million calls with an average-speed-to-answer of approximately 5 minutes. Beneficiaries can also use 1-800-MEDICARE to report instances of possible fraud or abuse.

The Budget includes $61 million, including $31 million in budget authority, for beneficiary materials, the majority going to the printing and distribution of the *Medicare & You* Handbook.

2020 LEGISLATIVE PROPOSALS

Rebase National Medicare Education Program User Fee

Despite growing enrollment in Medicare Advantage and Part D plans, the amount of user fees these plans pay to support beneficiary outreach and enrollment assistance through the National Medicare Education Program has not kept pace due to an outdated statutory cap. This proposal allows CMS to assess an increased amount of user fees, starting in FY 2021, from Medicare Advantage and Part D plans to more equitably support outreach and enrollment assistance activities. [$1.1 billion in additional user fees over 10 years]

Modernize Medicare Beneficiary Education Requirements

CMS is required to mail Medicare education materials to beneficiaries on an annual basis. This proposal provides the Secretary with increased flexibility to determine how to most efficiently and effectively communicate Medicare benefits information included in the *Medicare & You* Handbook with beneficiaries, including through electronic means instead of paper copies, in some cases. Offering digital alternatives will improve the efficiency of CMS Beneficiary Education activities. [No mandatory budget impact]

Tailor the Frequency of Skilled Nursing Facility Surveys to More Efficiently Use Resources and Alleviate Burden for Top Performing Nursing Homes

State Survey Agencies are required to survey all skilled nursing facilities every 12 months, with no greater than 15 months between surveys, regardless of a facility's Five Star Quality Rating. Effective FY 2020, this proposal gives the Secretary authority to adjust statutorily required survey frequencies for top-performing skilled nursing facilities and reinvest resources to strengthen oversight and quality improvement for poor performing facilities. This approach allows the frequency of nursing home surveys to be based on risk to health and safety, which reduces burden on high-performing facilities. [No budget impact]

NATIONAL MEDICARE EDUCATION PROGRAM FY 2020 PROGRAM LEVEL (DOLLARS IN MILLIONS)

Activity	2019	2020
Beneficiary Materials (e.g., Handbook)	70.8	61.1
1-800-MEDICARE and Beneficiary Claims Contact Center	243.5	273.1
Internet	36.6	27.8
Community-Based Outreach	3.0	3.0
Program Support Services/National Ad Campaign	25.9	19.6
Total NMEP Program Level	**379.9**	**384.6**

Includes funding from Program Management, user fees, and Quality Improvement Organizations.

Provide Mandatory Resources for Implementation

The Budget includes a comprehensive package of CMS legislative proposals to carry out Administration reforms to the Medicare, Medicaid, and CHIP program. This proposal provides $200 million in mandatory Program Management funding to implement these legislative proposals.

Administration for Children And Families: Overview

	dollars in millions			
	2018 /1	2019	2020	2020 +/- 2019
Mandatory				
Budget Authority /2	34,982	35,089	33,794	-1,295
Discretionary				
Budget Authority /3	22,997	23,210	18,327	-4,883
Total ACF Budget Authority	**57,979**	**58,299**	**52,121**	**-6,178**

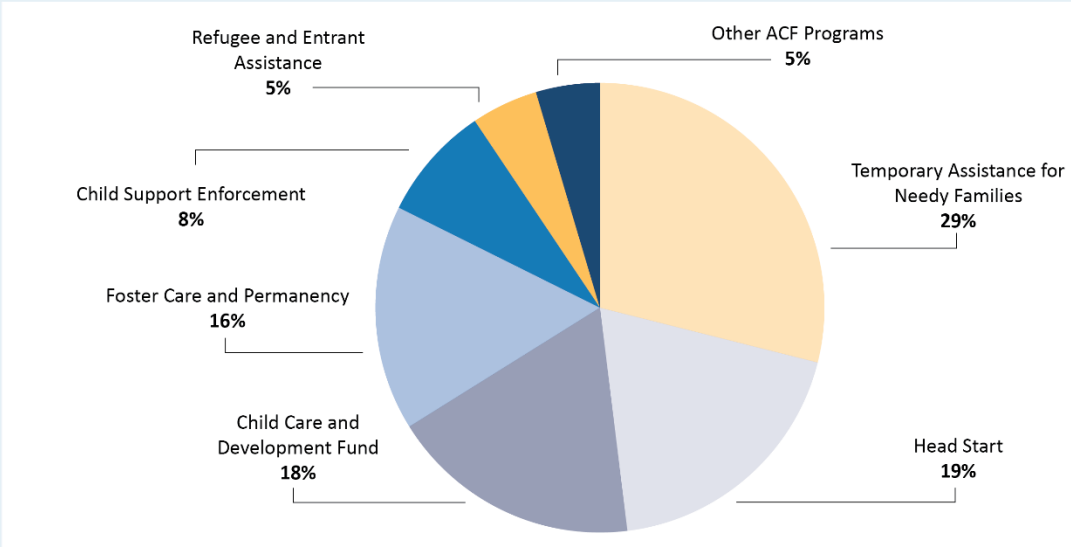
1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.
2/ Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.
3/ FY 2018 does not include $650 million for Head Start hurricane related funding provided by the Bipartisan Budget Act of 2018. Within the Refugee and Entrant Assistance Appropriation, FY 2018 does not include an offset of -$10 million from offsetting collections from federal sources.

The Administration for Children and Families fosters health and well-being by providing federal leadership, partnership and resources for the compassionate and effective delivery of human services.

The Fiscal Year (FY) 2020 Budget requests $52.1 billion for the Administration for Children and Families (ACF). ACF works in partnership with states, tribes, and communities to provide critical assistance to families and children, helping them achieve a path to success.

The Budget supports working families and promotes upward economic mobility through programs such as Head Start, Child Care, Child Support Enforcement, and Temporary Assistance for Needy Families. These programs promote personal responsibility, economic independence, productivity, and well-being by helping parents enter the workforce, care for their children, and form strong social networks and family bonds. ACF's child welfare programs promote safety, well-being, and permanency through foster care, reunification, adoption, and efforts to prevent child maltreatment.

ACF FY 2020 BUDGET AUTHORITY, PROPOSED



Administration for Children and Families: Discretionary

	dollars in millions			2020 +/- 2019
	2018/1	2019	2020	
Early Childhood Programs				
Head Start	9,839	10.063	10.063	--
Child Care Block Grant (discretionary)	5,213	5,276	5,276	--
Subtotal, Early Childhood Programs	**15,299**	**15,339**	**15,339**	**--**
Programs for Vulnerable Populations				
Runaway and Homeless Youth	126	127	119	-8
Child Abuse Programs	158	158	158	--
Child Welfare Programs	326	326	326	--
Promoting Safe and Stable Families (discretionary)	100	100	60	-40
Adoption Incentives	75	75	38	-37
Chafee Education & Training Vouchers	43	43	43	--
Native Americans	54	55	52	-3
Family Violence Prevention and Services Programs	168	175	175	--
Subtotal, Programs for Vulnerable Populations	**1,049**	**1,059**	**971**	**-88**
Refugee Programs				
Unaccompanied Alien Children	1,570	1,303	1,303	--
Transitional and Medical Services	245	354	319	-35
Refugee Supportive Services	202	207	151	-56
Survivors of Torture	11	14	14	--
Victims of Trafficking (Foreign and Domestic)	24	27	17	-10
Subtotal, Refugee Programs	**2,051**	**1,905**	**1,804**	**-101**
Discontinued Programs				
Low Income Home Energy Assistance	3,640	3,690	--	-3,690
Community Services Block Grant	715	725	--	-725
Preschool Development Grants	248	250	--	-250
Other Community Services Programs	28	29	--	-29
Subtotal, Discontinued Programs	**4,383**	**4,694**	**--**	**-4,694**
Other ACF Programs				
Social Services Research & Demonstration	7	7	7	--
Disaster Human Services Case Management	2	2	2	--
Federal Administration	205	205	205	--
Subtotal, Other Programs	**213**	**213**	**213**	**--**
Total Discretionary Budget Authority	**22,997**	**23,210**	**18,327**	**-4,883**
Full-Time Equivalents	1,261	1,469	1,443	-26

1/ Reflects FY 2018 Enacted, post required and permissive transfers and rescissions.

The Administration for Children and Families (ACF) provides services primarily through states, tribes, and local governments, as well as private, non-profit, faith-based, and community-based organizations. ACF human and social services programs promote the economic and social well-being of children, families, individuals and communities. Recipients have wide latitude to decide how to provide services and who receives them based on their unique local needs. The Fiscal Year (FY) 2020 Budget requests $18.3 billion.

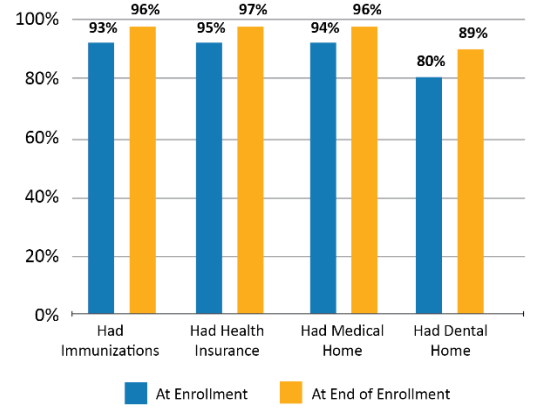
WORK SUPPORTS FOR FAMILIES

The Administration continues to prioritize programs that promote upward economic mobility for parents and enhance their children's early care and education. These programs support low-income Americans, including vulnerable children and their parents, with the goal of personal responsibility and self-sufficiency.

Head Start

Head Start promotes school readiness for infants and children up to five years of age from low-income families by enhancing cognitive, social and emotional development. Head Start programs offer a variety of service models to meet the needs of the local community. The Budget invests $10.1 billion, including $805 million for Early Head Start-Child Care Partnerships. With this investment, Head Start will serve an estimated 871,000 children.

HEAD START – CHILDREN'S HEALTH MEASURES



Head Start programs also work with families to help ensure children have access to needed services and resources. The number of children who received immunizations increased over the 2016-2017 program year. More families also had health insurance and medical and dental homes for their children at the end of the 2016-2017 program year than at the beginning.

Child Care and Development Block Grant

The Budget provides $5.3 billion for the Child Care and Development Block Grant, and $4.2 billion in mandatory child care funding for a total investment of $9.5 billion. This program provides low-income working families financial assistance for childcare and supports efforts to improve the quality of early care and education. The Budget proposes new incentives for states to recover improper child care payments and eliminates the duplicative requirement for a national child care hotline because every state now maintains a child care hotline.

SERVING VULNERABLE CHILDREN AND FAMILIES

The Budget supports services specifically assisting vulnerable children and families, including runaway and homeless youth and victims of child abuse and family violence.

Runaway and Homeless Youth

Each year thousands of youth experience homelessness, making them more vulnerable to violence and substance abuse. In 2017, the Department of Housing and Urban Development identified more than 40,500 youth under the age of 25 who were on their own and experiencing homelessness. The Budget provides $119 million to support 587 programs across the country serving as a lifeline for homeless youth through emergency shelters and transitional living programs. The Budget proposes to update definitions to support trafficked youth and to create performance-based contracting demonstrations aimed at improving outcomes.

Child Abuse Prevention

ACF provides formula grants to states to improve the investigation of child abuse, train child protective service workers, and support community-based efforts to prevent child abuse and neglect. These funds also support state plans for safe care of infants affected by substance use disorders and for their parents and caregivers. ACF also shares critical research findings and lessons learned to improve child outcomes across the country, for example, demonstrating how child

welfare agencies can work with local housing authorities to decrease family separation due to lack of adequate housing.

Promoting Child Welfare

To promote child welfare, the Budget supports at-risk families and enables children to remain safely with their families or to be safely reunified in a timely manner. When it is not possible for a child to safely remain with his or her family, ACF works to remove barriers to adoption, provide incentive awards to states that increase the adoption of children in their foster care programs, and provide education and training vouchers to help foster care youth become self-supporting.

Administration for Native Americans

The Budget includes $52 million for the Administration for Native Americans to award competitive grants to promote social and economic development, preserve native languages, and protect local environments. ACF awards the grants to federally recognized tribes, American Indian and Alaska Native organizations, Native Hawaiian organizations, and Native populations in U.S. Pacific territories.

Family Violence Prevention and Services

The Budget provides $175 million for Family Violence Prevention and Service Programs. This funding provides services to prevent family violence, domestic violence, and dating violence. It provides immediate shelter and support services for adult and youth victims. This total includes $10 million for the National Domestic Violence Hotline providing 24/7 crisis intervention, emotional support, counseling, safety planning, and resources to people experiencing domestic or dating violence.

REFUGEES, ENTRANTS, AND UNACCOMPANIED ALIEN CHILDREN

Unaccompanied Alien Children

ACF has the responsibility to provide shelter, care, and support for unaccompanied alien children apprehended by the Department of Homeland Security or other law enforcement authorities. ACF provides care for these children and identifies suitable sponsors, usually parents or other relatives, to care for them while their immigration cases proceed. While in ACF's care, children receive physical and mental health care, education, and recreation. Most children receive care through a network of permanent facilities, which are state-licensed and operated by grantees under the close supervision of ACF staff. ACF also operates temporary shelters in response to periodic rapid increases in the number of unaccompanied alien children requiring care.

The number of unaccompanied alien children requiring care is inherently unpredictable. Funding needed for this program has exceeded the program's appropriated funds in five of the last seven fiscal years. To ensure adequate shelter capacity and care in FY 2020, the Budget proposes a mandatory contingency fund providing up to $2 billion in additional resources over a three-year period.

Refugees and Other New Arrivals

ACF assists refugees and other eligible new arrivals to help them become self-supporting and assimilate to life in the United States through networks of nonprofits and state and local governments. New arrivals can receive up to eight months of financial support and medical assistance until they find employment. ACF provides transition support services, including English as a second language education, job training, case management, and counseling.

The FY 2020 estimate of eligible new arrivals is 93,000, including 30,000 refugees and 63,000 other new arrivals eligible for refugee benefits. The Budget includes $319 million for transitional and medical services and $151 million for refugee support services.

Victims of Trafficking

The Budget includes $17 million for victims of trafficking to screen and identify victims and to provide victims with services, including case management, emergency assistance, and medical services. In coordination with the Department of Justice's Office of Victims of Crime, ACF serves both foreign national and U.S. citizens or permanent residents who are victims of trafficking. In addition, ACF funds a National Human Trafficking Hotline and works to raises awareness to prevent human trafficking.

EVALUATION AND INNOVATION

Research and Demonstration

Program evaluation and the use of data and evidence are critical for ACF and its partners to improve service delivery and increase program effectiveness. Some programs, such as the Office of Head Start and the Office of Child Care, have dedicated research and

program evaluation funding, but many other programs do not. The Budget maintains funding for Social Services Research and Demonstration, allowing ACF to study programs which lack dedicated research and evaluation funds and for research into areas that affect multiple programs.

Federal Administration

Federal administration funds pay for staff and administrative costs of the majority of ACF's programs. Examples of administrative expenses include program management and required oversight, office space, and the development and maintenance of information technology systems. By increasing efficiency, ACF has managed recent program expansions, such as those included in the Family First Prevention Services Act, without increasing administrative funding. The Budget request for federal administration is $205 million.

Administration for Children and Families: Mandatory

	dollars in millions			2020 +/-
	2018 /1	2019	2020	2019
Current Law Budget Authority				
Child Care Entitlement to States	2,917	2,917	2,917	0
Child Support Enforcement and Family Support	4,395	4,322	4,290	-32
Children's Research and Technical Assistance	35	35	38	+3
Foster Care and Permanency	8,138	8,301	8,548	+247
Promoting Safe and Stable Families (mandatory only)	480	489	345	-144
Social Services Block Grant	1,672	1,680	1,700	+20
Temporary Assistance for Needy Families (TANF) /2	16,737	16,737	16,739	+2
TANF Contingency Fund	608	608	608	0
Refugee and Entrant Assistance (mandatory only)	--	--	--	--
Total, Current Law Budget Authority	**34,982**	**35,089**	**35,185**	**+96**
Proposed Law Budget Authority				
Child Care Entitlement to States	2,917	2,917	4,212	+1,295
Child Support Enforcement and Family Support	4,395	4,322	4,340	+18
Children's Research and Technical Assistance	35	35	38	+3
Foster Care and Permanency	8,138	8,301	8,579	+278
Promoting Safe and Stable Families (mandatory only)	480	489	565	+76
Social Services Block Grant	1,672	1,680	85	-1,595
Temporary Assistance for Needy Families (TANF) /2	16,737	16,737	15,237	-1,500
TANF Contingency Fund	608	608	0	-608
Refugee and Entrant Assistance (mandatory only)	--	--	738	+738
Total, Proposed Law Budget Authority	**34,982**	**35,089**	**33,794**	**-1,295**

1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.
2/ Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.

The Fiscal Year (FY) 2020 Budget requests $33.8 billion in budget authority for the Administration for Children and Families (ACF) mandatory programs, with an estimated $33.1 billion in outlays. ACF promotes the economic and social well-being of families, children, individuals, and communities through mandatory programs, including:

- Child Care Entitlement to States,
- Child Support Enforcement,
- Foster Care,
- Adoption Assistance,
- Guardianship,
- Independent Living,
- Promoting Safe and Stable Families, and
- Temporary Assistance for Needy Families (TANF).

ACF's proposals support the priorities of the Department and the Administration and focus on reducing poverty by increasing employment opportunities, creating economic mobility and strong social networks, increasing efficiency in human services programs, and addressing the impact of opioid misuse on families and children.

CHILD CARE ENTITLEMENT TO STATES

Program Description

The Budget includes $3.6 billion for the Child Care Entitlement to States, an increase of $743 million over FY 2019. The Child Care Entitlement to States provides mandatory funding to states and tribes for child care. The program requires states to spend at least 70 percent of mandatory child care funding on families receiving TANF, transitioning from TANF, or at risk of becoming eligible for TANF. In FY 2020, states must spend a minimum of nine percent of all child care funds, including the discretionary Child Care and Development Block Grant (CCDBG) to improve the quality and availability of healthy and safe child care for all families. Together with CCDBG, the Child Care Entitlement program helps families access and afford child care.

Legislative Proposals

The Budget requests $216 million for the Child Care Entitlement to States, an increase of $2.2 billion over 10 years. The Budget proposes a new, one-time $1 billion fund for competitive grants to states to increase child care services for underserved populations and stimulate employer investment in child care.

CHILD SUPPORT ENFORCEMENT AND FAMILY SUPPORT PROGRAMS

Program Description

The Budget includes $4.4 billion for the Child Support Enforcement program, a current law increase of $121 million over FY 2019. The Child Support Enforcement program is a joint federal, state, tribal, and local partnership operating under title IV-D of the Social Security Act. It allows children to count on their parents for the financial, emotional, and medical support that they need to be healthy and successful, even when the parents live in separate households. The program functions in 54 states and territories, and 62 tribes. The Federal Child Support Enforcement program ensures economic and emotional support for children from both parents by locating noncustodial parents, establishing paternity, and establishing and enforcing child support orders.

Legislative Proposals

The FY 2020 Budget requests $4.4 billion for Child Support Enforcement and Family Support Programs. The Administration will also work to improve child support cooperation with other public assistance programs, such as Medicaid and the Supplemental Nutrition Assistance Program.

As part of the Administration's commitment to promoting work and self-sufficiency, the Budget includes a proposal, Get Noncustodial Parents to Work, allowing states to use up to two percent of their child support expenditures to require work activities for all noncustodial parents who owe overdue child support. This proposal will increase regular child support collections, enable noncustodial parents to provide for their children through increased engagement in work activities, and offer families a pathway towards economic independence.

Parenting time, or visitation, is the time a noncustodial parent spends with the child. Research shows that when noncustodial parents engage in their children's lives, they are more likely to meet their financial obligations. Several studies show that joint custody and access and visitation programs correlate with increased parent-child contact and child support payments. To improve parent-child relationships and outcomes for children, the Budget increases federal funding by $34 million over 10 years for states to include parenting time provisions when establishing child support orders, at state option.

The Budget saves $1.2 billion over 10 years by creating a technology enhancement and replacement fund to acquire a next-generation child support system and make it available to states. This proposal maximizes proven technology, rather than separate systems developed by each state, to increase system security and integrity. The new technology enhancement and replacement fund would also create savings and cost efficiencies for states and the federal government, resulting in better service delivery to child support customers. Leveraging reusable technology provides a cost effective solution to the widespread and pressing issue of replacing aging child support systems.

The Child Support account includes the Repatriation program providing temporary assistance, through service loans, to eligible repatriates referred from the U.S. Department of State. The Budget proposes to increase the annual ceiling on the amount of temporary assistance from $1 million to $10 million. This will allow HHS to improve responsiveness when repatriated individuals do not have resources for needs

such as temporary housing, meals, health care, or transportation.

CHILDREN'S RESEARCH AND TECHNICAL ASSISTANCE

Program Description

The FY 2020 Budget includes $12 million in Children's Research and Technical Assistance for child support program training and technical assistance, an increase of $1.5 million over FY 2019. The Budget includes $25 million to operate the Federal Parent Locator System (FPLS), an increase of $0.8 million over FY 2019. Federal law authorizes and appropriates funds for Children's Research and Technical Assistance, which supports training and technical assistance to states on child support enforcement activities and the operation of the FPLS to assist state child support agencies in locating noncustodial parents.

Legislative Proposals

The Budget includes a package of proposals to provide access to the National Directory of New Hires (NDNH) – a federal database of employment and unemployment insurance information administered by the Office of Child Support Enforcement within HHS – for evidence and program integrity purposes, while ensuring privacy and security safeguards. Program integrity proposals include strengthening eligibility verification and/or reducing improper payments and evidence-building proposals include providing access for statistical agencies and evaluation offices, as well as access for State agencies. If enacted, these proposals would eliminate duplicative efforts to collect the same employment and earnings data already in NDNH and improve government efficiencies.

FOSTER CARE AND PERMANENCY

Program Description

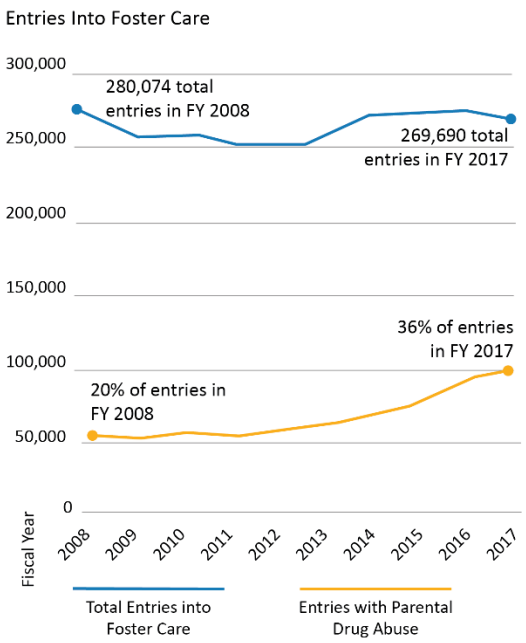
The Budget includes $8.4 billion for the Foster Care, Adoption Assistance, Guardianship Assistance, and Independent Living programs, a current law increase of +$559 million over FY 2019. These programs provide safety and permanency for children separated from their families, support services to prevent child maltreatment and the need for foster care, and prepare older youth in foster care for independence. The additional funding relative to FY 2019 will support the increased number of children participating in the Foster Care and Permanency program.

Funding goes primarily to:

- states as a partial reimbursement payment for board and care of eligible children in foster care,
- payments to families related to adoption and guardianship, and
- the Chafee Foster Care Program for Successful Transition to Adulthood, which assists current and former foster youth up to age 21 in obtaining education, employment, and life skills for self-sufficiency and successful transition to adulthood.

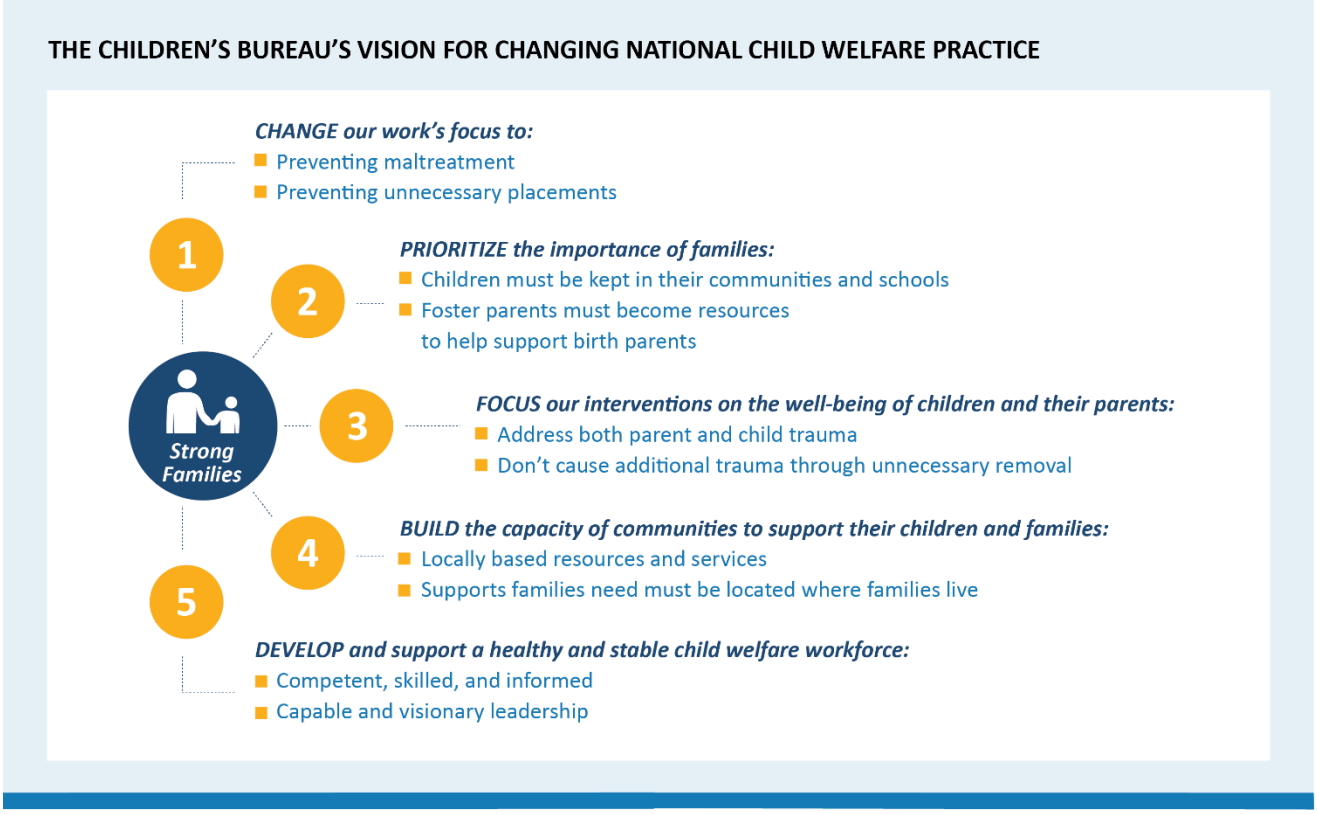
IMPACT OF PARENTAL DRUG ABUSE ON FOSTER CARE

Parental Drug Abuse as a Circumstance Associated with Removal has increased in absolute numbers and as a percentage of all entries into foster care.



Source: U.S. Department of Health and Human Services, Adoption and Foster Care Analysis Reporting System (AFCARS), as of September 4, 2018.

In February 2018, Congress enacted the Family First Prevention Services Act (Family First Act) (P.L. 115-123). This important law allows federal funding for evidence-based prevention services for up to 12 months for children who are at risk of entering foster care, pregnant or parenting foster youth, and their parents or kin caregivers. Federal funding is available without regard to whether the child meets



title IV-E income eligibility standards. The funds can be used for mental health and substance abuse services, including opioid misuse, and for in-home parent skill-based programs. The Family First Act restricted federal funding for congregate foster care, often called group homes, in favor of family foster homes. Unless a state exercises the option to delay, beginning in FY 2020, federal funding will not pay for new congregate care after 14 days, except in limited circumstances with ongoing documentation and judicial review requirements.

The Family First Act provides an opportunity to re-examine the child welfare system and how it can focus on the well-being of children, strengthen families and communities, prevent the need for foster care, reunify families, and provide permanency through adoption or guardianship when reunification is not possible. ACF's child welfare proposals support Family First Act implementation and will improve child welfare outcomes, prevent the need for foster care, and address the opioid crisis.

Legislative Proposals

The Promote Family Based Care proposals will increase the availability of family foster homes for children with more severe behavioral, physical, or emotional needs by allowing federal reimbursement for salaries for foster parents to care for these children. As states implement the Family First Act's funding restrictions on congregate care placements, they will need to develop alternate foster care options. This proposal invests $357 million over 10 years, including $7 million for technical assistance and oversight of activities related to the Family First Act (supplementing the $1 million already enacted).

Preventing entry into foster care is key to avoiding unnecessary trauma, disrupting intergenerational cycles of maltreatment, and achieving better outcomes for children and families. The cost-neutral proposal to Create a Child Welfare Flexible Funding Option builds on the Family First Act by expanding resources available for preventive services, regardless of eligibility for foster care. It would allow federal funds to reimburse spending on any of the purposes or services authorized for child welfare spending under titles IV-E and IV-B of the Social Security Act beyond the costs of foster care, adoption, guardianship, and for services authorized by the Family First Act. This approach would empower states to invest broadly in services that promote permanency and stability for children and to focus more resources on preventing child maltreatment before it occurs.

The Flexible Funding Option would provide additional flexibility in the type and duration of intervention services offered by states. This includes a focus on preventive services which help states address differing needs in areas faced by the severity of the opioid crisis and its impact on families and children. The Flexible Funding Option would remove burdensome and overly prescriptive title IV-E eligibility requirements and the need to participate in eligibility reviews, further increasing the resources available to provide valuable services to improve child well-being. The federal government would continue to monitor states' performance through Child and Family Services Reviews.

The Budget proposes a demonstration project to offer incentives to states to improve performance on Child and Family Services Reviews and reinvest penalties for poor performance in child welfare pursuant to an improvement plan. The incentives component adds a 10-year investment of $110 million.

PROMOTING SAFE AND STABLE FAMILIES

Program Description

The Budget includes $510 million for the mandatory portion of the Promoting Safe and Stable Families program for FY 2020, an increase of $42 million over FY 2019. These formula grants to states provide services to families, address child safety at home, and provide supportive services for reunifying and adoptive families. Funding supports Court Improvement Program grants to state and tribal courts to improve child welfare proceedings and Regional Partnership Grants, a competitive grant program that addresses the child welfare impact of substance abuse, including opioids. In recent years, parental substance abuse has grown as a circumstance associated with entry into foster care.

Legislative Proposals

The Budget increases funding for the Court Improvement Program by $280 million to help courts improve and transition to the new requirements of the Family First Act, such as reviewing congregate care placements and providing training for judges, attorneys, and legal personnel working in child welfare cases. The Budget also increases funding to expand Regional Partnership Grants by $368 million to serve more communities, especially rural communities affected by opioid misuse.

Promoting Safe and Stable Families includes the Personal Responsibility Education Program and the Sexual Risk Avoidance Education Program (formerly known as Abstinence Education). The Personal Responsibility Education Program provides formula grants to states and competitive grants to tribes and local organizations to educate adolescents on pregnancy prevention, sexually transmitted diseases, and adulthood preparation subjects such as healthy relationships and financial literacy. The Sexual Risk Avoidance Education Program provides formula grants to states and territories and competitive grants to local organizations for projects that educate youth on the health benefits of avoiding non-marital sexual activity. Programs focus on youth who are homeless, in foster care, live in rural areas or areas with high teen birth rates, or come from racial or ethnic minorities with disparities in teen birth rates. The Budget proposes a one-year reauthorization of each program at their current levels of $75 million in mandatory funding per year.

SOCIAL SERVICES BLOCK GRANT

Program Description

Under current law, the Budget includes $1.8 billion for the Social Services Block Grant (SSBG) appropriation account, which includes funding for SSBG and the Health Profession Opportunity Grants (HPOG) programs. SSBG provides support for a broad array of social services for children and adults. HPOG provides grants to support demonstration projects that provide Temporary Assistance for Needy Families (TANF) program recipients and other low-income individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand.

Legislative Proposals

The Budget eliminates funding for the SSBG. The Administration's goal is to support welfare programs that effectively help low-income families move to independence through paid employment, and focus limited taxpayer dollars on program outcomes, not inputs, to ensure effectiveness in helping low-income families. A 2011 Government Accountability Office report noted that the SSBG Grant is fragmented, provides duplicative or overlapping services, and has limited accountability. The program has not demonstrated effectiveness in improving economic and social well-being. Recognizing that the SSBG is

sometimes used to provide rapid and flexible funding for disaster relief, the Budget maintains the program's authorization for possible future use in emergencies.

The Budget proposes a one-year extension for current HPOG grantees, at the current level of $85 million in mandatory funding per year, to allow for continued evaluation and improvement.

TEMPORARY ASSISTANCE FOR NEEDY FAMILIES

Program Description

The Budget includes $15.1 billion for the TANF program, a current law decrease of $1.4 billion from FY 2019. The TANF block grant provides states, territories, and eligible tribes the opportunity to design programs that help families transition from welfare to self-sufficiency. As a result, the statute gives states, territories, and tribes flexibility in determining how to use their TANF dollars to meet their citizens' needs and get them back on their feet.

Legislative Proposals

The Budget proposes $15.1 billion for TANF State and Territory Family Assistance Grants. This funding level builds on the successes of welfare reform and re-focuses TANF as an effective anti-poverty program that promotes economic independence.

Despite its successes, the TANF program could perform better in moving low-income families from welfare to work. Over time, states have spent less on basic assistance and work, education, and training activities that help families achieve economic independence. Many states have taken advantage of provisions in the law that allow them to reduce their level of effort in engaging TANF recipients in work.
To address these challenges, the Budget strengthens the program's focus on work and self-sufficiency for low-income families and ensures that states invest in work activities that will benefit low-income families. The Budget proposes to simplify TANF's work participation rate and target federal and state funding to needy families to end state gaming of the program.

Statutory limits on TANF reporting and significant differences between state TANF programs make it impossible for HHS to report an improper payment rate as required under current law. The Budget proposes to resolve this problem by giving ACF authority to collect quantitative and qualitative program integrity information from TANF programs, which will lay the groundwork for the data collection efforts needed to provide information on states' improper payments requirement. Using this information, HHS will prepare and submit to OMB a report on state efforts to promote payment integrity and accuracy within their TANF cash assistance programs.

The Healthy Marriage Promotion and Responsible Fatherhood (HMRF) Grants promote and encourage healthy marriage and relationships, positive father and family interactions, and other activities that foster social and economic security. Funding for these grants expires at the end of FY 2019. The Budget proposes a 5-year reauthorization of the HMRF program with technical improvements to create greater flexibility in funding awards to eligible entities.

UNACCOMPANIED ALIEN CHILDREN

The Budget provides up to $2 billion in mandatory funding for an Unaccompanied Alien Children Contingency Fund. Please see the Unaccompanied Alien Children section of the ACF Discretionary chapter for a program description.

Administration for Children and Families: Mandatory

FY 2020 ACF Mandatory Outlays

	dollars in millions			
	2018 /1	2019	2020	2020 +/- 2019
Current Law Outlays				
Child Care Entitlement to States	2,358	2,819	3,296	+477
Child Support Enforcement and Family Support	4,137	4,235	4,307	+72
Children's Research and Technical Assistance	41	43	37	-6
Foster Care and Permanency	8,581	7,876	8,404	+528
Promoting Safe and Stable Families (mandatory only)	425	468	485	+17
Social Services Block Grant	1,587	1,619	1,844	+225
Temporary Assistance for Needy Families (TANF) /2	16,415	16,536	16,219	-317
TANF Contingency Fund	666	597	608	+11
Refugee and Entrant Assistance (mandatory only)	--	--	--	--
Total, Current Law Outlays	**34,209**	**34,191**	**35,197**	**+1,006**
Proposed Law Outlays				
Child Care Entitlement to States	2,358	2,819	3,562	+743
Child Support Enforcement and Family Support	4,137	4,235	4,356	+121
Children's Research and Technical Assistance	41	43	37	-6
Foster Care and Permanency	8,581	7,876	8,435	+559
Promoting Safe and Stable Families (mandatory only)	425	468	510	+42
Social Services Block Grant	1,587	1,619	487	-1,132
Temporary Assistance for Needy Families (TANF) /2	16,415	16,536	15,142	-1,394
TANF Contingency Fund	666	597	63	-534
Refugee and Entrant Assistance (mandatory only)	--	--	480	+480
Total, Proposed Law Outlays	**34,209**	**34,191**	**33,070**	**-1,121**

1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.
2/ Does not reflect offsetting collections to the TANF Program as a result of interactions with Child Support Enforcement legislative proposals.

Administration for Children and Families: Mandatory

FY 2020 ACF Mandatory Budget Proposals, Outlays

	dollars in millions		
	2020	2020 -2024	2020 -2029
Proposed Law Outlays			
Increase the Child Care Entitlement to States	216	1,080	2,160
Build the Supply of Child Care	50	1,000	1,000
Subtotal, Child Care (mandatory) (non-add)	***266***	***2,080***	***3,160***
Get Noncustodial Parents to Work /1	13	97	275
Fund States to Provide Parenting Time Services	1	11	34
Strengthen Child Support Enforcement and Establishment /2	--	--	--
Create a Technology Enhancement and Replacement Fund	35	-196	-1,185
Subtotal, Child Support Enforcement (non-add)	***49***	***-88***	***-876***
Increase the Repatriation Ceiling	0	4	9
Expand Access to National Directory of New Hires (NDNH)	--	--	--
Subtotal, Children's Research and Technical Assistance (non-add)	--	--	--
Promote Family Based Care	14	141	357
Create Child and Family Services Review Incentives	--	23	110
Create Child Welfare Flexible Funding Option	--	--	--
Interaction with Zero-Fund the Social Services Block Grant	17	104	214
Subtotal, Foster Care and Permanency (non-add)	***31***	***268***	***681***
Modernize and Expand the Court Improvement Program	9	125	280
Expand Regional Partnership Grants	11	162	368
Reauthorize the Personal Responsibility Education Program	3	73	73
Reauthorize Sexual Risk Avoidance Education	2	75	75
Subtotal, Promoting Safe and Stable Families (mandatory) (non-add)	***25***	***435***	***796***
Zero-Fund the Social Services Block Grant to States and Territories	-1,360	-8,092	-16,592
Reauthorize Health Profession Opportunity Grants	3	83	85
Subtotal, Social Services Block Grant (non-add)	***-1,357***	***-8,009***	***-16,507***
Reduce the TANF Block Grant	-1,099	-7,230	-15,284
Eliminate the TANF Contingency Fund	-545	-2,977	-6,017
Improve TANF by Strengthening Focus on Work and Families	--	--	--
Remake the Safety Net through Opportunity and Economic Mobility Demonstrations	22	300	500

	dollars in millions		
	2020	2020 -2024	2020 -2029
Provide for Alternative Improper Payments Reporting for the TANF Program	--	--	--
Reauthorize Healthy Marriage and Responsible Fatherhood	--	--	--
Child Support Enforcement Reform Proposals (TANF Impact)/3	-10	-85	-226
Subtotal, Temporary Assistance for Needy Families (TANF) (non-add)	***-1,632***	***-9,992***	***-21,027***
Establish an Unaccompanied Alien Children Contingency Fund	480	734	738
Subtotal, Refugee and Entrant Assistance (mandatory) (non-add)	**480**	**744**	**738**
Total Outlays, ACF Mandatory Legislative Proposals	**-2,138**	**-14,568**	**-33,026**

1/ The proposal outlays in this table do not incorporate estimated savings from the Supplemental Nutrition Assistance Program (-$16 million over 10 years) and the Supplemental Security Income program (-$117 million over 10 years). Outlay impacts from Federal Offsetting Collections related to recoveries to the TANF program are shown in the TANF section.
2/ The Strengthening Child Support Enforcement and Establishment proposal outlays in this table do not incorporate estimated savings from the Supplemental Nutrition Assistance Program (-$107 million over 10 years) and the Supplemental Security Income program (-$382 million over 10 years). Outlay impacts from Federal Offsetting Collections related to recoveries to the TANF program are shown in the TANF section.
3/ These estimates reflect outlay impacts of Child Support proposals from Federal Offsetting Collections related to recoveries to the TANF program.

Administration for Community Living

	dollars in millions			
	2018/1	2019	2020	2020 +/- 2019
Health and Independence Services				
Home & Community-Based Supportive Services	384	385	385	--
Nutrition Services	892	907	907	--
Native American Nutrition & Supportive Services	33	34	34	--
Preventive Health Services	25	25	25	--
Chronic Disease Self-Management /2	8	8	--	-8
Falls Prevention /2	5	5	--	-5
Aging Network Support Activities	12	17	12	-6
Subtotal, Health and Independence	**1,359**	**1,381**	**1,362**	**-19**
Caregiver Services				
Family Caregiver Support Services	180	181	151	-31
Native American Caregiver Support Services	10	10	8	-3
Alzheimer's Disease Program	23	24	19	-4
Lifespan Respite Care	4	4	3	-1
Subtotal, Caregiver Services	**217**	**219**	**181**	**-38**
Protection of Vulnerable Older Adults				
Long Term Care Ombudsman Program	17	17	16	-1
Prevention of Elder Abuse & Neglect	5	5	5	--
Senior Medicare Patrol Program (HCFAC)	18	18	18	--
Elder Rights Support Activities	16	16	14	-2
Subtotal, Protection of Vulnerable Older Adults	**55**	**56**	**53**	**-3**
Disability Programs, Research and Services				
State Councils on Developmental Disabilities	76	76	56	-20
Developmental Disabilities Protection and Advocacy	41	41	39	-2
Projects of National Significance	12	12	1	-11
University Centers for Excellence in Developmental Disabilities	41	41	33	-8
Nat'l Institute on Disability, Independent Living, & Rehab. Research	105	109	90	-19
Independent Living	113	116	109	-8
Traumatic Brain Injury	11	11	9	-2
Limb Loss Resource Center	3	4	--	-4
Paralysis Resource Center	8	9	--	-9
Subtotal, Disability Programs, Research and Services	**409**	**418**	**337**	**-81**
Consumer Information, Access and Outreach				
Voting Access for People With Disabilities (HAVA)	7	7	5	-2
Aging and Disability Resource Centers	8	8	6	-2
State Health Insurance Assistance Program	49	49	36	-13
Assistive Technology	36	36	32	-4
Medicare Improvements for Patients and Providers Act	38	38	38	--
Current Law Mandatory	38	38	--	-38
Proposed Law Mandatory	--	--	38	+38
Subtotal, Consumer Information, Access and Outreach	**138**	**138**	**117**	**-21**
Other Programs, Total, and Less Funds From Other Sources				
Program Administration	41	41	39	-2

	dollars in millions			
	2018/1	2019	2020	2020 +/- 2019
Total, Program Level	**2,219**	**2,253**	**2,088**	**-164**
Less Funds from Other Sources	83	81	18	--
Total Discretionary Budget Authority	**2,136**	**2,169**	**2,033**	**-137**
Full-Time Equivalents	188	198	189	-9

1/ Reflects FY 2018 enacted, post required and permissive transfers and rescissions.
2/ The FY 2020 Budget consolidates the Chronic Disease Self-Management and Falls Prevention Programs into the Preventive Health Service Program.

The Administration for Community Living maximizes the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers.

The Administration for Community Living (ACL) works with states, localities, tribal organizations, nonprofit organizations, businesses, and families to help older adults and people of all ages with disabilities live independently and participate fully in their communities. ACL also invests in innovation, research, and education to improve the quality and availability of services for older adults and people with disabilities.

The Fiscal Year (FY) 2020 Budget requests $2 billion for ACL. This total includes $2 billion in discretionary budget authority and $56 million in mandatory funding. The Budget prioritizes nutrition assistance and other key direct service programs. These direct service programs help seniors remain independent, assist and support families and caregivers, and empower individuals with disabilities to live independent lives and fully integrate into their communities.

PROMOTING ELDERS' HEALTH, SAFETY, AND COMMUNITY LIVING

Increased longevity has led to the rapid growth of the older population in the United States. Modern health care improvements allow older adults to stay active and healthy, and live independently. The U.S. population over age 60 is projected to increase by 31 percent between 2017 and 2030, from 70.8 million to 92.7 million.

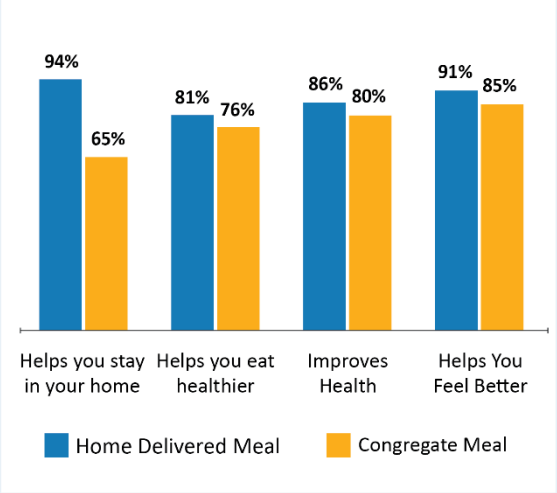
The Budget includes a new general provision to maximize funding flexibility for Older American Act funding, which includes Nutrition Services, Home and Community-Based Services, Family Caregiver Support Services, and Preventive Health Services Programs. This flexibility will allow states to direct funding to activities that are most needed in their communities. The Budget funds essential community-based services and supports that help older Americans stay healthy, independent, and living in their communities.

Nutrition Services Programs

The Budget requests $907 million for Nutrition Services. ACL's Congregate and Home-Delivered Nutrition Programs provide 221 million healthy meals to approximately 2.3 million older adults every year. ACL grantees provide meals in congregate facilities such as senior centers, and deliver to seniors who are homebound due to illness, disability, or geographic isolation.

RESULTS OF NUTRITION PROGRAM RECIPIENTS SURVEY (%YES)

Feedback from participants in ACL's Nutrition Programs.



Home and Community-Based Supports

The Budget includes $410 million for Home and Community-Based Supportive Services and Preventive Health Services. These two programs provide formula grants to states to help older adults, with and without disabilities, to live independently and avoid costlier care settings.

Through its Home and Community-Based Supportive Services program, ACL's budget supports 50.9 million hours of personal care, homemaker, and chore services as well as 10.2 million hours of adult day care.

The Budget consolidates the Falls Prevention Program and the Chronic Disease Self-Management Program into the Preventive Health Services Program. The Preventive Health Services Program prevents chronic disease and disability through formula grants to states and territories for evidence-based interventions. With this consolidation, states will have more flexibility to direct funding based on local needs.

Elder Rights and Support

Elder abuse and neglect affects at least 1 in 10 older Americans each year. The Budget provides $39 million to support the protection of vulnerable older adults, including $10 million for the Adult Protective Services Program. In collaboration with State Adult Protective Services agencies, ACL supports a national reporting system for Adult Protective Services programs and will provide targeted technical assistance grants to address opioid misuse in older adults.

Other Aging Programs

The Budget provides $46 million for two other health and independence services programs: Native American Nutrition and Supportive Services, and Aging Network Support Activities. The latter maintains funding for the Holocaust Survivor Assistance Fund.

CAREGIVER AND FAMILY SUPPORT SERVICES

The Family Caregiver Support Program enables family and informal caregivers to care for seniors and individuals with disabilities in their homes and communities, avoiding or delaying the need for costly nursing home care. The Budget provides $162 million for three programs designed to support family and informal caregivers.

The Family Caregiver Support Services Program, the Native American Caregiver Support Services Program, and the Lifespan Respite Care Program work with states, community-based, and tribal programs to provide coordinated support services including counseling, respite care, training, and supplementary services (such as access to medical equipment and transportation).

In FY 2020, ACL's caregiver support programs will serve approximately 800,000 family caregivers. In addition to these efforts, ACL will implement the Recognize, Assist, Include, Support, and Engage Family Caregivers Act and the Supporting Grandparents Raising Grandchildren Act to support family caregivers and their diverse needs.

Alzheimer's Disease

The FY 2020 Budget provides $19 million for Alzheimer's Disease activities. Alzheimer's Disease is the sixth leading cause of death in the United States. An estimated 5.3 million Americans age 65 and older are living with Alzheimer's Disease and related dementia, and nearly 14 million Americans are expected to be diagnosed with such diseases by 2050.

HELPING INDIVIDUALS WITH DISABILITIES PARTICIPATE IN THEIR COMMUNITIES AND ACHIEVE THEIR GOALS

ACL is dedicated to ensuring that individuals with disabilities and their families can live, work, play, and learn as contributing members of their communities. ACL works with states, territories, communities, and nonprofit organizations to improve access to community-based care.

State Health Insurance Program

The State Health Insurance Program assists Medicare-eligible individuals, their families, and caregivers to make informed health insurance decisions to optimize their access to care and benefits. The Budget provides $49 million in both discretionary and mandatory funding, for grants to states for local activities and community-based services.

Additionally, the Budget extends $38 million in mandatory funding for Aging and Disability Resource Centers, Area Agencies on Aging, the National Center for Benefits Outreach and Enrollment, and the State Health Insurance Assistance Program through FY 2021, which target low-income and rural populations.

State Councils on Developmental Disabilities

The Budget provides $56 million for State Councils on Developmental Disabilities, a nationwide network of state-based organizations that identify and address the most pressing needs of people with developmental disabilities in their state or territory. Councils on Developmental Disabilities focus on developmental disabilities that are lifelong, significant, and require ongoing support from existing and innovative services to improve the quality of life for these individuals. These services help individuals achieve independence, productivity, integration, self-determination, and inclusion in the community.

Independent Living

ACL's Independent Living programs coordinate services to individuals with disabilities, maximize their productivity and integration into communities, and foster working relationships among Centers for Independent Living. ACL's Centers for Independent Living help nearly 250,000 people with disabilities achieve greater independence and self-sufficiency each year. Independent Living services include peer counseling, information and referral, individual and systems advocacy, and independent living skills training.

The Budget provides $109 million for over 350 Centers for Independent Living, and includes funding to support program evaluation and performance measurement activities to improve efficient evidence-based decision-making.

National Institute on Disability, Independent Living, and Rehabilitation Research

The Budget provides $90 million for the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) within ACL to support and leverage NIDILRR's applied research with ACL's other programs. NIDILRR is committed to ensuring that its research and development promote the independent living, health, and function, employment, and community living outcomes of individuals with disabilities.

Other Disability Programs

The Budget provides $43 million for additional disability programs, research, and services. This includes $33 million for University Centers for Excellence in Developmental Disabilities and $1 million for Projects of National Significance.

The Budget also provides $9 million for the Traumatic Brain Injury Program to support grants for rehabilitation, counseling, and vocational services for individuals with traumatic brain injury.

RESPONSIBLE STEWARDSHIP AND DELIVERY OF SERVICES

The Budget discontinues funding for program activities carried out with other funding sources and available through other ACL programs, including the Limb Loss and Paralysis Resource Centers. Resources for individuals living with paralysis are available through other HHS programs, such as Centers for Independent Living and Assistive Technology, which provide resources to people with all types of significant disabilities.

Federal Administration

The Budget includes $39 million for program management and support activities. This funding helps ACL carry out its mission by ensuring adequate support for oversight and program integrity activities.

General Departmental Management

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Discretionary Budget Authority /1	**470**	**481**	**340**	**-141**
Public Health Service Evaluation Funds	65	65	69	+4
Health Care Fraud and Abuse Control Program /2	7	10	10	+3
Proposed User Fee Collections – Department Appeals Board	-	-	2	+2
Total, Program Level /3	**542**	**556**	**421**	**-132**
Full-Time Equivalents /3	1,030	1,029	1,130	+101

1/ The 2018 level reflects the 2018 Enacted level, post 2018 Secretary's Transfer for Unaccompanied Alien Children.
2/ The Health Care Fraud and Abuse Control Program allocation in FY 2019 is $7 million.
3/ This table does not include funding of Full-Time Equivalents for the Pregnancy Assistance Fund, nor does it include funding for the Physician-Focused Payment Model Technical Advisory Committee created by the Medicare Access and CHIP Reauthorization Act of 2015.

The General Departmental Management budget line supports the Secretary's role as chief policy officer and general manager of the Department.

LEADING THE NATION'S PUBLIC HEALTH ENTERPRISE

The Secretary oversees HHS programs, policies and operations to ensure effective stewardship of Department resources toward helping Americans live healthier lives. The Budget supports the Secretary's role in administering and overseeing the organization, programs, and activities of the largest cabinet Department through 11 Staff Divisions within the Office of the Secretary. The fiscal year (FY) 2020 President's Budget requests a program level of $421 million for General Departmental Management.

The Budget ensures health policy and program coordination across the Department as well as supporting Administration priorities such as the initiative *Ending the HIV Epidemic: A Plan for America*. Further, the Budget addresses critical operations including addressing Medicare claim appeals which have a direct impact on Medicare beneficiaries and providers.

PUBLIC HEALTH POLICY AND PROGRAM COORDINATION

The Office of the Assistant Secretary for Health (OASH) serves as the senior advisor to the Secretary for public health, science and medicine and coordinates public health policy and programs across the Staff and Operating Divisions of HHS. Additionally, the ASH oversees the Office of the Surgeon General and the United States Public Health Service Commissioned Corps (Corps).

OASH coordinates through 11 core program offices including the Office of Minority Health and the Office on Women's Health offices to lead policy coordination across the Department, government-wide, and with nongovernmental partners. This coordination enables the Department to address a diverse range of public health challenges, including OASH's lead role in defining best practices and opportunities for improvement in pain management to lessen dependence on opioids. OASH focuses on supplying information and tools that empower individuals, communities, and health systems to emphasize health promotion and disease prevention.

MINORITY HIV/AIDS FUND

Advances in prevention and treatment for HIV/AIDS make the prospect for ending the HIV epidemic in America possible. HHS has long-standing HIV/AIDS programs that have played a major role in addressing the impact of the epidemic. The Budget includes

$54 million for the Minority HIV/AIDS Fund. These funds provide the Department with the flexibility to target funding for hard-to-serve communities and individuals enabling HHS to implement programs that support the goals of the early phase of this initiative.

OFFICE OF MINORITY HEALTH

The Budget includes $52 million for the Office of Minority Health. The Office of Minority Health will continue to lead, coordinate, and collaborate on minority health activities across the Department, including leadership in coordinating policies, programs, and resources to reduce health and health care disparities and advance health equity in America.

OFFICE ON WOMEN'S HEALTH

The Budget includes $27 million for the Office on Women's Health. The Office on Women's Health will continue to lead, coordinate, and collaborate on women's health activities across the Department. The Office on Women's Health will continue to support the advancement of women's health programs with other government organizations and with consumer and health professional groups.

OFFICE OF SURGEON GENERAL & U.S. PUBLIC HEALTH SERVICE COMMISSIONED CORPS

As the nation's doctor, the Surgeon General provides Americans with the best scientific information available on how to improve their health and reduce the risk of illness and injury. The Surgeon General manages the daily operations of the Corps, which consists of approximately 6,500 uniformed public health professionals who underpin the nation's response network for public health emergencies. Corps officers, including physicians, nurses, dentists, pharmacists, social workers and engineers have supported the U.S. government response to natural disasters and other public health emergencies such as hurricanes and the Ebola outbreak.

The ASH initiated an extensive plan to modernize the Corps structure, organization, and force strength to meet the current and future needs of the nation. This modernization plan will: strategically decrease positions filled by Corps officers in non-mission-priority areas and functions; recruit new officers to serve specific underserved and vulnerable population missions; establish a highly trained, deployable, and fully capable Ready Reserve Corps; and deliver annual training to the Regular Corps to meet current and emerging mission requirements.

The FY 2020 Budget provides $3 million within the Immediate Office of the ASH to implement the planning phase for the Ready Reserve.

ADDRESSING MEDICARE CLAIM AND OTHER APPEALS

The Budget includes $20 million for the Department Appeals Board (DAB), an increase of $9 million above FY 2019. DAB provides impartial, independent review of certain disputed decisions, as detailed below. In the event of a disputed Medicare claim, the DAB serves as the final level of review before a claim can be appealed to federal court.

The Budget increase for FY 2020 will provide additional support to the Medicare Appeals Council to keep pace with the growing number of Medicare appeals. The Council provides the final administrative review of claims for entitlement to Medicare, individual claims for Medicare coverage, and claims for payment filed by beneficiaries or health care providers and suppliers.

DAB also hears cases initiated by outside parties who disagree with a determination made by an HHS agency or its contractor. Outside parties include states, universities, grantees, nursing homes, clinical laboratories, doctors, medical equipment suppliers, and Medicare beneficiaries. DAB decisions on certain cost allocation issues in grant programs have government-wide impact because HHS decisions in this area legally bind other Federal agencies.

OTHER GENERAL DEPARTMENTAL MANAGEMENT

The Budget includes $263 million for the remainder of the activities supported by General Departmental Management in the Office of the Secretary. The Budget funds leadership, policy, legal, and administrative guidance to 11 staff divisions and includes funding to continue ongoing programmatic activities, including strengthening program integrity by reducing fraud, waste, and abuse.

Office of the Secretary
Office of Medicare Hearings and Appeals

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Office of Medicare Hearings and Appeals				
Medicare Appeals Adjudication	182	182	182	--
Proposed User Fee Collections	--	--	*4*	+4
Program Level	182	182	186	+4
Subtotal	**182**	**182**	**186**	**+4**
Full-Time Equivalents	664	950	1,375	+425

The Office of Medicare Hearings and Appeals provides a forum for the adjudication of Medicare appeals for beneficiaries and other parties. This mission is carried out by Administrative Law Judges exercising decisional independence under the Administrative Procedures Act with the support of professional, legal, and administrative staff.

The Office of Medicare Hearings and Appeals (OMHA) administers the nationwide hearing process for appeals arising from Medicare coverage and payment claims for items and services furnished to beneficiaries.

The Fiscal Year (FY) 2020 Budget requests $186 million for OMHA, an increase of $4 million over the funding provided in FY 2019. The FY 2020 Budget increase consists of $4 million in proposed user fee collections that would allow OMHA to recoup a small part of the administrative costs resulting from unsuccessful appeals.

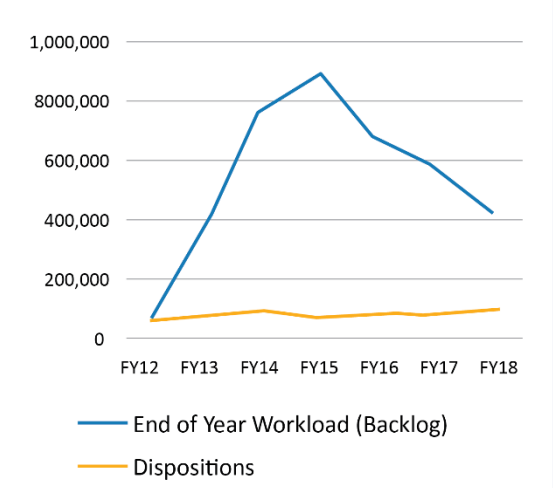
THE MEDICARE APPEALS BACKLOG

Since FY 2011, the growth in Medicare claims, partially driven by an aging population and HHS's Medicare program integrity efforts, has led to a significant increase in Medicare appeal claims. The claim increase has resulted in more appeals than OMHA could process within the 90-day case adjudication time frame required by law. Despite OMHA's efforts to resolve this issue, appeal receipts continue to exceed annual adjudication capacity, resulting in a backlog of appeals pending adjudication.

To address this challenge, the Department took a number of administrative actions to reduce the pending appeals workload, including alternative dispute resolution and settlement actions. Thanks to these efforts, the backlog of cases was reduced by 55 percent to approximately 400,000 appeals (from a high of nearly 900,000 in FY 2015).

In FY 2019, Congress funded OMHA at a level which enabled the agency to increase adjudication capacity and properly address receipt levels. This funding allowed OMHA to hire more Administrative Law Judges (ALJs) and adjudicatory staff to handle the incoming workload and reduce the backlog of appeals.

MEDICARE APPEALS BACKLOG VS. DISPOSITIONS



This additional adjudicatory capacity and staffing include the opening of four new field offices in

Albuquerque, New Mexico; Atlanta, Georgia; New Orleans, Louisiana; and Phoenix, Arizona.

The Department projects that the backlog of appeals will be resolved by FY 2022.

OMHA remains committed to continuous improvement in the Medicare appeals process by implementing initiatives to enhance the quality and timeliness of its services within its statutory authorities and funding levels. Through increased process efficiency and targeted addition of support staff, OMHA has streamlined its business processes and has implemented a number of new initiatives to the maximum extent possible without sacrificing program integrity.

Office of the Secretary, Office of the National Coordinator for Health Information Technology

	dollars in millions			
	2018 /1	2019	2020	2020 +/- 2019
Office of the National Coordinator for Health Information Technology				
Total Discretionary Budget Authority	**60**	**60**	**43**	**-17**
Full-Time Equivalents	176	164	164	--

1/ Reflects FY 2018 enacted, post required and permissive transfers.

The mission of the National Coordinator for Health Information Technology is to improve the health and well-being of individuals and communities through the use of technology and health information that is accessible when and where it matters most.

The Office of the National Coordinator for Health Information Technology (ONC) leads the nation's effort to advance health information technology (IT). Improved exchange of health information promotes the quality, safety and efficiency of health care for the American public. ONC supports the Administration's efforts to achieve interoperability, promote common data standards, encourage innovation and competition in the health IT industry, and improve patient and provider experiences with health IT.

In a large and complex health care delivery system, achieving an interoperable health IT system is critical. A safe, secure, and efficient health IT infrastructure improves health care delivery, reduces health care costs, and supports better health for all Americans. The Fiscal Year (FY) 2020 Budget prioritizes policy and rulemaking activities, standards development and implementation, and electronic health record (EHR) certification efforts to fulfill ONC's commitment to an interoperable health IT system. In FY 2020, ONC will accelerate development of data standards and the implementation of a trusted exchange framework and common agreement across health information networks, to accelerate the achievement of this goal.

The FY 2020 Budget includes a total of $43 million for ONC to support mission critical work that advances the interoperability and usability of health IT. Additionally, ONC will promote health IT approaches to combat the opioid epidemic through targeted collaborations with HHS partners.

POLICY DEVELOPMENT AND COORDINATION

The Budget reflects ONC's continued commitment to achieving a nationwide interoperable health IT system through coordination of health IT stakeholders. ONC works closely with public and private sector stakeholders, including providers, patients, payers, researchers, and policymakers, to advance a safe and secure health IT infrastructure. Through rulemaking and supporting activities authorized in the 21st Century Cures Act (Cures Act), ONC will continue to promote patient access to their health information and to reduce provider burden. In addition, ONC will coordinate federal health IT policy, lead Health IT Advisory Committee operations, and maintain the statutorily required website, HealthIT.gov.

Health IT Advisory Committee

The Budget supports a single Health IT Advisory Committee (HITAC), established by the Cures Act, that provides recommendations to the National Coordinator related to the implementation of a health IT infrastructure that advances the electronic access, exchange, and use of health information. The HITAC provides critical input from its 30 members, who represent a broad and balanced spectrum of the health care system. By the end of FY 2018, the HITAC and its task forces met 35 times to develop recommendations to address priority areas identified in the Cures Act. The HITAC has contributed to several ONC efforts, including the development of the Trusted Exchange Framework and Common Agreement, U.S. Core Data for Interoperability, and the Strategy for Reducing

Regulatory and Administrative Burden associated with the use of health IT and EHRs.

Promoting Trusted Exchange of Health Information

The Trusted Exchange Framework will establish a set of common principles, terms, and conditions that facilitate trust between health information networks. In FY 2020, ONC will implement this framework and work with private sector stakeholders to promote access, exchange, and use of relevant health information across networks. Through this exchange, patients and providers can access health information more easily and efficiently. This will enhance care coordination and delivery, and allow patients to participate in their care and manage their health information.

EFFECTS OF GAPS IN HEALTH INFORMATION

1 in 3 individuals who have seen a health care provider in the last year experienced at least one of the following gaps in information exchange.

Had to bring an X-Ray, MRI, or other type of test result with them to the appointment.

Had to wait for test results longer than they thought reasonable.

Had to redo a test or procedure because the earlier test results were not available.

Had to provide their medical history again because their chart could not be found.

Had to tell a health care provider about their medical history because they had not gotten their records from another health care provider.

Source: https://www.healthit.gov/sites/default/files/briefs/oncda-tabrief30_accesstrends_.pdf

Reducing Provider Burden

In the Cures Act, Congress directed ONC to work with healthcare stakeholders and CMS to reduce clinician burden from health IT.

For example, ONC and CMS heard from stakeholders—including physicians, nurse practitioners, physician assistants, and other clinicians who bill Medicare—that the evaluation and management documentation requirements are administratively burdensome and often medically unnecessary. In July 2018 CMS proposed the Physician Fee Schedule rule and announced plans to improve flexibility and reduce documentation requirements for office and outpatient evaluation and management billing. The final rule, published on November 1, 2018, significantly changed several documentation policies to reduce burden for clinicians who treat Medicare beneficiaries. These reforms could lead to more efficient and effective use of EHRs in clinicians' offices, and support patient-centered care. In FY 2020, ONC will continue to work with CMS and healthcare stakeholders to identify and implement efforts to reduce provider burden from health IT.

Addressing the Opioid Epidemic

ONC galvanizes health IT stakeholders, including healthcare practitioners, administrators, and physician practice owners, to leverage health IT to mitigate the opioid epidemic. In FY 2020, ONC will work closely with HHS partners to improve opioid prescribing practices, inform clinical practice, protect patients at risk, and reduce illegal use of prescription medications through health IT. This work will also advance the accessibility and interoperability of Prescription Drug Monitoring Programs.

STANDARDS, INTEROPERABILITY AND CERTIFICATION

ONC leads coordination, technical, and programmatic activities to develop and implement data standards to promote equity, scalability, integrity, and sustainability of information sharing. In FY 2020, ONC will advance nationwide health IT interoperability through implementation of the Cures Act. Interoperability will lead to improved patient care, inform consumers, and provide transparency into the cost and quality of care.

In FY 2020, ONC's standards work will focus on application programming interface standards, demonstration projects and pilots, implementation testing, and collaboration with industry stakeholders. These efforts will modernize health care computing through standardized application programming interfaces to improve clinical workflow, enable robust competition for useful and interoperable health IT products, and enhance patient access to their health

data which has shown positive benefits as illustrated below.

Health IT Certification Program

The FY 2020 Budget prioritizes ONC's mandate to operate the Health IT Certification Program, including the Certified Health IT Product List. The program maintains nearly 60 certification criteria used to standardize information across 21 federal efforts. By the end of 2018, the Certified Health IT Product List included health IT products from more than 600 health IT developers, and was used to register the EHR products of 550,000 care providers and hospitals participating in Medicare and Medicaid.

Combatting Information Blocking

In FY 2020, ONC's budget will prioritize interoperability and usability of electronic health information. The Cures Act directs ONC to continue its work to combat information blocking and build health IT exchanges. ONC will aggressively implement Certification Program rules that prohibit information blocking, create and promote channels for reporting information blocking, and enforce relevant provisions required of the Cures Act. The Certification Program will continue its oversight responsibilities and improve the surveillance of certified products for adherence to technical, security, and regulatory requirements for interoperability, and assess the potential for information blocking.

Promoting Operational Efficiencies

In FY 2020, ONC will continue to reduce operational and administrative costs in information technology, space, staff training, and agency travel. ONC will continue to seek additional administrative and operational efficiencies.

Office for Civil Rights

	dollars in millions			2020 +/- 2019
	2018	2019	2020	
Discretionary Budget Authority				
	39	39	30	-9
Civil Monetary Settlement Funds				
Settlement Funds	8	13	23	+10
Subtotal, Discretionary Budget Authority	**39**	**39**	**30**	**-9**
Total, Program Level	**47**	**52**	**53**	**+1**
Full-Time Equivalents /1	138	155	159	+4

1/ Includes Full-Time Equivalents supported at the Program Level.

The Office for Civil Rights is the Department's chief law enforcer and regulator of civil rights, conscience, religious freedom, and health information privacy and security.

The Fiscal Year (FY) 2020 Budget requests $30 million for the Office for Civil Rights (OCR), $9 million below the FY 2019 Enacted Level. OCR will use civil monetary settlement funds to support Health Insurance Portability and Accountability Act (HIPAA) enforcement activities, necessitating a smaller discretionary appropriation request. The Budget supports OCR's role as the primary defender of the public's right to:

- Nondiscriminatory access to, and receipt of, HHS-funded health and human services.
- Conscience and religious freedom protections.
- Access to, and privacy and security protections for, individually identifiable health information.

To carry out these functions, OCR investigates complaints, enforces rights, develops policy, promulgates regulations, and provides technical assistance and public education, to ensure understanding of, and compliance with, non-discrimination and health information privacy laws.

Case receipts across the range of complaints have continually risen the past few fiscal years and are expected to once again increase in FY 2020. In FY 2018, OCR received 33,194 complaints, an increase of 10 percent from FY 2017, resolving 28,466 cases, a 16 percent increase.

CIVIL RIGHTS

General Authorities

OCR works to safeguard individuals' access to health care, health coverage, and human services without discrimination. In particular, OCR enforces federal anti-discrimination laws with respect to race, color, national origin, disability, age, and sex in various programs that receive financial assistance from, or are conducted by, the Department.

OCR will continue to address a broad range of critical civil rights issues that address compliance issues and are of paramount importance to the American people. Examples of these activities include:

- OCR's national multimedia public education campaign (launched in 2018) to safeguard the civil rights of persons seeking treatment for opioid use disorder and ensure all persons have equal access to treatment.
- In January 2018, as part of its disability non-discrimination work, OCR partnered with the Office of the Inspector General and the Administration for Community Living to jointly publish a report to help improve the health and safety of, and respect for the civil rights of, individuals living in group homes. OCR continues to participate in a series of Department-coordinated outreach events to discuss the recommendations with stakeholders and to educate the general public.

HEALTH INFORMATION PRIVACY AND SECURITY

General Authorities

OCR administers and enforces the HIPAA Privacy, Security, and Breach Notification Rules (HIPAA Rules). OCR seeks to ensure covered entities understand and comply with their obligations under the HIPAA Rules, and to increase individuals' awareness of their HIPAA rights and protections. OCR accomplishes this objective by issuing regulations and guidance, conducting outreach, and providing technical assistance to the regulated community, in addition to pursuing investigations, settlement agreements, and civil monetary penalties.

OCR works to find and resolve substantial noncompliance with the HIPAA Rules. FY 2018 was a record year for OCR in enforcement: its collections, settlements, and judgments totaled over $25 million. High profile cases send important messages to industry stakeholders about the importance of protecting health information; however, they represent only a small portion of OCR's enforcement work. OCR investigates every breach affecting the health information of 500 or more individuals, and closes over 95 percent of its cases after investigation – often through the provision of technical assistance to ensure compliance with HIPAA regulations.

OCR continues to issue guidance to providers and consumers to facilitate access to needed health information and prevent inappropriate disclosures. For example:

- OCR published HIPAA guidance in FY 2018 empowering doctors to share information with loved ones to help persons with opioid use disorder. Throughout the year, OCR conducted outreach with key stakeholder groups to raise awareness of this new and important guidance.
- In June 2018, OCR issued additional guidance required by the 21st Century Cures Act explaining certain requirements for authorization to use or disclose protected health information for future research. The guidance also clarified aspects of the individual's right to revoke an authorization for research uses and disclosures of their personal health information.

CONSCIENCE AND RELIGIOUS FREEDOM

In FY 2018, OCR issued a notice of proposed rulemaking to promote effective and comprehensive compliance with and enforcement of 25 federal health care conscience and associated anti-discrimination laws. In addition, OCR established a Conscience and Religious Freedom Division to ensure protection of the conscience and religious freedom rights of individuals and entities working in health care and human services. The Conscience and Religious Freedom Division provides a central point at HHS to coordinate, oversee, and ensure compliance with federal laws protecting conscience and the free exercise of religion, and prohibiting coercion and religious discrimination. Examples of such laws include the Religious Freedom Restoration Act of 1993; the Church, Coats-Snowe, and Weldon Amendments; and section 1553 of the Affordable Care Act. The Division is actively engaged in outreach, enforcement, and policymaking.

OCR conducts nationwide investigations and enforcement activities under HHS's conscience and religious freedom authorities. Unlike the Civil Rights and Health Information Privacy Divisions, the Conscience and Religious Freedom Division is responsible for managing the totality of a conscience or religious freedom complaint, including all case processing and investigation.

Office of the Secretary

Office of Inspector General

	dollars in millions			
	2018	2019	2020	2020 +/- 2019
Health Care Fraud and Abuse Control (HCFAC) Program Discretionary	84	87	98	+11
HCFAC Mandatory	190	196	213	+17
HCFAC Collections	12	11	12	+1
Subtotal, HCFAC Oversight	**287**	**294**	**323**	**+29**
Public Health and Human Services Oversight Discretionary Budget /1	82	87	80	-7
Total, Program Level	**369**	**381**	**403**	**+22**
Full-Time Equivalents	1601	1650	1670	+20

1/ FY 2018 includes $1.5 million for the FDA transfer (PL 115-245). Funding level does not include supplemental hurricane appropriations ($2 million). FY 2019 Enacted includes the current annualized FY 2019 CR level of $1.5 million for the FDA transfer (PL 115-245) and $5 million required transfer from NIH in the Labor, Health and Human Services, and Education and Related Agencies appropriations bill.

The mission of the Office of Inspector General is to protect the integrity of Department of Health and Human Services programs, as well as the health and welfare of the people they serve.

The Department of Health and Human Services, Office of Inspector General (OIG) is the largest inspector general's office in the federal government, with approximately 1,600 employees dedicated to combating fraud, waste and abuse and improving the efficiency of HHS programs. A majority of OIG's resources goes toward the oversight of Medicare and Medicaid—programs that represent a significant part of the federal budget and affect our country's most vulnerable citizens. OIG's oversight extends to programs under other HHS agencies such as the Centers for Disease Control and Prevention, National Institutes of Health, and the Food and Drug Administration.

The Fiscal Year (FY) 2020 Budget requests $403 million for OIG, an increase of $22 million above FY 2019 primarily for Medicare and Medicaid oversight. These funds will enable OIG to target oversight efforts and ensure efficient and effective use of resources within the Department's programs through the development of new data models and tools to support data-driven audits, evaluations, and inspections.

OIG's areas of oversight fall into two broad categories:

- Public Health and Human Services Oversight.
- Medicare and Medicaid Oversight.

PUBLIC HEALTH AND HUMAN SERVICES OVERSIGHT

OIG uses discretionary budget funds to conduct program integrity and enforcement activities for HHS programs and operations. OIG will continue to review activities for any evidence of fraud, waste, and abuse, and oversee new and emerging issues related to HHS's international and domestic response to public health issues and new cyber-security threats facing the Department.

The FY 2020 Budget requests $80 million for Public Health and Human Services Oversight to strengthen the integrity of HHS programs through the following investments:

- **Indian Health Service:** OIG will continue providing oversight to promote quality of care, safety, and program integrity in the Indian Health Service.
- **Grants Oversight:** OIG will continue its focus on oversight of high-risk grant programs, including grants for services to children and grants for opioid abuse prevention and treatment programs provided under the 21st Century Cures Act. OIG will continue to provide training and education to prevent grant fraud, waste, and abuse. OIG will leverage successful approaches from Medicare and Medicaid oversight to help ensure high-risk grant

and contract funds are administered and used properly.

- **Privacy and Security:** OIG will enable HHS to enhance its cybersecurity and the security of public health data held in non-HHS systems through increased audits and penetration testing that identify risks and vulnerabilities. OIG will also support more investigations of cyber threats and criminals stealing valuable health care data to commit fraud.
- **Public Health Emergencies**: OIG will continue oversight of HHS grants for emergency preparedness and make recommendations to prevent fraud, waste, and abuse.

MEDICARE AND MEDICAID OVERSIGHT

Through its oversight work, OIG saves taxpayer dollars and works to ensure that patients receive medically appropriate care in the nation's largest health care programs—Medicare and Medicaid. OIG relies on principles of prevention, detection, and enforcement to address fraud, waste, and abuse in these programs. Two key focus areas are sound fiscal management of the programs and ensuring beneficiaries receive quality care.

OIG protects these programs and their beneficiaries using a multidisciplinary approach and through important partnerships, including with the Department of Justice and State Medicaid Fraud Control Units. Many fraudulent providers cheat both Medicare and Medicaid and the beneficiaries who rely on these programs. OIG fraud-fighting and patient protection activities often have cross-cutting impacts. The Health Insurance Portability and Accountability Act established the HCFAC Program to combat fraud, waste, and abuse in health care. The HCFAC Program provides funds to OIG dedicated to activities relating to Medicare and Medicaid fraud and abuse. Overall, HCFAC funding constitutes the major portion of OIG's annual operating budget.

The FY 2020 Budget for OIG includes $323 million for Medicare and Medicaid oversight, an increase of $29 million over FY 2019. The additional resources will support the development of new data models and tools to support data-driven audits, evaluations, and inspections. These models and tools will help OIG detect and target new and emerging fraud schemes, trends, and migration of known fraud schemes. Resources will be used to conduct reviews expected to result in new recommendations for targeted program safeguards and improvements to prevent fraud, waste, and abuse and patient neglect; create efficiencies; and promote patient-centered outcomes, while also eliminating unnecessary burden on legitimate providers. With these resources, OIG will focus oversight on new technologies, including telehealth and digital technologies, that are increasingly being used by Medicare and Medicaid beneficiaries in their homes.

Home Health and Other Noninstitutional-Based Services

Services provided in a beneficiary's home or other noninstitutional settings, including home health, hospice, and other home- and community-based services, are susceptible to fraud. OIG has identified serious health and human services program vulnerabilities in both the fiscal integrity of payments made for services delivered and the quality of care received in noninstitutional care settings. Funding will support expansion of prevention, detection, and enforcement efforts that help ensure the integrity, quality, and safety of the services rendered in homes and other noninstitutional care settings.

Medicaid Program Integrity

OIG work shows persistent and serious fraud vulnerabilities in Medicaid. OIG will continue to partner with states to identify high-risk areas and providers, and with Medicaid Fraud Control Units on joint criminal investigations to tackle fraud, including in home- and community-based services, including personal care services; prescription drugs; and fraud affecting both Medicare and Medicaid. OIG will continue program integrity efforts that identify needed improvements and best practices in critical areas, such as provider enrollment, data availability and accuracy, and safety of care.

OIG's "boots on the ground" initiative is designed to take enforcement actions against fraud perpetrators, including building OIG's capacity to respond to referrals generated by its own analyses.

OIG seeks to enhance program integrity in geographic hot spots through outreach, education, audits, evaluations, inspections, investigations, and administrative enforcement.

Medicare Managed Care

Approximately 30 percent of Medicare beneficiaries are enrolled in Medicare Advantage. OIG will continue to develop and implement a sustained, focused, and strategic initiative to combat fraud and abuse in Medicare Advantage. OIG will use audits, evaluations, investigations, and enforcement actions to prevent, detect, and remediate fraud, waste, and abuse in Medicare Advantage. These efforts will employ advanced data modeling and specialized clinical expertise, including medical record review.

Public Health and Social Services Emergency Fund

	dollars in millions			
	2018 /1	2019	2020	2020 +/- 2019
Assistant Secretary for Preparedness and Response (ASPR)				
Preparedness and Emergency Operations	25	25	25	--
National Disaster Medical System	57	57	77	+20
Hospital Preparedness Program	265	265	258	-7
Medical Reserve Corps	6	6	4	-2
Biomedical Advanced Research and Development Authority	537	562	562	--
Project BioShield	710	735	735	--
Strategic National Stockpile /2	604	610	620	+10
Policy and Planning	15	15	20	+5
Operations	31	31	31	--
Subtotal, ASPR	**2,249**	**2,305**	**2,331**	**+26**
Other Office of the Secretary				
Office of National Security (ONS) /3	8	7	7	--
Cybersecurity /3	50	59	68	+9
Subtotal, Other Office of the Secretary	**58**	**66**	**76**	**+9**
Pandemic Influenza				
No-Year Funding	215	225	225	--
Annual Funding	35	35	35	--
Subtotal, Pandemic Influenza	**250**	**260**	**260**	**--**
Total Discretionary Budget Authority	**2,557**	**2,631**	**2,667**	**+35**
Full-Time Equivalents	732	1,007	1,017	+10

1/ Reflects the FY 2018 enacted, post required and permissive transfers and rescissions. Funding level does not include supplemental hurricane appropriations ($80 million).
2/ HHS administratively transferred the SNS from CDC to ASPR in FY 2019. Funding in FY 2018 is comparably adjusted and includes a Secretarial transfer of $6.1 million to CDC for transition costs. Funding in FY 2019 does not reflect an additional Secretarial transfer of $6.1 million to CDC.
3/ FY 2018 total reflects a realignment of $1.04 million from Cybersecurity to ONS to support the cyber threat activities carried out by ONS.

The Public Health and Social Services Emergency Fund's mission is to directly support the nation's ability to prepare for, respond to, and recover from, the health consequences of naturally occurring and man-made threats.

Within the Office of the Secretary, the Public Health and Social Services Emergency Fund (PHSSEF) supports efforts across the U.S. Department of Health and Human Services (HHS) to safeguard the public and prepare the nation for a wide range of health security threats. The Fiscal Year (FY) 2020 Budget includes $2.7 billion, an increase of $35 million above FY 2019. Resources support the Department's biodefense capacity, information security needs, and disaster response capability. The additional funds support medical countermeasure stockpiling, pediatric care during emergencies, and cybersecurity enhancements.

BIOTERRORISM AND EMERGENCY PREPAREDNESS

PHSSEF agencies support bioterrorism and emergency preparedness activities that prepare the nation to respond to, and recover from, natural and man-made

public health threats. HHS leads the federal response to public health emergencies and incidents covered by the National Response Framework. These responsibilities include coordinating public health and medical services, and supporting the delivery of mass care, emergency assistance, housing, and human services when state and local response and recovery needs exceed their capability. The PHSSEF supports many of the Department's key crosscutting preparedness and response efforts, including:

- Responding to emergency situations,
- Developing, procuring, and stockpiling medical countermeasures,
- Enhancing state and local health care readiness in coordination with the Centers for Disease Control and Prevention (CDC) , and
- Supporting emergency response planning and policy coordination efforts across HHS.

ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

The mission of the Assistant Secretary for Preparedness and Response (ASPR) is to save lives and protect Americans from 21st century health security threats. In partnership with other HHS Operating and Staff Divisions, ASPR prepares the nation to withstand public health and medical emergencies by promoting resilient communities, deploying emergency resources and medical personnel, and managing logistical support for disaster areas. ASPR collaborates with academia, non-government organizations, and private sector companies, including the pharmaceutical industry, to develop and manufacture vaccines, drugs, devices, and technologies to combat chemical, biological, radiological, and nuclear threat agents.

The FY 2020 Budget includes $2.6 billion for ASPR, including Pandemic Influenza, an increase of $26 million above FY 2019. This total reflects the FY 2019 transfer of the Strategic National Stockpile (SNS) from the CDC to ASPR. The Budget prioritizes enhanced pediatric care during emergencies, biodefense strategy coordination, and the advanced development of medical countermeasures through procurement, storage, and deployment. These investments ensure ASPR can fulfill its unique federal role to protect all Americans from the impact of natural disasters, terrorist threats, and emerging infectious diseases on their health.

Biomedical Advanced Research and Development Authority (BARDA)

The Budget includes $562 million for BARDA to support the advanced development of medical countermeasures, including vaccines, therapeutics, diagnostics, and devices against chemical, biological, radiological and nuclear threats. BARDA works with public and private partners to transition candidate medical products from early development into the advanced and late stages of development and approval, licensure, or clearance by the Food and Drug Administration (FDA). BARDA provides clinical and non-clinical support services and advances innovative technologies and approaches to product development and manufacturing, including repurposing commercial products for biothreat needs and supporting the development of new multipurpose products for treating multiple illnesses.

MEDICAL COUNTERMEASURE ADVANCED RESEARCH AND DEVELOPMENT

BARDA has proven successes of building a robust research and development pipeline for medical countermeasures, supporting 43 Food and Drug Administration (FDA) product approvals since 2006.

In 2018, nine medical countermeasures supported by BARDA achieved FDA approval including:

- *Antibiotics for complicated infections*
- *Smallpox antiviral drug*
- *Treatment for radiation exposure*

In 2018, BARDA also supported critical manufacturing efficiency improvements to increase pandemic influenza vaccine production capacity.

The FY 2020 Budget will support advanced development of the highest priority medical countermeasures, including Ebola vaccines and therapeutics, broad-spectrum antimicrobials, treatments for illnesses caused by radiation and

thermal burns, and antidotes and diagnostics for chemical and biological agents. BARDA will also continue efforts under the Division of Research, Innovation, and Ventures (DRIVe) to expand public-private investment in innovative health security technologies and products. DRIVe accelerates health care innovation by supporting a nationwide network of accelerators along with venture capital practices to assist startups and businesses with developing transformative medical countermeasures. DRIVe is currently focused on enhancing medical countermeasure innovations in wearable diagnostics, distributed manufacturing technologies, and combatting sepsis.

Project BioShield

The Budget provides $735 million for Project BioShield to support late-stage development and procurement of medical countermeasures for the Strategic National Stockpile. Following successful advanced development of medical countermeasures, BARDA supports late-stage development and potential procurement of promising products through Project BioShield. The products need to be of sufficient maturity for potential use during a public health emergency. Project BioShield's goal is to support late-stage development of products towards FDA approval. The FY 2020 Budget will support development and procurement of products, including:

- Ebola vaccines and therapeutics,
- a next generation anthrax vaccine,
- new antibacterial drugs,
- a therapeutic to minimize injury resulting from exposure to chemical agents, and
- new countermeasures to detect and treat acute exposure to ionizing radiation.

Progress achieved through Project BioShield continues to improve the nation's readiness to respond to the medical consequences of public health threats to homeland security. BARDA's commitment to advanced development and enhanced partnerships with industry under Project BioShield has led to the late-stage development and procurement of 27 medical countermeasures, of which 15 were delivered to the SNS and 10 achieved FDA approval since 2004. Products developed and procured through Project BioShield protect against adverse health effects of anthrax, botulism, smallpox, viral hemorrhagic fever, and chemical, radiological, and nuclear agents. BARDA anticipates three new products transitioning to Project BioShield in FY 2020, as well as additional FDA product approvals.

BARDA's antimicrobial program leverages public-private partnerships to advance innovation in antibacterial drug, vaccine, and diagnostic development, supporting the government-wide National Action Plan for Combating Antibiotic Resistant Bacteria. Under BARDA's antimicrobial program, three products have been approved by the FDA that are able to treat hospital and community acquired bacterial infections and infections resulting from biothreat agents. BARDA also collaborates with the National Institutes of Health, academia, and private partners through the Combating Antibiotic Resistant Bacteria Accelerator (CARB-X), which accelerates the efforts of numerous companies developing novel classes of antibiotics and new approaches to treating drug resistant bacterial infections. The Budget provides funding to continue to support BARDA's antimicrobial drug pipeline, new diagnostic technologies, and CARB-X investments.

Strategic National Stockpile

The Strategic National Stockpile (SNS) is the nation's largest federally owned repository of life-saving pharmaceuticals, medical equipment and supplies, and Federal Medical Stations that can be rapidly deployed to support federal, state, and local emergency responses. The SNS is the only federal resource readily available to respond when state and local medical supplies are depleted, or when unique medical supplies are required but not commercially available. The Budget provides $620 million for the SNS, which is $10 million above FY 2019. The transfer of the SNS to ASPR has consolidated strategic decision-making for product development and procurement and streamlined leadership to enable nimble responses to public health emergencies. The Budget supports procurement of products transitioned from Project BioShield, inventory replenishments, and continued training for responders nationwide to sustain state and local capabilities to receive and use stockpiled products when deployed. The increased funding level supports procurements of a newly developed thermal burn bandage and smallpox antiviral drug.

Hospital Preparedness Program

The Hospital Preparedness Program (HPP) is the only source of federal funding devoted to readying the United States' complex health care system to save lives and protect Americans. ASPR supports hospitals and

health care coalitions through HPP to expand critical care during large-scale emergencies. HPP improves response systems, conducts realistic exercises, builds collaborative partnerships, and facilitates valuable information sharing. The Budget provides $258 million for ASPR's HPP, funding cooperative agreements with 62 awardees, including all 50 states, eight U.S. territories and freely associated states, and four localities, to continue support for hospital preparedness awards at the FY 2019 level. HPP will prioritize efficiency and effectiveness by continuing to incorporate risk into the funding formula.

National Disaster Medical System

The FY 2020 Budget provides $77 million, an increase of $20 million above FY 2019, to support the National Disaster Medical System (NDMS), a federally coordinated system of intermittent federal employees who deploy in the event of a natural or manmade disaster to provide critical medical services, protect public health, and help communities recover faster. The $20 million increase will continue support for the pediatric disaster care pilot initiative which aims to improve pediatric care during emergencies. NDMS includes clinical and emergency medical providers that deploy to provide medical, veterinary, and mortuary response activities; patient movement support; definitive care; and behavioral health support in coordination with the local health system in the impacted region(s).

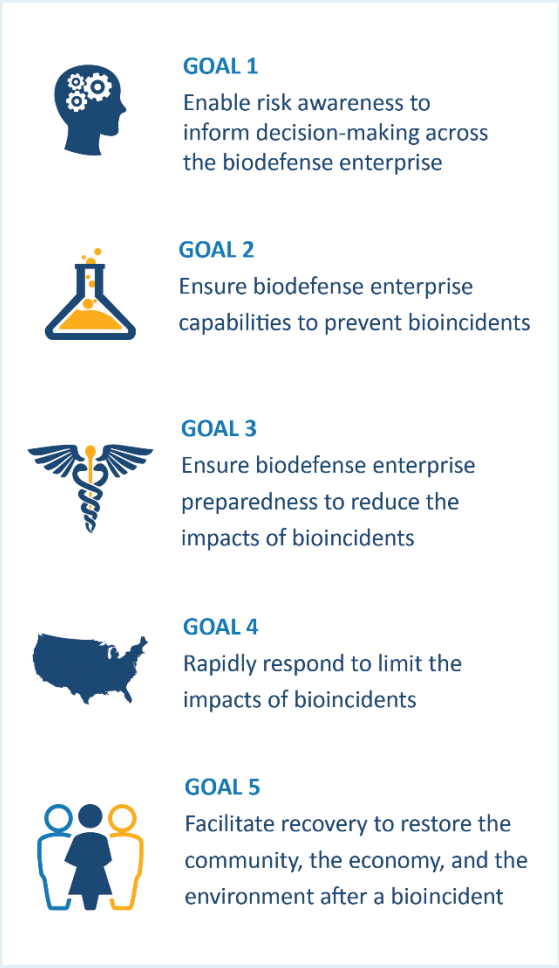
Medical Reserve Corps

The Medical Reserve Corps is a national network of over 200,000 volunteers organized into 1,000 community-based units across the U.S. The Budget provides $4 million for ASPR's management of the Medical Reserve Corps. Medical Reserve Corps units have supported numerous community public health missions, participated in local and regional exercises across the Nation, and responded during emergencies when called upon by state and local response agencies.

Office of Strategy, Planning, Policy, and Requirements

ASPR is tasked with implementing the government-wide, HHS-led National Biodefense Strategy. The President launched the National Biodefense Strategy in 2018 to protect America from modern biological threats. The strategy establishes the U.S. government's vision for biodefense, and also helps prioritize and coordinate federal biodefense activities. Led by the Secretary, the Strategy's implementation requires complex coordination, leadership commitment, and an effective governance structure. The Secretary directed ASPR to lead the day-to-day coordination team to advance a whole-of-nation approach to biodefense. The Budget includes an additional $5 million above FY 2019 to operationalize the Strategy across 17 covered agencies.

NATIONAL BIODEFENSE STRATEGY GOALS



PANDEMIC INFLUENZA

The Budget invests in pandemic influenza readiness by supporting domestic influenza vaccine manufacturing infrastructure; vaccine stockpiling; advanced development of novel influenza vaccines, therapeutics, diagnostics and respiratory protective devices; and international pandemic preparedness efforts. These activities maintain and improve the significant pre-pandemic preparedness and response capabilities

developed over the last decade, including technologies to improve and transform the nation's approach to pandemic readiness. The FY 2020 Budget provides a total of $260 million for pandemic influenza preparedness activities carried out by ASPR and the Office of Global Affairs.

The FY 2020 Budget will maintain current manufacturing capacity and accelerate the transition to, and further increase domestic production capacity of, modern cell or recombinant based influenza vaccines. The Budget also supports development of broadly effective influenza therapeutics or antivirals and rapid diagnostic tests to promote early detection of influenza viruses. ASPR invests in the advanced development of influenza countermeasure candidates through successful public-private partnerships with pharmaceutical companies that have the necessary infrastructure and manufacturing capacity to develop transformative influenza products.

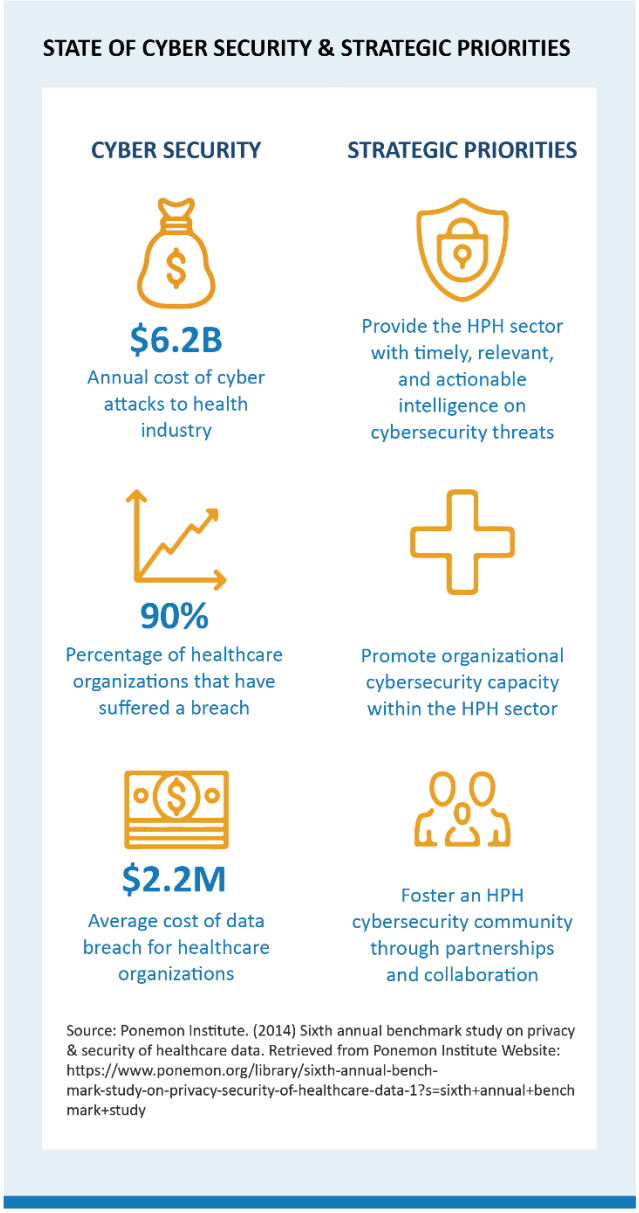
DEPARTMENT-WIDE INFORMATION SECURITY

Office of National Security

The FY 2020 Budget includes $7 million for the Office of National Security (ONS). ONS identifies, prioritizes, assesses, remediates, and protects critical infrastructure information for the health care and public health sectors. ONS integrates and synthesizes intelligence and all-source information on public health, terrorism, national security, weapons of mass destruction, and homeland security, and protects sensitive information for the Department. This funding will allow ONS to continue to serve clients across HHS, other U.S. government agencies, and 18 agencies within the intelligence community. ONS's activities provide policymakers with early indicators and warnings of potential national security threats.

Cybersecurity

The Cybersecurity program ensures the Department's critical information is secure. The FY 2020 Budget provides $68 million for the Cybersecurity program, an increase of $9 million above FY 2019. This funding supports solutions to identify, evaluate, acquire, coordinate, and deploy cybersecurity information and tools across the Department as well as the Health and Public Health sector. This increase will enable the Department to take action against cyber threats; limit the impact of those events; and engage with stakeholders, both internal and external to HHS, to provide cybersecurity solutions, workforce, and tools integration to enhance threat identification and management.



Abbreviations and Acronyms

A

ACF	Administration for Children and Families
ACL	Administration for Community Living
ACO	Accountable Care Organization
ACT NOW	Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome
AFM	Acute Flaccid Myelitis
AHRQ	Agency for Healthcare Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
ALJ	Administrative Law Judge
APM	Alternative Payment Model
ASPR	Assistant Secretary for Preparedness and Response
ATSDR	Agency for Toxic Substances and Disease Registry
ASP	average sales price

B

BA	budget authority
BARDA	Biomedical Advanced Research and Development Authority
BPCI	Bundled Payments for Care Improvement

C

CARB-X	Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator
CBRN	chemical, biological, radiological, and nuclear
CCBHC	Certified Community Behavioral Health Clinic
CCDBG	Child Care and Development Block Grant
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CPI-U	Consumer Price Index for all Urban Consumers
CR	Continuing Resolution
CY	Calendar Year

D

DAB	Departmental Appeals Board
DAWN	Drug Abuse Warning Network
DEA	Drug Enforcement Agency
DME	Durable Medical Equipment
DMEPOS	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
DOJ	Department of Justice
DRIVe	Division of Research, Innovation, and Ventures
DSH	Medicaid Disproportionate Share Hospital

E

E/M	evaluation and management
EHR	electronic health record
ESRD	End-Stage Renal Disease
ET3	Emergency Triage, Treat, and Transport

F

FDA	Food and Drug Administration
FSMA	Food Safety Modernization Act
FY	Fiscal Year
FUL	Federal Upper Limit

G

GDM	General Departmental Management
GME	Graduate Medical Education

H

HCFAC	Health Care Fraud and Abuse Control
HEAL	Helping to End Addiction Long-term
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HITAC	Health Information Technology Advisory Committee
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immune Deficiency Syndrome
HMRF	Healthy Marriage Promotion and Responsible Fatherhood
HPOG	Health Profession Opportunity Grants
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
HSA	Health Savings Accounts

I

ICU	intensive care unit
IDeA	Institutional Development Award
IHS	Indian Health Service
InCK	Integrated Care for Kids Model
IPPS	Inpatient Prospective Payment System
IT	Information Technology

L

LTCH	Long Term Care Hospital
LIS	Low-income subsidy

M

MA VBID	Medicare Advantage Value Based Insurance Design
MAGI	Modified Adjusted Gross Income
MEPS	Medical Expenditure Panel Survey
MIPS	Merit-based Incentive Payment System
MOM	Maternal Opioid Misuse
MSA	Medicare Savings Accounts

N

NCI	National Cancer Institute
NDMS	National Disaster Medical System
NDNH	National Directory of New Hires
NEMT	Non-Emergency Medical Transportation
NIDILRR	National Institute on Disability, Independent Living, and Rehabilitation Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NIRSQ	National Institute for Research on Safety and Quality
NVDRS	National Violent Death Reporting System

O

OASH	Office of the Assistant Secretary for Health
OCR	Office for Civil Rights
OIG	Office of Inspector General
OMHA	Office of Medicare Hearings and Appeals
ONC	Office of the National Coordinator for Health Information Technology
ONS	Office of National Security
OPPS	Medicare Outpatient Prospective Payment System

P

PACE	Program of All-inclusive Care for the Elderly
PHS	Public Health Service
PHSSEF	Public Health and Social Services Emergency Fund
PrEP	pre-exposure prophylaxis

R

RADV	Risk Adjustment Data Validation
RCORP	Rural Communities Opioids Response Program
RFI	Request for Information
RWHAP	Ryan White HIV/AIDS Program

S

SAMHSA	Substance Abuse and Mental Health Services Administration
SEP	Special Enrollment Period
SNS	Strategic National Stockpile
SSBG	Social Services Block Grant
STI	Sexually-Transmitted Infections

T

TANF	Temporary Assistance for Needy Families
TrOOP	true out-of-pocket costs
TB	tuberculosis

W

WAC	wholesale acquisition cost

Exhibit B to the Request for Judicial Notice

GUIDELINES FOR REGULATORY IMPACT ANALYSIS

2016

Office of the Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services

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These *Guidelines for Regulatory Impact Analysis* were prepared for the U.S. Department of Health and Human Services (HHS) Analytics Team, under the leadership of Amber Jessup (Office of the Assistant Secretary for Planning and Evaluation). The primary authors were Lisa A. Robinson and James K. Hammitt (Harvard University Center for Risk Analysis and Center for Health Decision Science) and Jennifer R. Baxter (Industrial Economics, Incorporated, IEc). The work was performed between 2013 and 2016 under subcontract to IEc and Mathematica Policy Research; Ms. Baxter was the IEc Project Leader. Dr. Hammitt's work was also supported by an HHS Intergovernmental Personnel Act agreement. The authors were assisted by IEc staff including Lindsay Ludwig, who helped develop the initial drafts of several sections; Margaret Black, who provided additional editorial support and helped draft the related primer; and Michael Welsh, who helped develop the index and glossary.

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This guidance represents the current thinking of the Department of Health and Human Services (HHS) on the conduct of regulatory impact analysis. It does not establish any requirements for any person and is not binding on HHS, any HHS agencies or the public. You can use an alternative approach if it satisfies the requirements of the applicable Executive Orders and regulations. To discuss an alternative approach, contact the Office of the Assistant Secretary for Planning and Evaluation.

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Acronyms

ASPE	Assistant Secretary for Planning and Evaluation
BLS	U.S. Bureau of Labor Statistics
CBO	Congressional Budget Office
CDC	Centers for Disease Control and Prevention
CEA	cost-effectiveness analysis
Census	U.S. Census Bureau
CPI	Consumer Price Index
CPS	Current Population Survey
CRA	Congressional Review Act
DOT	U.S. Department of Transportation
ECEC	Employer Costs for Employee Compensation
ECI	Employer Cost Index
EQ-5D	EuroQol-5 Dimensions
FDA	Food and Drug Administration
FICA	Federal Insurance Contributions Act
FRFA	Final Regulatory Flexibility Analysis
G&A	general and administrative
GAO	Government Accountability Office
GDP	gross domestic product
GSA	U.S. General Services Administration
HHS	U.S. Department of Health and Human Services
HRQL	health-related quality of life
HUI	Health Utilities Index
ICR	Information Collection Request
IRFA	Initial Regulatory Flexibility Analysis
IRS	Internal Revenue Service
NCS	National Compensation Survey
NHTSA	National Traffic Highway Safety Administration
O&M	operations and maintenance
OES	Occupational Employment Statistics
OMB	U.S. Office of Management and Budget
PRA	Paperwork Reduction Act
QALY	quality-adjusted life year
QCEW	Quarterly Census of Employment and Wages
QWB	Quality of Well-Being
RFA	Regulatory Flexibility Act
RIA	regulatory impact analysis
SBA	Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act
SOP	standard operating procedure
UMRA	Unfunded Mandates Reform Act

VSL	value per statistical life
VSLY	value per statistical life year
WTA	willingness to accept compensation
WTP	willingness to pay

Chapter 1
Introduction

Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011) call for a regulatory system that protects "public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation." To achieve these goals, the Department of Health and Human Services (HHS) analyzes the benefits, costs, and other impacts of significant proposed and final rulemakings, consistent with the requirements of the executive orders.

In the HHS 2011 *Plan for Retrospective Review of Existing Rules*, the Assistant Secretary for Planning and Evaluation (ASPE) was asked to establish an agency-wide Analytics Team to provide recommendations for strengthening regulatory analysis, leveraging the existing expertise of economists and analysts from throughout the Department's operating divisions.[1] The Analytics Team investigated current challenges and determined that guidance was needed to address common difficulties and to ensure consistent treatment across agencies. To meet that need, the Department developed these *Guidelines for Regulatory Impact Analysis* to assist its agencies in conducting economic analyses that meet the goals of the executive orders. This chapter briefly introduces related requirements and the contents of these *Guidelines*.

1.1 WHAT IS REGULATORY IMPACT ANALYSIS?

A regulatory impact analysis (RIA) reflects a well-established and widely-used approach for collecting, organizing, and analyzing data on the impacts of policy options, to promote evidence-based decision-making. It provides an objective, unbiased assessment that is an essential component of policy development, considering both quantifiable and unquantifiable impacts. Along with information on legal requirements, general policy goals, the distribution of the impacts, and other concerns, it forms the basis of the ultimate policy decision.

The RIA describes the effects of the regulation rather than advocating a particular approach. The arguments supporting the agency's decision are provided separately in the preamble to the *Federal Register* notice for the proposed and final regulation. The core of the RIA is an assessment of the benefits and costs of regulatory and other policy options in comparison to a "without regulation" (or "no action") baseline. In addition, the RIA includes supplementary analyses that respond to various statutory and administrative requirements.

WHY PREPARE AN RIA?

RIAs provide objective information and analysis that is essential for evidence-based decision-making. They include a benefit-cost analysis as well as other analyses mandated by various statutes and executive orders.

The RIA framework is described in general terms in Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011).[2] More specific guidance and oversight is provided by the Office of Information and Regulatory Affairs within the U.S. Office of Management and Budget (OMB), which is part of the Executive Office of the President. OMB reviews both the regulation and the supporting analysis prior to promulgation.[3] Its primary analytic

[1] We provide links to those documents that are freely available on the internet in the reference list. Where possible, we link to the webpage that features the document rather than to the document itself, so that readers can check for updates.

[2] These requirements apply only to the extent allowable by law.

[3] Under the Congressional Review Act (CRA), agencies must also submit final rules and supporting analyses to the Government Accountability Office (GAO) for congressional review prior to promulgation. This submission must indicate whether the rule is "major" as defined under the CRA (5 USC §804(2)): "'major rule' means any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in — (A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. The term does not include any rule promulgated under the Telecommunications Act of 1996 and the amendments made by that Act." More information is available on the GAO website (http://www.gao.gov/legal/congressact/cra_faq.html).

guidance is provided in *Circular A-4* (2003); it summarizes related requirements in a checklist for agencies (2010), a compilation of frequently-asked questions (2011a), and a primer (2011b). The OMB checklist is replicated in Appendix A of this document. Examples of RIAs completed by HHS and other agencies can be found by searching regulations.gov; however, analysts should be aware that many of the HHS analyses were completed prior to issuance of these *Guidelines*.[4]

In addition to the assessment of the benefits and costs, the RIA may include supplementary analyses that address the following, as relevant.

- the distribution of the impacts;
- the Unfunded Mandates Reform Act;
- the Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Act;
- Executive Order 13132, "Federalism;"
- Section 1102(b) of the Social Security Act, small rural hospitals; and,
- the Paperwork Reduction Act.

More information on these requirements, as well as on the conduct of the benefit-cost analysis, is provided in the subsequent chapters of this guidance.

1.2 WHAT ARE THE BENEFITS AND COSTS OF CONDUCTING AN RIA?

The most important goals of the RIA are (1) to indicate whether Federal regulation is necessary and justified, and, if so, (2) to identify the regulatory option that is most economically efficient, providing the largest net benefits to society. A well-conducted RIA has numerous additional benefits. It develops the evidence to support well-informed decision-making and supplies a record of the data, assumptions, and analyses considered – providing a reasonable basis for rulemaking as required by the Administrative Procedures Act.

The RIA plays several other useful roles. For example, it:

- encourages comprehensive consideration of impacts;
- provides information on important regulatory outcomes expressed in physical and behavioral terms;
- estimates the economic value of the outcomes, based on the preferences of those who are affected;
- anticipates potential side effects, beneficial and adverse;
- supports consideration of non-quantifiable effects and uncertainty; and,
- aids decision-makers and stakeholders in clarifying areas of agreement and disagreement.

The costs of conducting RIAs include the need to devote staff and funding to preparing these assessments rather than to other tasks. To ensure the efficient use of these resources, the analysis should be carefully tailored to focus on providing the information that is most important for decision-making. Screening analysis, discussed in the following chapter, is a useful tool for targeting efforts.

1.3 WHEN IS AN RIA REQUIRED?

An RIA is required for significant and economically significant regulatory actions as defined under Executive Order 12866 (§3(d-f)) and Executive Order 13563. An economically significant regulatory action is one that:

- is likely to **impose costs, benefits, or transfers of $100 million or more** in any given year, or
- "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities" (Clinton 1993, §3(f)(1)).

[4] Many agencies also post their RIAs on their websites. For example, analyses completed by the Food and Drug Administration (FDA) can be found at: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.

If a regulation is economically significant, then the analysis discussed in OMB *Circular A-4* (and described in more detail in these *Guidelines*) must be completed (Clinton 1993, §6(a)(3)(C)).

In addition, many other regulations are considered "significant," defined as those that:

- "[c]reate a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- [m]aterially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- [r]aise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order" (Clinton 1993, §3(f)(2-4)).

For regulatory actions that are significant, but not economically significant, Executive Order 12866 requires:

- "a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need," and
- "[a]n assessment of the potential costs and benefits of the regulatory action" (Clinton 1993, §6(a)(3)(B)).

Agencies may wish to complete RIAs for regulations that are not defined as significant to improve the foundation for decision-making and to demonstrate the rationale and basis for the action.

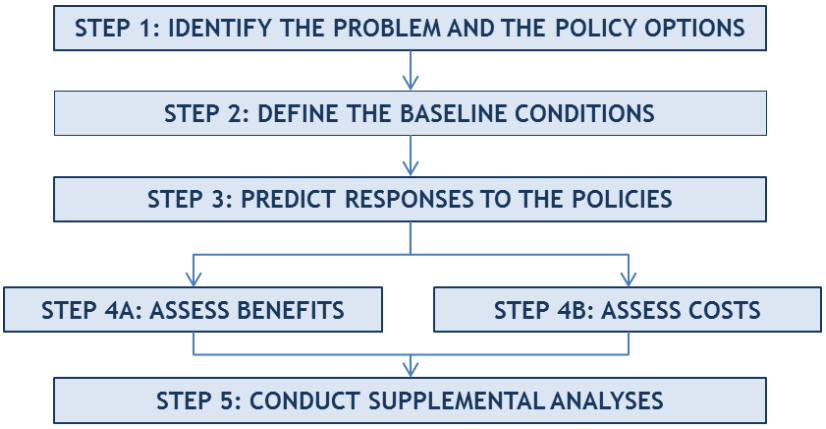
HOW DOES OMB INTERPRET THE $100 MILLION THRESHOLD?

An RIA is required for economically significant regulations. In defining "economically significant," OMB (2011a) states, "The $100 million threshold applies to the impact of the proposed or final regulation in any one year, and it includes benefits, costs or transfers." The word "or" is important: the categories are considered separately, not summed, so $100 million in any of the three categories -- annual benefits, or costs, or transfers -- is sufficient. For example, a regulation with $75 million in benefits, $60 million in costs, and $40 million in transfers is not economically significant. An RIA is also required for regulations deemed to be significant for other reasons and is an essential element of good regulatory practice.

1.4 WHAT ARE THE BASIC COMPONENTS?

The remaining chapters of this guidance are organized around the major components of an RIA, as illustrated in Figure 1.1.

FIGURE 1.1. MAJOR RIA COMPONENTS



- The first three steps are discussed in **Chapter 2: Frame the Analysis**.
- Steps 4A and 4B are described in detail in **Chapter 3: Assess Benefits** and **Chapter 4: Assess Costs**.
- Topics that affect the assessment of both benefits and costs are considered in **Chapter 5: Account for Timing** and **Chapter 6: Address Uncertainty and Nonquantifiable Effects**.
- The analyses under step 5 are discussed in **Chapter 7: Conduct Distributional and Other Supplementary Analyses.**
- The presentation of the results is considered in **Chapter 8: Communicate the Approach and Results.**
- The *Guidelines* conclude by turning from the discussion of *ex ante* (prospective) analysis to *ex post* analysis in **Chapter 9: Conduct Retrospective Analysis.**

Supplementary information is provided in the appendices.

Chapter 2
Frame the Analysis

Conducting an RIA involves first defining the problem to be addressed, identifying the policies to be assessed, exploring their potential consequences, and developing the approach for subsequent analytic work. This chapter describes these steps, focusing on the benefit-cost analysis that forms the core of the RIA. As introduced in Chapter 1 and discussed in more detail in Chapter 7, an RIA includes several supplementary analyses, to which the principles discussed in this chapter also apply. These analyses should be initiated in the early stages of the regulatory development process, to inform both internal agency deliberations and discussions with other stakeholders.

Benefit-cost analysis is a well-established systematic framework, based on economic welfare theory, for assessing and comparing the positive and negative impacts of policy options. It addresses the question of whether those affected by the policy, in the aggregate, value the benefits they receive more than the costs they incur. The distribution of the impacts (who receives the benefits and who bears the costs) is assessed separately (see Chapter 7).

The goal of the benefit-cost analysis is to indicate how limited resources can be best allocated to maximize net social welfare. Welfare is based on individual preferences, and money is used as a convenient and practical numeraire (or measuring rod) that describes the extent to which individuals are willing, as a society, to reduce their consumption of other goods and services to achieve the policy outcomes.

Conducting a benefit-cost analysis is often useful and informative even if the resulting summary measure – net benefits (benefits minus costs, which may be positive or negative) – is not used as a decision-making criterion or is only one of many factors considered.[5] The data and analysis provide a wealth of information on possible impacts, including many that often were not anticipated or predicted, and this information has important implications for regulatory design and implementation. The analysis should be descriptive, providing unbiased and objective information.

Framing the analysis involves defining what will be assessed and developing the general analytic approach. This chapter describes related activities, including explaining the need for the action and identifying the alternatives to be addressed, specifying the baseline, and determining the consequences of the regulation. It concludes by describing how screening analysis can be used to target analytic resources.

2.1 EXPLAIN THE NEED FOR ACTION AND IDENTIFY ALTERNATIVES

Consistent with OMB *Circular A-4*, agencies must first describe the market failure or other social purpose that leads to the need for regulatory action. They must also describe why action at the Federal level, rather than at the State or local level, is necessary or desirable. Agencies must indicate the significance of the regulation, based on the definitions in Executive Order 12866 that are replicated in the previous chapter.

[5] The normative basis for using benefit-cost analysis in decision-making begins with the Pareto principle, which states that a policy is desirable if it makes at least one person better off and no one worse off. While attractive in theory, few policies meet this criterion: most will harm (or impose costs on) at least a few people. To address this limitation, variations were developed by Nicholas Kaldor and John Hicks. These variations state that a policy is desirable if it makes the winners better off by an amount large enough to compensate the losers, and, alternatively, that it should be rejected if the losers could compensate the winners to not pursue the policy. These criteria do not demand that actual compensation take place. They imply that a policy for which costs exceed benefits should not be adopted and, if more than one policy provides positive net benefits, the one with the largest net benefits should be adopted. This principle is rarely applied strictly, as regulatory and other policy decisions are based on several considerations in addition to the results of the benefit-cost analysis.

Agencies must also consider a range of regulatory and non-regulatory alternatives, regardless of whether the statute or other authorities prescribe the option they can ultimately implement.[6] OMB *Circular A-4* lists the types of alternatives that should be considered, not all of which will be applicable to a particular regulation:

- different choices defined by statute;
- different compliance dates;
- different enforcement methods;
- different degrees of stringency;
- different requirements for different sized firms;
- different requirements for different geographic areas;
- performance standards rather than design standards;
- market-oriented approaches rather than direct controls; and,
- informational measures rather than regulation.[7]

HOW MANY ALTERNATIVES MUST BE ANALYZED?

Agencies must justify the need for regulatory action and consider a range of policy alternatives. These alternatives must, at minimum, include at least one that is more stringent and one that is less stringent than the preferred option; additional options should also be assessed.

Considering a wide-range of options both helps inform agency decision-making and encourages public comment. The versions of the analysis published to support the proposed and the final rule must include, at the very least, comprehensive analysis of one option that is more stringent and one that is less stringent than the preferred option; in total, more than three options should be assessed. These options should represent diverse approaches to meeting the policy goals and should be sufficiently distinct for the analysis to differentiate among them. In some cases, the statute or other legal constraints, or issues of technical feasibility, will limit the types of alternatives considered; this should be explicitly noted in the RIA. However, an option does not need to be legally permissible to be assessed.

Prior to promulgation, the analysis conducted to support the regulatory development process should consider a substantially broader array of options, which may be subject to varying degrees of assessment depending on their feasibility and likely impacts. These additional options also should be discussed in the RIA documentation to encourage public review and comment.

Selecting alternatives for assessment is an iterative process. As analysts gain a better understanding of the benefits and costs of the options, the alternatives to be included in the final RIA are likely to be altered and refined. Screening analysis, discussed later, can be used to eliminate many alternatives from detailed consideration. The rationale for excluding and including alternatives, and the alternatives excluded, should be explicitly discussed when documenting the analysis.

2.2 DEFINE THE "WITHOUT REGULATION" BASELINE

Each regulatory and non-regulatory alternative must be compared to a "no new regulatory action" baseline that reflects expected future conditions.[8] The analysis should, at minimum, compare conditions with and without the policy once the policy is fully implemented. This may occur several years from the present, given the time needed for notice and comment as well as implementation. In many cases, benefits and costs that accrue over the transition period may be significant and should be assessed. In some cases, there may be a significant time lag between when costs are incurred and when benefits accrue or vice-versa. In such cases, the analysis should cover the full time period between when the impacts first occur and when benefits and costs are expected to

[6] RIAs also aid the agency in identifying ways in which the statute can be improved. OMB *Circular A-4* notes: "You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost." (OMB 2003, p. 17)

[7] Alternatives that provide information and disclosure are discussed in more detail in Sunstein (2010a).

[8] If the regulation is required by statute, the baseline should reflect the absence of the statutory requirement.

achieve equilibrium.[9] The RIA should generally consider benefits and costs that accrue over a 10 to 20 year time period, unless the program is expected to end sooner.

Analysts should explore likely trends rather than simply assuming that current conditions will continue. These projections should address future economic and health conditions as well as other factors that may affect the regulatory environment. Where future conditions are uncertain and changes in baseline assumptions significantly affect the analytic results, analysts should consider modeling more than one baseline or testing the sensitivity of their results to key assumptions.

WHAT IS THE APPROPRIATE TIMEFRAME FOR THE ANALYSIS?

In theory, the timeframe for the analysis should begin when regulated entities or others begin to change their behavior in response to the regulation (which may occur before or after the effective date of the regulation) and end when the impacts of the regulation cease. However, it is generally difficult to reasonably forecast effects far into the future. OMB suggests that if the proposed regulation has no predetermined sunset provision, the agency should use its best judgment about the foreseeable future. "For most agencies, a standard time period of analysis is 10 to 20 years, and rarely exceeds 50 years" (OMB 2011a).

Any difference between the baseline and a policy alternative may have both positive and negative consequences, and both should be considered. Conversely, neither the costs nor the benefits of changes predicted in the absence of the regulation should be attributed to the rule. For example, if a change in food handling procedures is expected under the baseline, the associated costs would not be counted as costs of the regulation. Similarly, the benefits of that change would have materialized in the baseline and cannot be attributed to the regulation.

When developing the baseline, analysts should also consider who has "standing;" i.e., whose benefits and costs should be counted. OMB *Circular A-4* (2003) indicates that the analysis should focus on U.S. residents and citizens. At times, determining standing raises difficult issues, such as how to address the preferences of those engaged in illegal activities. When such issues arise, the analysts should explicitly discuss their treatment in the RIA documentation.

If a regulation is likely to have impacts outside of the United States, these impacts should be assessed separately (see Chapter 7). A related issue is whether to assess only the immediate or direct impacts of the regulations, or to also account for second-order or indirect effects, which may affect different groups of people. Screening analysis is a useful tool for determining whether these less immediate effects are significant enough that they should be considered.

2.3 DESCRIBE THE CONSEQUENCES OF EACH POLICY ALTERNATIVE

One of the most difficult steps in conducting regulatory analysis is predicting responses to the policy options, given an evolving baseline, complex regulatory requirements, data gaps, and the diversity of the individuals and organizations affected. Regulatory requirements typically lead to a series of consequences (events and outcomes). It is important to distinguish between the initial requirement (e.g., hospitals must report certain adverse drug reactions); subsequent events (e.g., hospital staff change their prescribing behavior); the ultimate outcome (e.g., greater health improvements for some patients in comparison to the baseline); and its evaluation (e.g., the monetary value of the behavioral changes and the health improvements). Evidence must be used to establish the causal link between these events and outcomes. Analysts often find it useful to map these relationships as a decision tree (Raiffa 1968) or as a logic model (Centers for Disease Control and Prevention (CDC) 2007, Sundra et al. 2003, Wholey et al. 2010), which can be updated as more is learned about likely impacts.

[9] For meaningful comparison, benefits and costs should be measured over the same time period. If the nature of the impacts is such that assessing some over longer periods than others provides important information, the time period over which only some impacts are assessed should be reported separately when summarizing the analysis to avoid misleading comparisons.

Whether a particular consequence is classified as a benefit or cost does not affect the estimated net benefits, as long as the sign is correct (i.e., positive benefits and negative costs increase net benefits; negative benefits and positive costs decrease net benefits).[10] However, for clear communication, analysts should follow a consistent approach. Impacts categorized as benefits should relate to the intended outcome of the regulation (e.g., improved health); impacts categorized as costs should relate to the investment or inputs needed to achieve those outcomes (e.g., safety expenditures by industry). In this case, any negative effects that relate to the intended outcomes (e.g., through substitution of less safe drugs or less healthy foods for those that are regulated) would be combined with the benefit estimates, while any offsetting savings from regulatory compliance (e.g., increased efficiency from automation of previously manual tasks) would be combined with the cost estimates.

Understanding these consequences is an iterative process, as each step in the analysis often provides new insights. Initially, analysts should describe the possible outcomes ("fewer cases of cardiac and respiratory disease," "higher production costs") in as much detail as possible. What is ultimately assessed and quantified, and the level of detail, will depend on the results of the subsequent screening, as well as on what is learned in the course of the analysis.

WHEN SHOULD AN IMPACT BE CLASSIFIED AS A COST VERSUS A BENEFIT?

Costs are the inputs needed to implement the regulation (e.g., industry expenditures to improve safety); benefits are the intended outcomes (e.g., health improvements). Counterbalancing effects, such as cost-savings (e.g., lower operating costs if the regulation allows industry to replace older technology with more efficient equipment) or negative benefits (e.g., health risks of substituting less safe drugs or less healthy foods) should be assigned to the same category as the effect they offset; i.e., as costs and benefits respectively.

Analysts should comprehensively consider all potentially important consequences, including both those that are intended and unintended (positive or negative). They should also consider whether behavioral anomalies will lead to different outcomes than expected under the rational actor model typically assumed in economics. For example, individuals may respond to policies intended to increase safety by reducing their level of precaution, or such polices may lead to changes in social norms that lead to healthier behaviors. Another example is hyperbolic discounting (or present bias, sometimes described as self-control problems), which can lead individuals to engage in behavior (such as eating too much, exercising too little, or continuing to smoke) that is contrary to their own self-described preferences.[11]

Evaluating these consequences, through estimating their monetary value, is discussed in Chapters 3 and 4. These monetary values should be estimated as accurately and comprehensively possible, given analytic goals and time and resource constraints. Effects that cannot be quantified should be highlighted for consideration by decision-makers, as described in Chapter 6. That chapter also discusses methods for addressing uncertainty in the quantitative results.

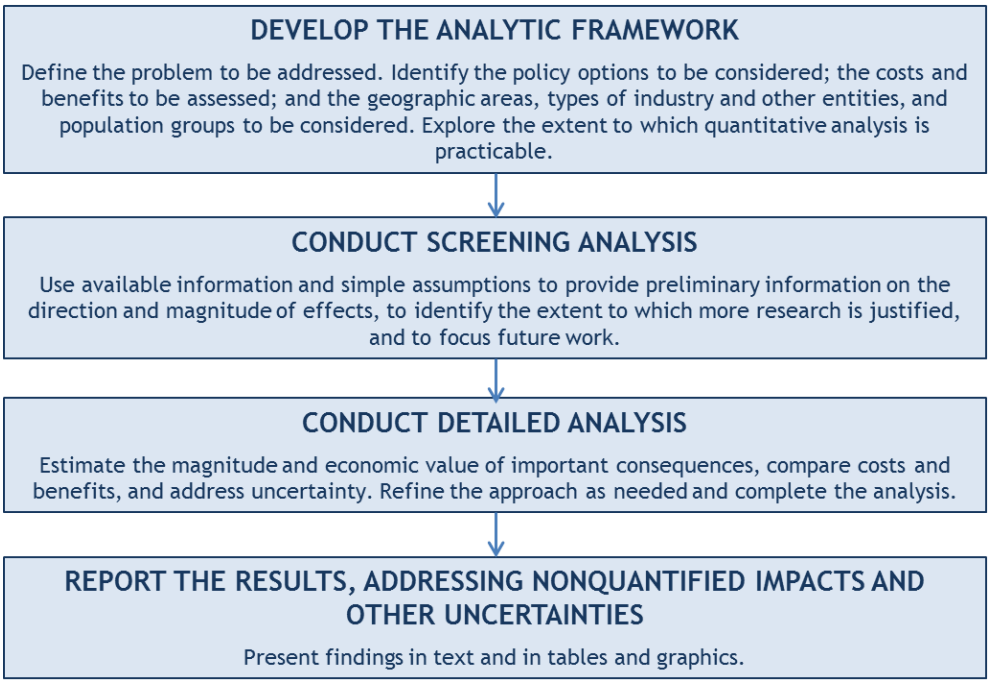
2.4 USE SCREENING TO FOCUS THE ANALYSIS

Once the initial framing of the analysis is completed, as discussed above, the subsequent steps involve determining how to best target future work, conducting the analysis, and reporting the results, as illustrated in Figure 2.1. Analysts will need to follow a similar process to determine the types of supplemental analyses to be conducted and the focus of that work. These processes are iterative; each step in the analysis will result in another round of decisions about whether to address certain impacts in more detail or focus attention elsewhere.

[10] Whether an impact is counted as a benefit or cost will affect the ratio of benefits to costs. As noted in OMB *Circular A-4*, benefit-cost ratios (and cost-benefit ratios) can be misleading (OMB 2003, p. 10) and generally should not be used as an indicator of economic efficiency. To avoid misunderstanding, such ratios should not be reported unless accompanied by information clarifying their appropriate interpretation.

[11] For more discussion of the valuation of the benefits of HHS policies that address habitual or addictive goods, see Cutler et al. (2015).

FIGURE 2.1. ANALYTIC STEPS



Screening analysis is a useful tool for targeting subsequent work. Such analysis is typically based on easily accessible data and simple assumptions; its goal is to provide preliminary information on the possible direction and magnitude of the effects and to inform decisions about future work. For example, high-end values can be used to determine whether various types of outcomes are likely to be significant even under extreme assumptions. Depending on the results, this screening may be followed by more detailed assessment that involves collecting additional data, refining the methods used, and possibly expanding the scope of the analysis as discussed in the following chapters. The analysis should discuss non-quantified impacts along with the quantitative results, and include assessment of uncertainties. The RIA should clearly document the results, as well as discuss the data sources and analytic steps and the implications of uncertainties.

Because analytic resources are limited, the ideal regulatory analysis will not assess all policy options, nor quantify all outcomes, with equal precision. In some cases, the cost of analyzing a particular policy option or quantifying a specific outcome will be greater than the likely benefit of assessing it, given its importance for decision-making.[12] In other words, the analysis may not sufficiently improve the basis for decision-making to pass an informal benefit-cost or value-of-information test. Conversely, options and outcomes that are important for decision-making should receive substantial attention. "Importance" may depend on the likely magnitude of the impacts; it may also depend on the need to respond to questions likely to be raised by decision-makers and others.

The content and level of detail, and the length of the RIA (which may be very short or very long), are likely to depend on the nature of the regulation, the characteristics of its benefits and costs, the populations affected, and the data and other analytic resources available. It is not possible to design a "one size fits all" approach; analysts need to exercise professional judgment in tailoring the analysis for an individual regulation. Generally, conducting screening analysis and following a phased approach will help ensure that the work is carefully focused and useful.

[12] Such decisions include those related to assessing whether statutory change may be desirable; as noted earlier, the analysis need not be limited to considering options allowed under current law.

Chapter 3
Assess Benefits

HHS regulations have many beneficial outcomes, including cost-savings as well as reduced health risks. As introduced in Chapter 2, the distinction between benefits and costs is not always clear. Generally, impacts categorized as benefits should relate to the intended outcomes of the regulation; i.e., the welfare improvements that comprise its goals. Impacts categorized as costs should relate to the investment or inputs needed to achieve those outcomes.

Methods for assessing both increases and decreases in costs are discussed in Chapter 4; this chapter addresses changes in health risks.[13] Such benefits are often the primary goal of HHS regulations and generally cannot be valued using market measures.[14] Calculating these benefits requires first estimating the change in risk associated with each regulatory and non-regulatory option (in comparison to the baseline) then estimating its monetary value. Below, we focus on valuation, first introducing basic concepts and methods, then describing specific approaches for application in HHS analyses.

3.1 BASIC CONCEPTS

The starting point for valuation is an estimate of the impact of each regulatory option on specific health effects, generally expressed as a change in the probability of illness or death for the average affected individual. The monetary value of the benefit to the average individual can be calculated as the change in probability of the illness or death multiplied by the value per statistical case, and summed across the affected population.

In practice, there is often little information on how the risk reduction or the value per statistical case varies across individuals. It is common practice to aggregate the changes in risk over the affected population to calculate the number of "statistical" cases averted by a regulation or other policy, and to multiply this by an average value per statistical case.[15] If, for example, a regulation would decrease the individual risk of a particular illness or death by 10/20,000 annually throughout a population of 200,000, then 100 statistical cases would be averted each year. The calculation is straightforward:

10/20,000 risk reduction x 200,000 individuals annually

= 100 statistical cases

Thus averting a statistical case or "saving" a statistical life is not the same as preventing an identifiable individual from becoming ill or dying; rather, it is a sum of probabilities.[16]

The question for the regulatory analyst is thus how to best estimate the value of these risk changes. Because we currently lack high quality, applicable studies that can be used to value the combined risk of illness and death, we generally estimate the number of averted statistical cases of premature mortality and of morbidity separately, then apply values to each and sum the results. The framework and methods for estimating these values is described below.

[13] Information on valuing other types of benefits, such as environmental improvements, is available in the U.S. Environmental Protection Agency's *Guidelines for Preparing Economic Analysis* (2014) and in Freeman et al. (2014).

[14] The goal of some regulations is to provide cost-savings rather than risk reductions. In such cases, these savings would be categorized as benefits and the methods described in the cost chapter would be used to value them. At times, whether to include an impact as a benefit or cost will be unclear, and analysts will need to document this uncertainty in describing how the impact is categorized in the RIA.

[15] This second approach yields the same result as the first, theoretically correct, approach if the risk reduction is the same across individuals, or the value per statistical case is the same across individuals, or the risk reduction and value per statistical case are uncorrelated in the population.

[16] In is typically impossible to identify *ex ante* whose illness or death will be prevented by a rule; in many cases, it is also impossible *ex post*.

3.1.1 ECONOMIC FOUNDATION

The approach for valuing mortality and morbidity risk reductions, as well as other policy impacts, is grounded in four basic assumptions that underlie the standard economic model. The first is that each individual is the best judge of his or her own welfare. This principle of consumer sovereignty means that benefit values should be based on the preferences of those affected by a policy. Such framing allows analysts to provide decision-makers with information on how those who would benefit are likely to value the improvement in their own health or longevity.

The second is that individuals can be modeled as deriving utility (well-being) from the goods and services they consume. If an individual chooses to buy a good or service, economists conventionally assume (consistent with consumer sovereignty) that he or she values the good or service more than the other goods or services he or she could have used that money to buy. Thus an individual's willingness to exchange money for different goods and services can be used to measure the utility he or she receives from their consumption. The monetary value of a risk reduction is appropriately measured by determining the change in wealth that has the same effect on utility as the risk reduction.

The third is that estimates of individual willingness to pay (WTP) provide a conceptually appropriate measure of value.[17] WTP is the maximum amount of money an individual would voluntarily exchange to obtain an improvement, given his or her budget constraints. It indicates the point at which the individual would be equally satisfied with having the good and less money, or with spending the money on other things. In addition to reflecting the trade-offs individuals make in everyday decisions related to spending on health and safety, this framing mimics the actual trade-offs implicit in regulation. If we as a nation choose to spend more, for example, on regulations that reduce food pathogen risks, we will have less to spend on other goods or services – including other risk-reducing measures.

The fourth key assumption is that benefit values are determined by the change in the amount by which aggregate WTP exceeds the market price, or "consumer surplus." When WTP exceeds price, the individual benefits from the fact that he or she can acquire the good or service for less than his or her willingness to pay. If price exceeds WTP, the individual would not purchase the good or service. The difference between WTP and price can be aggregated across individuals to determine the consumer surplus associated with different price levels. Consumers generally benefit from price decreases, because WTP then exceeds price by a larger amount, and vice-versa. More information on this concept is provided in Appendix B.[18]

WHAT IS THE BASIS FOR VALUATION?

Benefits are valued based on the maximum amount of money an individual would willingly exchange for the improvement, reducing his or her ability to purchase other things. This means that the value of mortality and morbidity risk reductions is determined by the affected individuals' willingness to pay for the change in their own risk.

3.1.2 VALUATION METHODS

For goods such as mortality and morbidity risk reductions, prices do not exist because they are not directly bought and sold in markets. Instead, we use the methods described below to estimate how much individuals would be willing to pay for the risk reductions. We can then compare aggregated WTP for these risk reductions (and other benefits) to the costs of a policy to determine the extent to which it is likely to yield net benefits.

[17] Estimates of willingness to accept compensation (WTA); i.e., of the least amount of money an individual would accept to forgo an improvement, are also consistent with this framework (see Robinson and Hammitt 2011, 2013). We refer to WTP throughout this discussion because it is more frequently studied. In addition, regulations generally involve spending for improvements from the status quo, rather than compensation to forego an improvement, in which case WTP is conceptually more appropriate.

[18] A similar concept applies to producers, who earn a surplus when they can supply units of a good for less than the market price, as discussed in Appendix B.

For nonmarket outcomes, economists typically rely on revealed or stated preference studies to estimate WTP.[19] Each has advantages and limitations: the choice of approach depends on the quality of the available research and the extent to which it measures an outcome similar to the policy outcome.

Revealed preference studies rely on observed market behavior to estimate the value of related nonmarket goods. For example, wage-risk (hedonic-wage) studies examine the compensation associated with jobs that involve differing risks of death or nonfatal injury, using statistical methods to separate the effects of these risks from the effects of other job and personal characteristics. While such methods have the advantage of relying on actual behavior with real consequences, it may be difficult to find a market good that can be used to estimate the value of a particular policy outcome.

Stated preference methods typically employ survey techniques to ask respondents about their WTP for the outcome of concern. Such surveys may directly elicit WTP for a particular scenario, or may present respondents with two or more scenarios involving different attributes and prices.[20] In the latter case, estimates of WTP are derived from the way in which respondents choose, rank, or rate alternatives. Stated preference methods are attractive because researchers can tailor them to directly value the outcomes of concern; for example, the survey can describe a particular type of illness from a particular type of exposure. A potential weakness is that respondents do not directly experience the consequences of their decisions and may have limited incentives to consider the questions carefully. Such surveys must be carefully designed and administered and satisfy various tests for coherence to be considered reliable for use in regulatory analysis.

Analysts often must rely on existing studies when estimating parameters values as well as their interrelationships, due to the substantial time and expense associated with conducting new primary research. When used to value benefits, this approach is typically referred to as "benefit transfer," and generally consists of the five steps described in Figure 3.1. It requires careful review of the literature to identify high-quality studies that are suitable for use in a particular context. "Quality" can be evaluated by considering the likely accuracy and reliability of the data and methods used, referencing guidance on best practices.[21] "Suitability" or "applicability" involves considering the similarity of the risks and the populations affected.

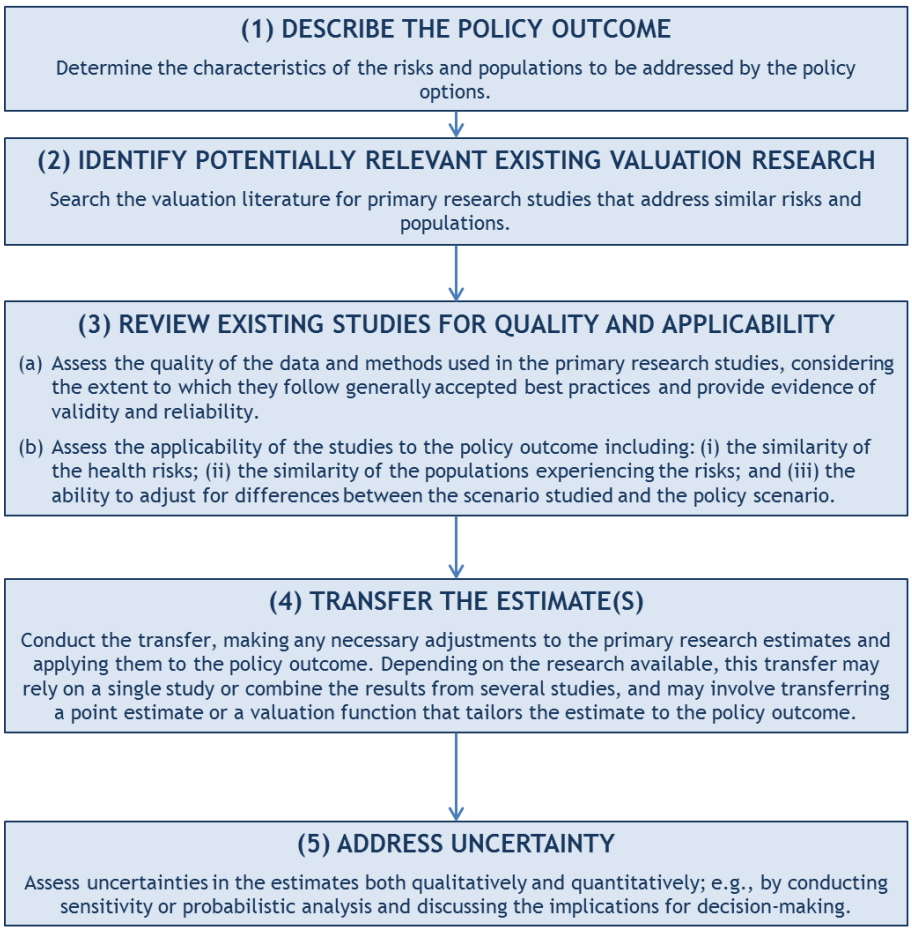
In the subsequent sections, we describe how this framework should be used by HHS regulatory analysts to value mortality and morbidity risk reductions. Numerous studies of the value of mortality risk reductions have been conducted; morbidity risk reductions have received substantially less attention. In the latter case, because fewer studies have been completed, analysts often rely on proxy measures.

[19] Experimental methods (see, for example, Shogren 2005) and structural models that combine theoretical expectations with data from various sources (see, for example, Smith et al. 2006) are less frequently applied but may be useful in some cases.

[20] Although the terminology is not always used consistently, the first type of study is usually referred to as a contingent valuation survey; the second as a choice experiment.

[21] Some guidelines for determining study quality are provided in OMB (2003) and EPA (2014) as well as in the sources cited in this guidance. Because these methods are continually evolving as additional research provides new insights, analysts should also consult recent articles and reports for updated guidance.

FIGURE 3.1. BENEFIT TRANSFER FRAMEWORK



3.2 VALUING MORTALITY RISK REDUCTIONS

The approach for valuing mortality risk reductions is generally based on estimates of the value per statistical life (VSL), from which a value per statistical life year (VSLY) is sometimes derived.[22] We first introduce both concepts then discuss recommendations for HHS analyses.

3.2.1 THE VALUE PER STATISTICAL LIFE AND THE VALUE PER STATISTICAL LIFE YEAR

As noted earlier, the starting point for valuation is typically an estimate of the individual risk change associated with each regulatory option. Valuation also starts at the individual level, estimating what an individual would be willing to pay for a defined change in his or her own risk, consistent with the principle of consumer sovereignty. Values for mortality risk reduction reflect the rate of tradeoff between money and small changes in mortality risk, referred to as the marginal rate of substitution between wealth and risk (Hammitt 2000). This value is conventionally reported in dollars per statistical life (the VSL), and often estimated by dividing the value of a small risk reduction by the size of the risk change.[23] For example, if an individual is willing to pay $900 for a 1 in 10,000 reduction in his or her risk of dying in the current year, his or her VSL is calculated as:

$900 WTP ÷ 1/10,000 risk change

= $9.0 million VSL

[22] Recommendations related to the use of the VSL or VSLY in HHS RIAs are discussed later in this chapter.

[23] For the U.S. population, the annual likelihood of dying at each year of age increases from about 10/10,000 to about 100/10,000 between age 20 and age 65, conditional on surviving to that age (Arias 2014).

The key parameter is the individual's WTP for the 1 in 10,000 risk reduction (i.e., the $900); it is expressed as the VSL (i.e., the $9.0 million) largely for convenience.[24] The value of a *statistical* life is not the value of saving an individual's life with certainty.

In principle, WTP should change nearly in proportion to the change in risk, as long as the risk change is small enough that WTP does not substantially limit other spending. Thus a single VSL can be used to value a range of small risk changes.[25] In other words, if we decrease the risk change in the above equation by a factor of 10, to 1/100,000, we assume that WTP will also decrease by a factor of 10, so the VSL will still be $9.0 million (= $90 WTP ÷ 1/100,000 risk change).

The VSLY is a related concept. In contrast to the VSL, which is the rate at which the individual substitutes money for reductions in current mortality risk (within the current year or other short time period), the VSLY is the rate at which he or she substitutes money for gains in life expectancy. A reduction in current mortality risk implies a corresponding increase in life expectancy and hence a corresponding gain in life years.[26]

Under the VSLY approach, a reduction in mortality risk is typically valued by calculating the corresponding gain in life expectancy and multiplying it by a VSLY. (Generally, future life years are first discounted to account for time preferences; discounting is discussed in more detail in Chapter 5.) As does WTP more generally, both the VSLY and the VSL vary depending on the characteristics of the individual and of the risk, and may increase, decrease, or remain the same depending on the age (and remaining life expectancy) of the affected individual. However, few primary research studies directly estimate the VSLY; it is typically instead derived from a VSL estimate using simple assumptions.

3.2.2 LITERATURE REVIEW

HHS commissioned a review of the VSL literature to identify values that are suitable for use in its regulatory analyses (Robinson and Hammitt 2016). The review had two goals: (1) to identify studies that meet evolving criteria for "best practices" for VSL research; and (2) to tailor the estimates used by HHS to the types of risks it regulates.

The criteria for that review were derived from several reports and articles that describe best practices for valuing mortality risk reductions in regulatory analyses (OMB 2003, EPA 2010, Kling et al. 2011, Cropper, Hammitt, and Robinson 2011, and U.S. Department of Transportation (DOT) 2015a). The criteria are listed in Figure 3.2 and discussed in more detail by Robinson and Hammitt (2016) as well as in these source documents.

[24] The VSL is at times described as aggregating individual WTP across a population; i.e., if each individual is willing to pay $900 for a 1 in 10,000 risk, and the population included 10,000 such individuals, then the value per statistical case would be $9 million ($900 * 10,000 individuals). This definition can be misleading, however, because WTP for a similar risk reduction is likely to vary across individuals.

[25] Many VSL studies consider risks in the range of 1/10,000 or 1/100,000. While applying the resulting VSL to smaller risk changes is appropriate, care must be taken in cases where the risk change is substantially larger. As the risk change increases, WTP will be increasingly limited by income, reducing the VSL (see Alolayan et al. 2015 for more discussion).

[26] Because death can be postponed but not prevented, reducing the risk of dying at one time necessarily increases the risk of dying at some later time. Similarly, reducing the chance of dying from one cause necessarily increases the risk of dying from some other cause. For example, if a policy were to reduce the chance of dying this year from 5 percent to 2 percent, then the chance of dying in a future year would increase from 95 percent to 98 percent. In general, a regulation may reduce individuals' hazard function (the chance of dying at specific dates or ages conditional on being alive). This shift in the hazard can be expressed as a reduction in the expected number of deaths in a specified time period (less than one for an individual) or as an increase in the expected number of years lived; the individual's WTP for the shift in the hazard can be expressed as a VSL or a VSLY by dividing WTP by the expected change in deaths or years lived (see Hammitt 2007).

FIGURE 3.2. SELECTION CRITERIA FOR VSL STUDIES

General Criteria

1. Be publicly available.
2. Be written in English.
3. Provide estimates for the general U.S. population.

Criteria for Revealed Preference Studies

4. Use hedonic methods that address the trade-off between wages and job-related risks.
5. Control for potentially confounding factors, such as nonfatal injury risk as well as both industry and occupation.
6. Rely on high quality risk data, equal or superior to the Census of Fatal Occupational Injuries.

Criteria for Stated Preference Studies

7. Elicit values for private risk reductions that accrue to the respondent.
8. Express the risk change as a probability.
9. Estimate willingness to pay, not willingness to accept compensation.
10. Provide evidence of validity, including sensitivity of willingness to pay to changes in risk magnitude.

The review yielded six revealed preference studies that meet the selection criteria, all of which consider the trade-off between wages and occupational risks, as well as one meta-analysis of these studies.[27] Of the stated preference studies, three met the selection criteria.[28] These latter studies consider fatal risks associated with motor vehicle accidents, ingesting pesticide residues on food, and unspecified causes. One considers only fatal injuries, the other two also address illness-related fatalities.

When adjusted for inflation and real income growth, the VSLs highlighted in these studies range from $4.4 million to $14.2 million, with a mid-point of $9.3 million (2014 dollars and income levels).[29] Applying these results in HHS analyses requires additional adjustments, as described below.

3.2.3 RECOMMENDED VALUES

The range of VSL estimates that result from this review form the basis for HHS' approach for valuing mortality risk reductions; HHS anticipates periodically updating these estimates to reflect the results from new research. This section discusses issues related to adapting these values for application in different regulatory contexts and in different years. The approach it discusses should be applied in all HHS RIAs to provide a common reference case that is comparable across analyses. However, analysts may also report results using alternative estimates or assumptions, if well-justified given the characteristics of the policy and the available research.[30]

WHAT VSL SHOULD BE APPLIED IN HHS ANALYSES?

For analyses conducted in 2014 dollars, risk reductions that occur in 2016 should be valued using a central VSL estimate of $9.6 million. Analysts should test the sensitivity of their results to values of $4.5 million and $14.6 million. The text describes how to adjust these values for other years.

We expect the VSL to vary depending on individual characteristics such as age and health status, and on risk characteristics such as whether death occurs immediately or after an extended illness. However, the effects of many of these characteristics have not been well-studied, and the results of the available research are often inconsistent. Thus the same population-average VSL should be applied in all RIAs, accompanied by discussion of

[27] The six wage-risk studies are: Viscusi (2004), Kniesner and Viscusi (2005), Hersch and Viscusi (2010), Lee and Taylor (2013), Scotton (2013), and Viscusi (2013). The meta-analysis of wage-risk studies is Viscusi (2015).

[28] The three stated preference studies are Corso, Hammitt, and Graham (2001), Hammitt and Haninger (2010), and Cameron and DeShazo (2013).

[29] The estimates reported in Robinson and Hammitt (2016) ranged from $4.2 million to $13.7 million, with a mid-point of $9.0 million (2013 dollars and income levels). They have been updated to 2014 dollars and income levels in these *Guidelines*, using the approach described below.

[30] See Chapter 6 for more discussion of the analysis of uncertainties.

uncertainties.[31] The values cited above should be adjusted for inflation and real income growth as well as for latency or cessation lag if relevant.[32] Sensitivity analysis also should be conducted in cases where the individuals affected are predominantly very young or very old. Each of these adjustments is discussed below.

The first set of adjustments is needed to reflect the time that has elapsed since the VSL studies were conducted, and involve addressing both inflation and changes in real income. The process for inflating values to reflect economy-wide price levels as of a common dollar year is discussed in Chapter 5.[33] Adjusting for real income growth is a separate step that requires two inputs: an estimate of the change in population-wide real income per person, and an estimate of the extent to which WTP is expected to change in response to the income change. The latter is generally expressed as the percentage change in the VSL associated with a one percent change in real income; i.e., the income elasticity.

Although both economic theory and numerous empirical studies suggest that the VSL increases as real income increases, the rate of increase is uncertain (Hammitt and Robinson 2011, DOT 2015a). Some research suggests that a one percent change in income leads to less than a one percent change in the VSL (e.g., Viscusi and Aldy 2003), and other research suggests that it leads to more than a one percent change (e.g., Kniesner, Viscusi and Ziliak 2010, Viscusi 2015). Given this uncertainty, HHS analysts should apply an income elasticity of 1.0 in their analyses.[34]

Once the VSL has been inflated to the common dollar year used in the analysis, the formula for adjusting for real income growth (assuming a constant rate of income growth and a constant income elasticity) is:

$$VSL(\text{year } y) = VSL(\text{year } x) * (1+\text{real income growth rate})^{\text{elasticity} * (y-x)}$$

Because no single source provides data on both actual and projected changes in real income, analysts will need to use different sources depending on the time period. More specifically, analysts should use Current Population Survey (CPS) data to adjust for past income growth, and Congressional Budget Office (CBO) data to adjust for future income growth; both focus on earnings, consistent with the measures generally used in the VSL studies.[35] The most recent CBO report (2015, p. 112) projects real earnings growth at 1.4 percent per year for 2015 through 2040.

Table 3.1 provides an example of the adjustments to these values over a 10-year period using the data sources identified above, including a VSL income elasticity of 1.0 and real income growth of 1.4 percent per year. (Note that while values should be inflated only to the common dollar year used in the analysis (2014 in this example), the adjustment for real income growth is needed for each subsequent year that the analysis covers.) As indicated by the table, if the analysis is conducted in 2014 dollars, mortality risk reductions that accrue in 2016 would be valued using a central VSL estimate of $9.6 million. At minimum, analysts should test the sensitivity of their results to the values at the low and high ends of the range; i.e., $4.5 million and $14.6 million.

[31] This implies there should be no adjustment for morbidity prior to death for fatal cases. If regulation of a hazard (such as a foodborne pathogen) can prevent both fatal and nonfatal illness, the expected reduction in fatal cases should be valued using the VSL and the expected reduction in nonfatal cases should be valued using appropriate estimates of WTP or monetized QALYs as discussed in Section 3.3.

[32] Latency is the time between when an individual is exposed to a hazard and when the adverse effect results; cessation lag is the time between when an individual's exposure to a hazard ends (or is reduced) and when his or her risk of adverse effect declines. These time periods are not necessarily equal.

[33] The calculations in the text use the Consumer Price Index (CPI, available at http://www.bls.gov/cpi/) to adjust for inflation. As discussed in Chapter 5, analysts may use the Gross Domestic Product implicit price deflator instead of the CPI.

[34] If changing the income elasticity estimate is likely to substantially change the analytic results, analysts should explore the effects of applying alternative elasticities.

[35] More specifically, for income growth in prior years, analysts should use CPS data on the annual median usual weekly earnings of employed wage and salary workers, for fulltime workers (usual working hours over 35), reported on an average per capita basis in constant dollars, which are available at http://www.bls.gov/cps/earnings.htm. For income growth in future years, analysts should use the estimates in the CBO Long-Term Budget Outlook. The 2015 CBO report is available at https://www.cbo.gov/publication/50250. See Chapter 4 of these *Guidelines* for more discussion of the use of median versus mean values.

TABLE 3.1. VSL ESTIMATES BY YEAR (2014 DOLLARS)

YEAR	LOW VSL ESTIMATE	CENTRAL VSL ESTIMATE	HIGH VSL ESTIMATE
2014	$4.4 million	$9.3 million	$14.2 million
2015	$4.4 million	$9.5 million	$14.4 million
2016	$4.5 million	$9.6 million	$14.6 million
2017	$4.5 million	$9.7 million	$14.8 million
2018	$4.6 million	$9.9 million	$15.0 million
2019	$4.7 million	$10.0 million	$15.2 million
2020	$4.7 million	$10.1 million	$15.4 million
2021	$4.8 million	$10.3 million	$15.6 million
2022	$4.9 million	$10.4 million	$15.9 million
2023	$4.9 million	$10.6 million	$16.1 million
Note: See text for discussion of assumptions and calculations.			

Thus if a regulation reduced the number of statistical cases of premature mortality by 75 in 2016, applying the central VSL estimate would result in benefits of $720.0 million (75*$9.6 million), with a low of $337.5 million (75*$4.5 million) and a high of $1,095.0 million (75*$14.6 million).

In some cases, analysts may also need to adjust the VSL estimates to reflect a lag or delay between when exposure to a hazard is reduced and when the risk change occurs. If the risk reduction is expected to occur in the same year that the regulatory costs are incurred, then the VSL for that year should be applied. If the risk change occurs later, then the VSL should be applied at the time when the risk change occurs, rather than in the year in which the associated regulatory costs are incurred.[36] In other words, using the values above, if both the costs and the risk reductions occur in 2016, than $9.6 million would be used as the central VSL estimate. If instead the costs are incurred in 2016 but the risk reduction does not occur until 2018, then the central estimate would be $9.9 million, which would be discounted back to 2016 for comparison with the costs incurred in that year, using the same discount rate as applied elsewhere in the analysis. Recommended rates, as well as the mechanics of discounting, are discussed in Chapter 5.

Finally, some regulations may predominantly affect the very young or very old, rather than those of all ages. In these cases, the age distribution of those affected is likely to differ significantly from the age of those included in the VSL studies that underlie the approach discussed above, which often address individuals between the ages of 18 and 65 (with some exceptions). There is substantial uncertainty regarding how VSL varies with age (see, for example, Aldy and Viscusi 2007, Krupnick 2007, and Hammitt 2007; Robinson and Hammitt 2016 discuss related theory and empirical research in more detail).

If a regulation largely affects the very young or the very old, analysts should at minimum provide a supplemental sensitivity analysis based on estimates of the expected value of future quality-adjusted life years (QALYs).[37] In other words, regulations that primarily affect young children or the elderly should include two calculations: a primary benefit estimate based on the VSL recommendations in this section, and a sensitivity analysis based on monetized QALY estimates, which are discussed in detail in the next section. In this sensitivity analysis, the value per QALY is multiplied by the present value of the expected life year gain.[38]

In addition to the uncertainties represented by the ranges of values and adjustments discussed above, analysts should provide a qualitative discussion of the other limitations of this approach. The major limitations include differences in the types of risks addressed in the underlying studies and those addressed by the particular policy,

[36] As noted earlier, this delay is described as the "cessation lag" when it refers to risk reductions rather than risk increases.

[37] Analysts may also explore the effects of alternative assumptions regarding the relationship between the VSL and age or life expectancy, if clearly explained and well-justified. Many analyses have used a VSLY estimate rather than an estimated value per QALY to explore these effects.

[38] Such sensitivity analysis would not noticeably change the results if the age distribution of those affected by the regulation is similar to the U.S. age distribution, as long as the value per QALY (or VSLY) is calculated from a population-average VSL.

as well as in the population affected. Thus this approach may over- or understate the value of mortality risk reductions. Where the analytic conclusions are particularly sensitive to the approach used to value mortality risks, analysts may also wish to conduct breakeven analysis to identify the VSL at which the costs would be equal to the benefits, as discussed in Chapter 6.

3.3 VALUING MORBIDITY RISK REDUCTIONS

Valuing morbidity risk reductions is more complicated than valuing mortality risk reductions for two reasons. First, morbidity risks are more diverse, differing in duration and severity as well as in the attributes of health that are affected (e.g., physical or cognitive functioning). Second, high quality WTP estimates are not available for many morbidity risks, requiring the use of proxy measures. Thus, as discussed below, HHS analysts should first review the literature to determine whether WTP estimates of reasonable quality are available for risks similar to those addressed by the regulation, applying the benefit transfer framework described previously.[39]

HOW SHOULD MORBIDITY RISK REDUCTIONS BE VALUED?

Analysts should first review the literature to determine whether suitable WTP estimates of reasonable quality are available. If not, they should use monetized QALYs as a proxy, following the approach described in this section.

If such estimates are not available, analysts should instead apply values that combine estimates of the resulting QALY gain with estimates of the monetary value per QALY. Cost-savings that are not reflected in the QALY measure may be added to these values, including those that accrue to third parties (such as savings in insured medical costs). Because of the diversity of the health effects and the gaps in the research literature, the discussion that follows focuses on the approach analysts should follow to develop estimates, rather than recommending values for particular health conditions.

3.3.1 QUALITY-ADJUSTED LIFE YEARS

The QALY is a nonmonetary measure that integrates the duration and severity of illness. QALYs are widely used to rank and prioritize public health programs, analyze the cost-effectiveness of health policy and medical treatment decisions, and compare health status across individuals or population groups. In these contexts, QALYs are generally not assigned a monetary value, but monetization is needed to apply these estimates in regulatory analysis.[40]

QALYs are derived by multiplying the amount of time an individual spends in a health state by a measure of the health-related quality of life (HRQL) associated with that state. HRQL is estimated using a scale anchored at zero and one, where one corresponds to full health and zero corresponds to a state that is as bad as dead (values cannot be greater than one but may be less than zero for states that are judged to be worse than dead). In principle, the HRQL associated with a health state may vary among individuals, but in practice a common value is used for each health state. Expected QALYs are then calculated by weighting the HRQL experienced in each future year of life by the probability of living in that year (i.e., by the survival curve).[41] In addition, future QALYs are usually discounted using the same rates as applied to monetary values. Appendix C provides more information on the estimation of QALYs.

Once HRQL is determined for a particular health state and multiplied by the duration of that state, the resulting QALYs can be summed across the health states (e.g., acute and chronic phases) associated with a particular illness, and across the illnesses associated with a particular hazard. For example, for foodborne illness, QALYs

[39] Due to the lack of a reasonably recent and comprehensive review of this research, analysts will need to search bibliographic databases, such as EconLit (http://www.aeaweb.org/econlit/index.php) and EVRI (https://www.evri.ca/Global/HomeAnonymous.aspx), to identify potentially applicable studies and conduct a criteria-driven review that follows the benefit transfer framework introduced above.

[40] In cost-effectiveness analysis, valuation is implicit, because monetary thresholds are needed for comparison to the cost-effectiveness ratio to determine whether an intervention is worth implementing. In addition, valuation is implicit in any policy decision that results, which involves choosing to fund a particular invention rather than using the money for other goods or services.

[41] For the U.S. population, survival curves are updated annually by the CDC; see http://www.cdc.gov/nchs/products/life_tables.htm.

can be summed across cases of acute gastrointestinal illness, including those that do and do not require hospitalization, as well as more severe effects. For regulatory analysis, health status with the regulation or other policy must be compared to health status in the absence of the regulation, which is likely to be less than full health. In particular, health status generally deteriorates with age, so that average HRQL for older individuals is generally less than 1.0 (see Hamner et al. 2006). Some regulations may also target individuals with pre-existing conditions or lifestyle characteristics that will not be ameliorated by the regulation.

An example of these calculations is provided in Figure 3.3. For simplicity, in this example we do not discount future impacts; however, as discussed in Chapter 5, discounting should be used to reflect time preferences when similar calculations are performed in regulatory analyses.

FIGURE 3.3. EXAMPLE OF QALY CALCULATIONS

- Assume that, in the absence of the policy, the average individual affected will experience health-related quality of life of 0.7 throughout their estimated remaining life span of 20 years.
- With the policy, assume that the average individual affected will instead experience health-related quality of life of 0.9 over the same time period
- The QALY gain attributable to the policy is the difference between 20 years with a health status of 0.9 (18 QALYs) and 20 years with a health status of 0.7 (14 QALYs), which equals 4.0 QALYs, prior to discounting.

The research base for estimating QALYs is extensive, including numerous primary research studies as well as population databases that collect HRQL data for a wide range of conditions. Thus regulatory analysts can generally rely on existing research to estimate the QALY gains associated with reducing the risks of various types of morbidity.[42] Estimates from many previously completed studies can be found in the Tufts Cost Effectiveness Analysis (CEA) Registry (described in Thorat et al. 2012), using the benefit transfer process discussed earlier to assess their quality and applicability. However, this database does not include studies that estimate QALYs or HRQL without comparison to costs, so analysts should search the research literature to identify other potentially applicable studies.

Another option is to rely on population-wide surveys. Some large national surveys (such as the U.S. Medical Expenditure Panel Survey or MEPS) have at times included one or more of the generic HRQL indices, such as the EQ-5D which is described in more detail in Appendix C. These HRQL estimates can then be multiplied by duration estimates from research on the health state of concern. Relying on such surveys can be particularly useful for regulatory analysis, because they provide consistently-derived estimates across a wide range of outcomes and enable analysts to control statistically for the effects of other factors (such as age and co-morbidities) on HRQL.[43] For some health effects, however, these surveys may not include enough cases to reliably estimate HRQL.

A 2006 Institute of Medicine report provides more detailed discussion of these measures and their application in regulatory analysis, recommending factors that should be considered in selecting among the available sources of HRQL and QALY estimates. In particular, to the extent possible, QALY estimates should satisfy the criteria listed in Figure 3.4.

[42] In those rare cases where suitable estimates are unavailable, analysts may need to rely on expert judgment to estimate the QALY gains associated with the regulation. Analysts should apply the EQ-5D index with U.S. weights when implementing this approach.

[43] For example, EQ-5D scores for a large number of health conditions based on MEPS are provided in Sullivan and Ghushchyan (2006). This article, and a calculator that allows users to retrieve EQ-5D scores by International Classification of Disease code and demographic characteristics, is available online at http://www.ohsu.edu/epc/mdm/webResources.cfm.

FIGURE 3.4. SELECTION CRITERIA FOR QALY ESTIMATES

1) QALY estimates should be based on research that addresses the risks and populations affected by the regulation.
2) The description of the effects of the health state on quality of life should be based on information from those who have experienced the condition (such as patients).
3) The preference weights placed on the health states should be based on a survey representative of the general U.S. population.
4) The "without new regulation" baseline (with the condition) should be compared to a realistic estimate of "with-regulation" health status, which takes into account factors (such as age and co-morbidities unrelated to the regulated hazard) that may lead those affected to be in less than perfect health once the regulation is implemented.[44]
5) The implications of related uncertainties should be discussed and addressed quantitatively if significant.

Developing approaches for measuring QALYs and testing their implementation is an active area of research. There continue to be diverse opinions on many technical issues such as the dimensions of health that should be considered, the types of survey questions that should be used to explore these dimensions, the elicitation of preferences, and the statistical analysis of the results (Lipscomb et al. 2009). Thus the approaches described above continue to evolve, and new options are under development.

3.3.2 THE VALUE OF A QALY

To use QALY estimates to value morbidity risk reductions in regulatory analysis, they must be assigned a monetary value. One approach would be to rely on emerging research that explicitly considers individual WTP per QALY (e.g., Haninger and Hammitt 2011); HHS is currently exploring this research to determine whether it is possible to develop a function that reflects how the value varies depending on factors such as the severity and duration of the effect.

In the absence of such a function, analysts often assume that the value per QALY is a constant, frequently applying a VSLY estimate, calculated by dividing the VSL by the discounted expected number of life years remaining. A preferable approach is to calculate a constant value based on expected QALYs rather than expected life years. Future QALYs are generally less than future life years because health tends to deteriorate with age. Dividing the VSL by future QALYs yields an average value per QALY larger than the VSLY (see Hirth et al. 2000).

For analyses conducted in 2014 dollars, HHS analysts should estimate the value of a QALY based on the VSLs reported in Table 3.1. For analyses that use a different dollar year, the VSL estimates will first need to be adjusted to reflect inflation and real income growth, as discussed earlier.

Based on data reported in the underlying VSL studies, analysts should assume that the average individual in these studies is 40 years of age. Table 3.2 reports the value of a QALY that results when health-related quality of life in each subsequent year is estimated using the U.S. EQ-5D results reported in Hamner et al. (2006) and the conditional likelihood of survival for each year of age is based on the population-averages in Arias (2014).[45] The value of future years should be discounted at the same rates as used elsewhere in the analysis. The table provides the results of these calculations for risk reductions that occur in 2016, in 2014 dollars.[46]

[44] This point is of particular importance in regulatory analysis, which is intended to realistically reflect the health of the affected population without and with the policy. In the absence of regulation, this population may suffer from a variety of health conditions, some of which will not be affected by the policy change. For example, a food safety regulation that targets the risk of gastrointestinal illness is not likely to affect air pollution-related respiratory effects. In addition, health status generally declines with age. Thus the average health of the affected population is likely to be less than perfect health (i.e., less than HRQL = 1.0) even after the regulation becomes effective.

[45] Arias (2014) provides life tables for 2009. Updated values may be used when available; see: http://www.cdc.gov/nchs/products/life_tables.htm.

[46] Many previous analyses value QALYs using a constant VSLY rather than the value per QALY presented here. As noted earlier, both are calculated from a VSL based on the average life expectancy of the individuals studied. The difference is that the resulting VSLY estimate implicitly averages over future health, while the value per QALY estimate takes into account the expected decline in health status associated with aging.

TABLE 3.2. VALUE PER QALY IN 2016
(2014 DOLLARS)

VSL	VALUE PER QALY	
	3% DISCOUNT RATE	7% DISCOUNT RATE
$4.5 million	$230,000	$380,000
$9.6 million	$490,000	$820,000
$14.6 million	$750,000	$1,200,000

For example, if a regulation leads to a 0.2 QALY gain per affected individual on average in 2016, then applying the central VSL estimate (using a 3 percent discount rate) from Table 3.2, the value of that gain would be $98,000 (0.2*$490,000). If the gain accrues to 75 members of the population, than the total value of the risk reduction would be $7,350,000 (75*$98,000).

Estimates of the averted costs of illness may be added to estimates of WTP or monetized QALYs, as long as the same cost-savings are not counted elsewhere in the analysis (see Chapter 4 for more discussion of medical costs).[47] These cost estimates should always be reported as a separate line item in the RIA, so that their treatment is clear. If a WTP study is used for valuation, the analysts should review the study to ensure that the costs are not already captured in the WTP estimates. Typically, WTP studies may capture out-of-pocket costs and lost earnings, and possibly informal care provided by household members, but do not include costs paid by third parties, such as medical expenses paid by insurance. If a regulation reduces these costs, the savings can be added to the WTP estimate. Any cost-savings included in the analysis of regulatory costs should not also be added to the benefit estimates.

If monetized QALYs are used for valuation, the extent to which costs are included is highly uncertain given that the measure does not directly reflect monetary consequences. Occasionally, studies that estimate HRQL instruct respondents to assume their medical costs and lost income will be offset by insurance. In the absence of more specific information, analysts may add medical costs paid by third parties to the monetized QALYs, but should not add estimates of lost productivity or income to avoid potential double-counting.

Estimates based on QALYs monetized using a constant value are likely to be less accurate than approaches based on direct estimation of WTP, but may provide a reasonable proxy when WTP estimates are unavailable. The limitations of this approach relate in part to the characteristics of the QALY measure and in part to the approach used for valuation, and should be discussed when documenting the analysis.

The construction of the QALY assumes that how individuals value health states is independent of the duration of the state, the age at which it is experienced, the individual's remaining life expectancy, and his or her wealth and income (Hammitt 2002, 2013, Institute of Medicine 2006). Moreover, QALYs do not explicitly account for the changes in wealth or income that result from changes in health, nor for how individuals are willing to trade off spending on particular risk reductions versus spending on other goods and services.

[47] For some rules, whether medical costs should be counted as a "cost" or "benefit" will be uncertain, and analysts will need to be clear about how these costs are treated when documenting the analysis. Generally, if changes in medical costs are part of the implementation of the requirements (i.e., a policy input), then they should be counted on the cost-side of the equation. If they are one of the policy outcomes, then they should be included in the benefit calculation.

In addition, relying on a constant value per QALY does not reflect the likely variation in value due to factors such as duration and severity.[48] More research is needed to develop a valuation function for QALYs that better approximates individual WTP for risk reductions.

Given the above discussion, HHS analysts should first consult the WTP research to determine whether suitable estimates are available for the morbidity risk reductions of concern. If not, they may use monetized QALYs as a proxy, recognizing that we are uncertain whether the resulting values under- or overstate individual WTP for the risk reduction. Regardless of whether WTP or monetized QALY estimates are applied, analysts should document any concerns about the quality or applicability of the selected studies.

[48] Given these concerns, an expert panel recommended against assigning monetary values to QALYs in regulatory analysis (Institute of Medicine, 2006); however, OMB has not amended *Circular A-4* to adopt this recommendation. It continues to suggest that the use of monetized QALYs is acceptable as long as analysts acknowledge the limitations of the approach.

Chapter 4
Assess Costs

HHS regulations may impose costs on individuals, industries, other organizations (both for-profit and nonprofit), and government entities. In some cases, costs may be offset by savings; for example if a regulation reduces or streamlines existing requirements by replacing paper with electronic recordkeeping and reporting.[49] This chapter begins by describing some basic concepts that are particularly important when estimating costs. It then describes approaches for estimating the most common types of costs in more detail.

4.1 BASIC CONCEPTS AND APPROACH

Below, we describe economic concepts that are of particular importance when estimating costs: opportunity costs, transfers, and producer surplus. A discussion of the general approach to the cost analysis follows.

4.1.1 ECONOMIC FOUNDATION

Three fundamental notions from economic theory are of particular importance in assessing costs. The first is that economists measure costs by the value of forgone opportunities. In other words, costs are incurred when resources are used for one purpose and hence cannot be used for another purpose. The opportunity costs are the value of the benefits that could have been provided by devoting the resources to their best alternative use. This interpretation differs from the concept of accounting costs (i.e., actual expenses plus depreciation of capital equipment). It is consistent with the concept of WTP, as discussed in Chapter 3.

The second is the distinction between resource costs and transfers. Transfers are monetary payments between persons or groups that do not affect the total resources available to society.[50] They are a benefit to recipients and a cost to payers, with zero net effect. For example, some types of taxes, fees, and surcharges can be categorized as transfer payments. Such transfers often can be ignored in benefit-cost analysis, as long as they do not lead to behavioral changes that significantly affect the calculation of net benefits. However, transfers should be included in the distributional analysis, as discussed in Chapter 7.

OPPORTUNITY COST VERSUS ACCOUNTING COST

Opportunity costs are easy to confuse with accounting costs. Some may argue that a proposed regulation will not have any "costs" because regulated entities will simply re-allocate existing resources to comply with the regulation; no new expenditures are incurred.

However, if resources are shifted for compliance purposes, other productive uses of those resources are forgone. If labor is shifted to compliance from production, for example, the opportunity cost is the value of forgone production.

Where the imposition of transfer payments affects behavior, associated impacts should be taken into account in the benefit-cost analysis. For example, reductions in government payments to hospitals would often be viewed as a transfer. However, the affected hospitals may accept fewer patients or use less expensive treatments, in turn affecting health outcomes. This change in health should be addressed in the benefit-cost analysis, if significant. Similarly, taxes can also change behavior; for example, taxes on wages provide a disincentive for working and higher taxes may lead more people to stay out of the labor force.[51] In addition, transfers involve transaction costs that may be significant in some cases. When identifying the costs to be

[49] As discussed in Chapter 2, analysts should decide whether to report offsetting cost savings as negative costs or positive benefits depending on whether these savings relate to the inputs needed to achieve regulatory goals, or the outcomes associated with those goals.

[50] Because RIAs focus on the effects on the U.S. population, transfers from the United States to other nations, and from other nations to the United States, should be included in the benefit-cost analysis.

[51] HHS regulations rarely, if ever, affect tax rates. If such rates are affected, analysts may wish to consult Boardman et al. (2011) and other resources on estimating the associated deadweight loss, typically referenced as the marginal excess tax burden.

quantified, analysts should consider the potential for significant net losses or gains nationally resulting from the imposition of transfer payments.[52]

The third fundamental notion is the difference between compliance costs and changes in producer and consumer surplus. As introduced in Chapter 3 and discussed in Appendix B, consumer surplus is the benefit that consumers receive when they are able to purchase products for less than they are willing to pay; producer surplus is the difference between the revenue producers receive and their cost of production. When a regulation increases production costs, the market price is likely to increase, inducing consumers to reduce their consumption and producers to reduce production. The cost of the regulation includes both the direct compliance costs and the "deadweight loss" associated with the reduction in output. However, regulation often has negligible impact on prices, in which case the deadweight loss will be quite small and compliance costs will be a reasonable approximation of total costs. We return to this issue later in this chapter, when discussing the use of partial and general equilibrium models.

4.1.2 GENERAL APPROACH

Social cost is the sum of the resource costs incurred as a result of implementing the regulation. These costs may include costs incurred by regulated entities in the form of resources (labor, material, equipment) used to comply with the regulation, valued by their opportunity costs. Social cost may also include costs incurred by governments to implement and enforce the regulation. Other effects, such as consumer decisions to replace the regulated product with a substitute, may also occur in response to the compliance costs.

In principle, analysts could develop a model that includes all the interactions between regulated entities, consumers, and related markets to capture the total social cost of a regulation. However, such analysis is usually impractical given data, time, and resource constraints. Furthermore, most regulations are likely to have negligible impacts on price, in which case such complex modeling is not necessary to understand key impacts. During the framing and screening process (see Chapter 2), analysts should determine the cost categories of interest and the modeling techniques to be applied, recognizing that this is an iterative process. Changes in the approach may be needed as more is learned about the potential impact of the policy options. Nonquantified costs, as well as the reason for not quantifying them, should be reported as well (see Chapter 6).

In most cases, the analysis focuses on estimating the incremental compliance costs incurred by the regulated entities, assuming full compliance with the regulation, and government costs.[53] Compliance costs include the resources used by the regulated entities to comply with the regulation. These costs often account for the largest proportion of social costs and are an important input into the supplemental analyses discussed in Chapter 7. The analysis should also include costs incurred by the government. Such costs generally involve guiding and monitoring implementation of the regulation, as well as providing information and training as needed. In some cases, the government may have an ongoing operational role; for example, it may provide services in addition to those provided by the regulated community. Government costs also include enforcing the regulation through activities such as inspections and reporting requirements. When significant, these government costs should be quantified.

If compliance costs are significant on a per entity or industry basis, they may result in other impacts. If these additional effects are sufficiently large, they should be quantified. For example:

- Compliance costs may result in substituting behaviors. If industry or consumers shift to alternative products, or if industry develops new products to replace the regulated products, analysts should consider the net effect on society.

[52] As noted in Chapter 1, an RIA is required for regulations resulting in significant transfers, because of the additional costs or benefits that may result.

[53] Analysts should consider the uncertainty associated with an assumption of full compliance and provide analysis of alternative assumptions, as appropriate.

- Compliance costs may result in changes in available services, which could result in additional, and possibly non-pecuniary, costs (e.g., time losses associated with needing to find new doctors or traveling farther for treatment). Such costs should also be taken into account.[54]

Finally, care should be taken to identify transfer payments as discussed earlier. For example, proposed regulations may require the payment of fees to HHS agencies for processing paperwork or adjudicating claims. The fees may be set to recover the HHS labor and other costs associated with administering the program. If the opportunity cost to HHS of administering the requirement is already captured in the analysis, the fees represent a transfer payment that should not be counted. However, if the HHS opportunity costs are not separately calculated, then the fees paid by regulated entities might be a reasonable proxy for these opportunity costs and should be included as a social cost.

4.2 ASSESSING COMPLIANCE AND GOVERNMENT IMPLEMENTATION COSTS

Chapter 2 discusses the screening process used to identify key cost categories. Typical categories include administrative costs (including time, materials, and travel), capital and operations costs, and medical costs. As discussed above, government implementation costs should also be considered.

4.2.1 ADMINISTRATIVE COSTS

Most regulations impose administrative costs on regulated entities or the implementing government agency. Related activities may include, for example, reviewing the new regulations, developing protocols for compliance, collecting and reporting data, and training staff on implementation. The following sections describe how to quantify and monetize the components of these costs, including estimating the amount of time required for administrative tasks, valuing this time in monetary terms, and locating data on administrative expenditures.

Amount of time required: Estimating the amount of time needed to comply with administrative requirements is relatively straightforward.[55] Usually, time should be measured in terms of "hours" so that the quantity can be easily combined with information on the value of time, which is generally measured in terms of hourly compensation (see below).[56] Analysts may obtain estimates of the number of hours needed to review the requirements, fill out forms, transmit data, or complete other similar tasks using surveys, information interviews, past analysis, or Information Collection Requests (see Chapter 7). Who is undertaking these activities is also important, as it affects the monetary value of time. Finally, care must be taken to ensure that the hours estimates reflect the net effect of the regulation. For example, the regulation may require that workers discontinue some activities (e.g., completing paper forms) and replace them with others (e.g., maintaining records electronically). The time saved by discontinuing activities will offset time spent on the new activities to some extent.

Table 4.1 lists the types of administrative tasks that may result from new regulations and provides suggestions for quantifying the amount of time associated with each task, noting associated costs (such as travel or materials) that should also be addressed. Time spent complying with a regulation may vary by establishment type or size. Thus, analysts should explore differences across key groups. In addition to providing more accurate cost estimates, this information is used in the supporting analyses that address impacts on entities of differing sizes and types (see Chapter 7).

[54] For a detailed discussion of the identification and assessment of secondary effects, see Chapter 5 of Boardman et al. (2011).

[55] The same general approach can be used when regulations affect other types of time use.

[56] For rules requiring substantial amounts of labor, such as the hiring of additional, full-time employees, analysts might instead estimate the number of new employees needed and annual salaries using the data sources identified in the next section.

TABLE 4.1. TYPICAL ADMINISTRATIVE TASKS

ADMINISTRATIVE TASK	EXAMPLES OF SOURCES OR METHODS USED FOR QUANTIFICATION
Regulation and Guidance Review: All regulated entities, including those who incur no other compliance costs, will require time to read and interpret the regulation.	• Interview representatives of the affected community to obtain estimates of the amount of time required to review regulations, including time spent by legal or technical experts. • Review prior agency analyses for relevant data or conduct other literature reviews. • Assume reviewers read at the average adult reading speed (approximately 200 to 250 words per minute) and allow time for both review and interpretation.
Development or Revision of Standard Operating Procedures (SOPs): The affected entities may need to devise a compliance plan that may require them to change their SOPs. SOPs are "detailed, written instructions to achieve uniformity of the performance of a specific function" (International Conference on Harmonization).	• Interview the affected community to obtain estimates of the amount of time required to review and revise SOPs. • Review prior agency analyses for relevant data or conduct other literature reviews.
Training: Once new SOPs are established, entities will spend time training staff on how to implement the regulation.	• Interview the affected community to obtain estimates of the amount of time required for training. • Review prior agency analyses for relevant data or conduct other literature reviews. • Note that training may also require travel costs.
Sampling and Testing: A regulation may require entities to sample or test materials.	• Contact third party vendors to obtain estimates of sampling or testing costs. In such cases, the cost per test likely includes both labor and materials. • Some entities may be able to conduct the testing more cheaply using in-house staff. Interviews with the affected community may provide data on the amount of time required. In these cases, material costs should be added.
Record Keeping and Reporting: Some rules require entities to perform additional record keeping to track training, inspections, and infractions. In addition, entities may be required to submit recurring reports to the regulating agency.	• Interview the affected community to obtain estimates of the amount of time required for record keeping and reporting. • Review prior agency analyses for relevant data or conduct other literature reviews. • Note that record keeping may also result in substantial storage costs.

Valuing time: Once the amount of time needed has been calculated, analysts multiply these hours by a per hour value of time. This value will vary depending on the characteristics of the activities, the preferences of those affected, the duration of the activities, and other factors. As in other components of the analysis, the approach to valuation requires comparing the value of time use with and without the regulation, to calculate the opportunity costs the regulation imposes.

In RIAs, as in other types of analysis, time use is often valued based on simplifying assumptions that allow analysts to use readily accessible data on compensation. We introduce the default assumptions for HHS analyses below, then discuss their implications in more detail. If the characteristics of the regulation and the available data justify a different approach, the rationale for the approach should be included in the RIA along with the detailed calculations.

The value of time is an active area of research, and HHS is now working on a project that will further explore these values.[57] This new work will investigate the extent to which the default values discussed in this section appropriately measure different types of time use, including the suitable treatment of overhead costs. In the interim, analysts should apply the default values described below. Regardless of the approach used, the assumptions and related uncertainties should be addressed as discussed in Chapter 6.

[57] See Boardman (2011) and DOT (2015b) for more discussion of the related literature.

The starting point for valuing changes in time use involves distinguishing between paid and unpaid time; i.e., between market production and nonmarket activities including leisure, household tasks, and volunteer work. The first default assumption is that regulatory activities undertaken by paid employees will displace other paid work tasks, while activities undertaken during non-work time will replace other unpaid activities. In other words, the work-related administrative requirements likely to be imposed by HHS regulations (e.g., completing additional reports) would not require that the affected individuals spend more time at work and less time on leisure activities; instead they would spend less time on other tasks associated with their current occupation and the employer might rearrange work assignments. If new employees are hired, this approach assumes that the activities required for regulatory compliance would replace the activities they pursued in their previous job; those hired would be transitioning between similar jobs rather than moving from unemployment to employment.

The second default assumption is that average or median estimates appropriately measure the value of a marginal unit of time. In reality, this marginal value will likely vary based on a variety of factors, such as the amount of time (e.g., a few hours versus days or months) or the types of time use affected. However, marginal estimates generally are not readily available; most easily accessible data sources provide averages or medians.

The third default assumption is that the value of activities conducted during paid work time can be best approximated by the cost of labor to the employer. The standard economic model assumes that employers are willing to incur labor costs equal to the value of workers' marginal product. Conceptually, this amount represents the value of what the employee would have otherwise produced in the absence of the regulation. Thus the opportunity cost of paid work time can be approximated based on the employer costs, including pay, benefits, taxes, and associated overhead.

The fourth default assumption is that the opportunity cost of unpaid time can be best approximated by post-tax wages. Consistent with the standard economic model, this approach assumes that individuals decide whether to engage in paid work depending on whether the incremental income exceeds the value they place on unpaid time, a decision generally described as the labor-leisure trade-off. Taxes and benefits are usually excluded from this calculation, assuming that individuals focus on their take-home pay in making related decisions. In other words, an additional hour of paid work is valued differently by the employee than the employer, because many costs to the employer are not received by employees (e.g., income and payroll taxes) or may not be visible to the employees (e.g., benefits) and hence are unlikely to be taken into account in their decision-making. As is the case throughout the analysis, particularly if the value placed on time use significantly influences the analytic conclusions, then the approaches discussed in Chapter 6 should be used to assess the implications of related uncertainties.[58]

Table 4.2 summarizes the assumptions used to develop default estimates of the value per hour of time. Below, we discuss these assumptions in greater detail.

[58] Estimating the value of time for individuals who are not active in the labor market, such as children or seniors, is particularly challenging. As discussed later in this chapter, analysts should apply the same approach for valuing non-work time to all individuals.

TABLE 4.2. CONSTRUCTING DEFAULT ESTIMATES OF THE VALUE OF TIME

CONTEXT	COSTS INCLUDED IN HOURLY VALUE	DATA SOURCES AND KEY ASSUMPTIONS
Employees undertaking administrative tasks while working	• Pre-tax wages	• OES or NCS ECEC data on wages
	• Benefits: - Paid time off - Health benefits - Retirement benefits - Other legally required benefits - Payroll taxes • Other overhead costs: - General and administrative (G&A) - Fixed overhead - Insurance - Accounting profit	• Industry-specific data as available, or assume benefits plus other overhead costs equal 100 percent of pre-tax wages (i.e., for a fully-loaded wage rate, multiply pre-tax wages by a factor of "2")
Individuals undertaking administrative tasks on their own time	• Post-tax wages	• OES or NCS ECEC data on wages • Adjust wage estimates using data on household income before and after taxes collected in the CPS
Acronyms: CPS – Current Population Survey, available at http://www.census.gov/cps/data/cpstablecreator.html (U.S. Census Bureau) ECEC – Employer Costs for Employee Compensation, available at http://www.bls.gov/ncs/ect/ (U.S. Bureau of Labor Statistics) NCS – National Compensation Survey, available at http://www.bls.gov/ncs/ (U.S. Bureau of Labor Statistics) OES – Occupational Employment Statistics, available at http://www.bls.gov/oes/home.htm (U.S. Bureau of Labor Statistics)		

On-the-job activities: For paid work-related activities, the opportunity cost, or value, of a unit of time devoted to regulatory compliance equals the marginal value of the product that would have otherwise been produced in the absence of the regulation. Another way to frame this concept is to ask, what benefit to the economy would the employee have produced with an additional hour of time?[59] Data on this value are not readily available; however, market data on employee compensation provide a reasonable proxy.

From an employer's perspective, when making a decision about whether to hire more help, the company will think about the entire cost of the new employee, including wages, fringe benefits, and other overhead costs needed to support the employee in accomplishing the work. Thus, to estimate the value of an hour of time, analysts should sum the costs of these items. Wages (pre-tax) generally include base pay, cost-of-living allowances, guaranteed pay, hazardous-duty pay, incentive pay (commissions, bonuses), and tips.[60] Fringe benefits generally include paid time off, health benefits, retirement benefits, other legally required benefits (e.g., worker's compensation) and payroll taxes.[61] The combination of wages and fringe benefits is often referred to as the employer costs of compensation.

In addition, employers incur other costs that support labor and are not directly relatable to the production of goods and services. These costs are generally referred to as "overhead costs," and may include the following categories:

[59] Analysts should generally assume that time losses associated with HHS regulations only affect the quantity of hours worked, not the price of goods and services produced with that time. Thus, the analysis focuses on the marginal value of production associated with an hour of time. If a proposed regulation will result in time reallocations that are sufficiently large to affect the price of goods and services produced, more complex analysis may be required.

[60] Throughout the remainder of this chapter, the term "wages" is used generally to refer collectively to all of these categories.

[61] Conceptually, payroll taxes are included in this calculation because analysts need a full accounting of the total cost paid by employers for their employees' time. As explained above, this cost is used as a proxy for the value of the employees' production.

- General and administrative (G&A) costs, such as human resources, payroll, accounting, sales personnel, executive salaries, legal fees, office supplies, equipment, communications, administrative buildings, office space, travel, subscriptions, and other items related to administrative activities that support operating (production) labor;
- Fixed costs, such as building services (safety, general engineering, general plant maintenance, janitorial, cafeteria);
- Insurance costs, such as liability, property, and travel; and
- Accounting profit, which reflects the opportunity cost of equity capital.[62]

Thus combining data on wages, benefits, and other overhead costs approximates the value of time from the employer's perspective.[63]

Two data sources published by the U.S. Bureau of Labor Statistics (BLS) provide national information on hourly wages by industry sector (see bottom of Table 4.2 for hyperlinks to data sources).[64] The Occupational Employment Statistics (OES) are generated from a semiannual mail survey that covers a broad number of establishments across the United States.[65] The National Compensation Survey (NCS) is an in-person survey of a subset of establishments and provides information on quarterly changes in employer costs (the Employer Cost Index, or ECI) and cost levels (Employer Costs for Employee Compensation, or ECEC).[66,67]

Both surveys use statistical methods to collect nationally representative samples. The OES survey is larger, covering a greater range of occupations and geographic areas, and provides estimates of median, as well as mean, wages.[68] In contrast, the NCS program samples fewer establishments, but conducts the survey in-person and collects more detailed information on occupations within an establishment. In addition to reporting wage and salary information (pre-tax, average only), the NCS provides data on other compensation, including benefits (paid leave, insurance, retirement). Generally, OES is the preferred source for national estimates of hourly wages given its broader geographic coverage. The ECEC is useful for identifying compensation rates for specific categories of employees (e.g., managers).

USING MEDIAN VS MEAN WAGE DATA

Whether the median or mean (i.e., average) is the best central tendency estimate of compensation depends on the extent to which the distribution is highly skewed for workers in the occupations of concern. When considering the overall population, the average is significantly greater than the median because of the small number of people who are very highly compensated. Thus, if only a fraction of the U.S population is affected by a regulation, the best estimate may be the median (which is the center of the income distribution), rather than the mean (which is closer to the upper tail of the distribution). However, if the entire population is affected, applying the mean may be appropriate. Analysts should consider the specific characteristics of the rule when selecting the most appropriate measure.

[62] "Accounting profit" is a different concept from "economic profit." Firms require the investment of capital to operate and must provide a reasonable return on that investment, or the capital would be put to other uses. Accounting profit is a measure of the return on this capital investment. Economic profit, in contrast, equals sales revenue minus all costs, including the cost of equity capital. Under perfect competition, long-run economic profits are zero. See U.S. Environmental Protection Agency's Science Advisory Board (2007) for more discussion.

[63] Publicly-available estimates of overhead costs may include fringe benefits; thus whether to separately include benefits will depend on the data sources used in the analysis. The overhead rate discussed in this section is intended to be inclusive of fringe benefits; therefore it is applied to an estimate of wages that does not include benefits.

[64] We focus on data sources providing hourly wage data, as opposed to weekly, annual, or household estimates, to avoid the need for additional assumptions about the number of hours worked and/or the number of employed workers in a household. If data on annual salaries is required, additional sources, such as the U.S. Bureau of Labor Statistics' Quarterly Census of Employment and Wages (QCEW, available at http://www.bls.gov/cew/), may also be used.

[65] OES excludes farm establishments and self-employed persons.

[66] See http://www.bls.gov/oes/ pages on "OES Frequently Asked Questions" for a comparison of the OES and NRC.

[67] NCS excludes federal government employees.

[68] Ideally, analysts would use estimates of the marginal wage rate (i.e., the increment paid for the last hour worked) rather than the average cost across all hours worked. However, average or median values are generally used due to the lack of data on marginal rates.

Obtaining data on other overhead costs is challenging. Overhead costs vary greatly across industries and firm sizes. In addition, the precise cost elements assigned as "indirect" or "overhead" costs, as opposed to direct costs or employee wages, are subject to some interpretation at the firm level.

No readily available, national data exist on overhead rates by industry or sector. Data available in the ECEC suggest that benefits average 46 percent of wages and salaries.[69] Because this figure excludes overhead costs other than benefits, it represents a likely lower bound on the overhead rate. In the private sector, analysts often use a "rule of thumb" assumption that total overhead costs (benefits plus other overhead) equal 150 percent of wages. As a an interim default, while HHS conducts more research, analysts should assume overhead costs (including benefits) are equal to 100 percent of pre-tax wages (roughly the midpoint between 46 and 150 percent), and they should test the sensitivity of their results to alternative assumptions. Figure 4.1 provides an example of this calculation.

FIGURE 4.1. SAMPLE CALCULATION OF THE VALUE OF TIME SPENT ON A PAID ADMINISTRATIVE TASK

Assume a proposed rule will result in five additional hours each year of administrative work for occupational therapy assistants (OES Occupation Code 31-2011). The opportunity cost of the time spent undertaking these activities would be calculated as follows:

Mean wages for occupational therapy assistants (national estimate) (OES, May 2014):	$27.53 per hour[(a)]
Overhead cost per direct labor hour:	100 percent
Hours spent per employer:	5 hours
Opportunity Cost Per Employee:	$27.53 * 2 * 5 = $275.30

[(a)] Because all occupational therapy assistants employed throughout the United States will assume additional administrative tasks in response to the regulation, use of the mean is appropriate in this example.

Unpaid activities: HHS regulations may also impose administrative burdens on individuals (e.g., filling out additional paperwork for health care reimbursements) unassociated with their job. Unlike individuals employed in the labor market, those engaged in nonmarket labor activities are not compensated. As a result, the rationale for selecting a rate for valuing time spent performing such activities is less straightforward than for market labor.

As discussed earlier, economists often assume that the marginal value of an hour of uncompensated activity is equal to marginal compensation received. In other words, the opportunity costs of not working equal the value of the compensation the individual would have received if he or she chose to work. This value is generally estimated based on the post-tax wage an individual would have received for market work. This interpretation applies both to people employed in the labor force, who (in principle) could adjust their working hours and compensation, as well as to those out of the labor force, who presumably have chosen not to work because they value their time more highly than the rate at which they would be compensated.[70]

To estimate the hourly value of unpaid administrative tasks, analysts should apply the post-tax wage rate. This rate can be obtained by adjusting the pre-tax wage rates reported in the OES or NCS to remove taxes, which vary as a percentage of wages over time and across locations.[71]

[69] See http://www.bls.gov/news.release/ecec.t01.htm, Table 1. Civilian workers, by major occupational and industry group (September 2015). Total benefits account for 31.4 percent of total compensation (wages and salaries plus benefits). To calculate the size of total benefits relative to wages and salaries, apply the following equation: 31.4/(100 – 31.4) = 45.8 percent.

[70] Analysts should also apply this approach when valuing time costs incurred by children or seniors (e.g., time spent at additional medical appointments), noting related uncertainties.

[71] National estimates of the Federal and State income taxes paid as a percentage of pre-tax income are difficult to obtain. The Internal Revenue Service (IRS) provides detailed reports of total Federal income tax collected relative to adjusted gross income; however, these data exclude State taxes (see, for example, "Individual Income Tax Rates and Tax Shares" at https://www.irs.gov/uac/SOI-Tax-Stats-Individual-Income-Tax-Rates-and-Tax-Shares).

To estimate the tax rate, including both Federal and state taxes, analysts should use data on household income before and after taxes collected in the CPS, a joint effort by the U.S. Census Bureau (Census) and BLS. The CPS collects data from a nationally-representative sample of 60,000 households on a monthly basis.[72] The Census maintains a tool called the "CPS Table Creator," which allows analysts to create customized data tables.[73] It provides both mean and median income; as with wage rates, which central tendency estimate analysts should use will depend on the specific characteristics of the rule.[74] Figure 4.2 provides an example calculation of the value of time spent on unpaid administrative tasks.

For both paid and unpaid work time, the representativeness of the wage and tax rate estimates is likely to be uncertain. Where plausible alternative estimates exist, analysts should test the sensitivity of their results to these assumptions (see Chapter 6), particularly if the alternative estimates significantly affect the analytic conclusions.

Materials: Materials used to complete administrative activities may include office supplies or other items. Generally, analysts should obtain cost estimates from readily-available office supply catalogs or websites and courier services (e.g., the U.S. Postal Service, Federal Express, United Parcel Service, DHL). In addition, the rule may generate a need for records storage, either electronically or on paper. If a substantial amount of data must be stored, analysts should consider the costs of electronic file storage and backup, rent for additional storage space, or the cost of filing cabinets or boxes.

Travel: Administrative costs may include travel, particularly where the new rule creates a need for meetings or training activities. The U.S. General Services Administration (GSA) provides per diem travel rates for lodging and meals.[75] For air travel, plane fares can be obtained using internet travel search engines. For travel by car, the Internal Revenue Service (IRS) publishes reimbursement rates for mileage.[76] The mileage rate can be applied to estimates of miles traveled obtained from internet websites providing travel directions. Analysts should also include travel time, as discussed earlier.[77]

[72] Household tax rates are appropriate because ideally individuals should make decisions based on the tax rates they actually pay.

[73] To estimate mean or median household income before taxes, under "Data Options" select the relevant calendar year and get a count of "Persons-All." Next, "Define Your Table" by selecting "Household Income – Alternative" as a row variable. Under the "Statistics" section, in the subsection called "Additional numeric variable statistics" choose "Household Income-Alternative" and "Mean" or "Median." In the "Income Definition" section, select "Customize your own income definition" and then select "1. Earnings (wages, salaries, and self-employment income)" and "19. Federal Earned Income Credit." For household income after taxes, follow the same steps and add the following additional selections in the customized income definition: "20. Federal Income Taxes after refundable credits except EIC," "21. State income taxes after all refundable credits," and "22. Payroll taxes (FICA and other mandatory deductions)." For 2014 (select 2015 as the most recent year of data), median pre-tax household income ($53,000) minus post-tax income ($44,599) and divided by median pre-tax income results in a median tax rate of 16 percent. (To access the CPS Table Creator, see http://www.census.gov/cps/data/cpstablecreator.html).

[74] As with wage rates, ideally, analysts would use estimates of the marginal tax rate (i.e., the tax rate applied to the last dollar of income earned) to make this adjustment, rather than the average tax rate paid for all income. While data on the distribution of marginal tax rates paid by the U.S. tax filers are available from the IRS, they only include Federal taxes; excluding State or other taxes. Thus, analysts should use the CPS data, even though it provides mean or median, rather than marginal rates, because it includes both Federal and State taxes.

[75] See GSA's website "Per Diem Rates Look-up" at http://www.gsa.gov/portal/category/100120.

[76] See IRS's website "Standard Mileage Rates" at http://www.irs.gov/Tax-Professionals/Standard-Mileage-Rates.

[77] See DOT (2015b) for recommended adjustment factors for the hourly estimates of value of time spent traveling, for different types of travel (available at: http://www.dot.gov/office-policy/transportation-policy/guidance-value-time). That document provides a detailed discussion of the theoretical and empirical basis for these adjustment factors.

FIGURE 4.2. SAMPLE CALCULATION OF THE VALUE OF TIME SPENT ON AN UNPAID ADMINISTRATIVE TASK

Assume a proposed rule will result in five additional hours each year of administrative work for a subset of affected individuals (working and non-working adults, children, and seniors) in the United States. The opportunity cost of the time spent undertaking these activities would be calculated as follows:

Median wages, all occupations (OES, May 2014)	= $17.09 per hour[(a)]
Median household tax rate (CPS, 2014 data)	= 16 percent[(a)]
Hours spent per individual	= 5 hours
Opportunity cost per individual	= $17.09 * [1-0.16] * 5 = $71.78

[(a)] In this instance, the distribution of income among the subset of the population subject to the regulation may not be representative of the U.S. income distribution. Therefore, the median may represent the best central tendency estimate of wage and household tax rates for affected individuals.

4.2.2 CAPITAL AND OPERATIONS AND MAINTENANCE COSTS

Regulated entities may also need to purchase and operate new equipment to comply with regulatory requirements. For example, they may need to purchase new computers and software, change equipment or maintenance schedules at a production facility, or adopt other new technology. In this section, we describe methods for estimating such costs.

Equipment and other capital components: Capital costs generally refer to the reallocation of resources needed to purchase and operate additional equipment or other inputs that are not immediately consumed in the production process.[78] Typical capital costs may include, for example: purchasing computers and software to support administrative tasks; or installing or retrofitting new equipment associated with the production of food, drugs, or other goods. Some regulations may lead to capital expenditures to acquire buildings or land.

Generally, analysts use market data to estimate the price of purchasing and installing such equipment. These data may be obtained through interviews, literature reviews, review of online merchandise catalogues, or other sources. In some cases, the cost of the equipment may include installation costs and it will not be necessary to separately estimate the costs of associated labor. Otherwise, labor costs should be estimated in terms of the fees paid to licensed installers or, if the work is completed in-house, using the approach for valuing paid time described above. Information describing the useful life of the equipment is also necessary to determine whether the equipment must be replaced during the time period of the analysis. Finally, a side cost often associated with installation is the temporary shutdown of operations (i.e., forgone revenues net of avoided variable operations and maintenance (O&M) costs). In many cases these costs are minimized by installing or retrofitting equipment during regular downtimes (e.g., for maintenance).

Operations and maintenance costs: O&M costs include the annual costs of labor, utilities, and other resources required to operate and maintain capital equipment, as well as other expenditures that do not involve the purchase of a capital asset. Typical O&M costs include labor costs (discussed earlier); electricity and other utilities; replacement parts; raw materials and other inputs to production. O&M costs may be variable, in that

[78] Note that capital costs described in this section should not be confused with the fixed overhead component of the overhead rate used to estimate the value of time (see Table 4.2). In the latter case, overhead costs are used as a proxy to estimate the value of time. This section, in contrast, describes the valuation of additional equipment or other goods that may be necessary to implement a proposed regulation. Where an entity purchases new equipment (e.g., hard drives) to store compliance information and shifts staff resources (without hiring additional staff) to undertake administrative tasks, time cost and capital cost should be summed (they are not duplicative).

they fluctuate with production levels, or fixed, where the costs are not tied to production levels.[79] Again, analysts generally use market data to estimate such costs.

For both capital and O&M costs, analysts must be careful to estimate incremental costs. For example, if a firm needs to purchase new and improved equipment to replace current machinery (or the machinery they would purchase during their next scheduled turnover), the incremental costs of the rule include only the costs above and beyond those associated with the equipment the firm would have otherwise purchased. Therefore, data are required on the cost and useful life of both the existing equipment and the newer technology needed to comply with the regulation.[80]

4.2.3 MEDICAL COSTS

Medical costs may be relevant to either the benefit or cost calculations depending on the characteristics of the regulation. As noted in Chapter 2, costs are generally the inputs and benefits are the outputs or outcomes of a policy. Thus if increases or decreases in medical costs are part of the implementation of the requirements (i.e., an input), they should be counted on the cost-side of the equation. If they are part of the intended outcome, then they should be included in the benefit calculation, taking care to avoid double-counting with other benefit measures. For some rules, whether medical costs or savings should be counted as a "cost" or "benefit" will be uncertain, and analysts will need to discuss where they are counted in documenting the analysis. Medical costs generally should be presented as a separate line item in the calculations so their treatment is clear.

The appropriate calculation of medical costs in benefit-cost analysis is an area where more work is needed, because of the substantial distortions introduced by regulation of the health care sector and the effects of government and private insurance reimbursement policies. These distortions drive a wedge between market prices and opportunity costs, which make estimation difficult. Comparison across studies suggests that different approaches can lead to noticeably different results (e.g., Bloom et al. 2001; Akobundu et al. 2006; Larg and Moss 2011), but there is no established set of recommended best practices. In addition, much of the available data were developed to support reimbursement decisions and are not necessarily appropriate for estimating opportunity costs. HHS is now undertaking a project to further explore this issue; in the interim analysts should follow the general approach described below and discuss associated uncertainties.

When benefits consist of mortality and morbidity risk reductions, as discussed in Chapter 3, only some types of costs should be added to the estimates of individual WTP used for valuation. More specifically, the value per statistical life (VSL) estimates used to value mortality risk reductions, and the WTP estimates used to value morbidity risk reductions (including the estimates of monetized QALYs) used as proxies when suitable WTP estimates are not available), may include costs borne by the affected individuals. They presumably reflect the effect of the risk reductions on the activities the individual undertakes (including the allocation of both work and non-work time), and may also reflect out-of-pocket costs. Hence to avoid double-counting, savings in medical costs are generally not added to these benefit values. The one exception is when the costs in the absence of the regulation would be borne by third parties, in which case any savings in resource costs (excluding transfers) may added.

When a regulation imposes costs on the health care sector, for example by establishing or changing requirements for treatment, then medical costs may be included in the cost analysis. As a simple illustration, assume that a regulation requires monitoring the health of all workers exposed to contaminants while cleaning up after a natural disaster. The costs of the regulation would include the incremental cost of the medical

[79] For example, variable costs, such as raw materials used as inputs to production, will rise or fall with production levels. Fixed costs, such as rent or utilities, do not vary with production levels in the near-term.

[80] Analysts should consider whether compliance costs may decrease over time as regulated entities gain experience with the new regulation. A significant body of literature related to the operation and management of industrial processes suggests that the per-unit cost of producing or using a given technology declines as experience with that technology increases over time (see Baloff 1971, Dutton and Thomas 1984, and Epple et al. 1991). For a review of the literature measuring the "learning rate" for different industries and technologies, see Auerswald et al. (2000).

monitoring. The health benefits that result from earlier detection and treatment (than in the absence of such monitoring) would be valued using the approaches discussed in Chapter 3.

Analysts must also consider whether the cost assessment requires prevalence-based or incidence-based per case estimates. The former typically reflect the average costs of all cases in a given year, and may be appropriate for short-lived effects, such as acute health conditions or time-limited monitoring and treatment programs (e.g., in the immediate wake of a natural disaster). Incidence-based estimates instead track or model the lifetime costs per case, and are desirable when the regulation affects the incidence of chronic conditions or longer-term monitoring and treatment programs. In these cases, costs are likely to fluctuate over time, and extrapolating lifetime costs from prevalence-based estimates may understate or overstate actual costs. Incidence-based estimates that consider the entire, multi-year progression of the disease may be preferable. The appropriate measure will depend on the data available as well as the nature of the health effect.

Analysts will need to review the existing literature for recent studies of the specific health effects and types of costs needed for a particular regulatory analysis. Akobundu et al. (2006) and Larg and Moss (2011) provide useful overviews of the characteristics and limitations of different measurement approaches applied by researchers. Lund et al. (2009) provide a comprehensive inventory of relevant data sources. In addition, analysts should consider contacting health economists who focus on the conditions of interest, such as technical experts at the Centers for Disease Control and Prevention, academic institutions, or nonprofit research organizations. The series of articles included in Yabroff et al. (2009) also provide useful information.

In summary, estimating medical costs requires substantial professional judgment; the appropriate approach will depend on the characteristics of the practices affected by the regulation as well as the available data. Analysts are encouraged to work with subject matter experts if they are unfamiliar with methods used to estimate medical costs or with the particular health effect of interest.

4.2.4 GOVERNMENT IMPLEMENTATION COSTS

Government entities may also incur costs, either as an implementing or regulated entity. For example, a regulation may impose new review, reporting, and record keeping requirements on State or local government entities responsible for recording vital statistics, such as births and deaths. In this example, the HHS may incur implementation costs related to developing guidance, conducting training, and increasing enforcement. Likewise, State and local governments may incur compliance costs to train staff, adjust their electronic databases and reporting systems, and alter how they store information.

If the government is involved in implementing the regulation, the costs to the agency represent an opportunity cost of the regulation, as do similar costs imposed on industry, even if no new staff are hired. The effort undertaken to implement the regulation would otherwise be spent on other productive tasks. Thus, these costs should be counted in the analysis, using the methods discussed above. Information included in internal budget estimates, such as full-time equivalent labor needed for the program or requests for capital expenditures, are useful sources of data for these cost estimates.

If the government is the subject of the regulation, estimating related costs also follows the same approaches described elsewhere in this chapter. If grants or other funding are provided by HHS to support implementation of the regulation by industry or others, these funds are transfers and should not be included as costs, assuming they have no behavioral impacts that could affect the estimates of national net benefits. However, the amount of the funding may serve as a proxy estimate of the compliance costs imposed by the rule, to the extent that related costs are fully covered.

4.3 ESTIMATING MARKET-LEVEL IMPACTS

The preceding sections assume that the proposed regulation will not significantly affect the quantity of goods produced (e.g., a new regulation resulting in increased costs to electronically store and transmit data related to certain medical procedures will not affect the quantity of procedures performed). When the regulation is anticipated to affect the quantity of goods produced, a more precise estimate of social costs would involve estimating changes in consumer and producer surplus (see Appendix B) using partial or general equilibrium models.

Where a single market or a small number of unconnected markets are affected, partial equilibrium analysis provides a useful tool for estimating welfare changes. Analysts use information about the quantity and price of goods produced without the regulation, compliance costs, and elasticities of supply and demand to estimate the equilibrium output with the regulation and net changes in consumer and producer surplus (see Appendix B and Boardman et al. 2011).[81] In addition to providing a more precise estimate of welfare changes, a partial equilibrium model also provides insight into who bears the cost of the regulation. Such information may be important if analysts anticipate the regulation will have significant distributional impacts (see Chapter 7).[82]

WHEN SHOULD ANALYSTS USE PARTIAL OR GENERAL EQUILIBRIUM MODELS?

Analysts should consider employing partial or general equilibrium models when changes in consumer and producer surplus are likely to significantly affect the analytic conclusions. For example, such effects might be important if large sectors of the U.S. economy are affected or if impacts are likely to be measurable at a national scale (e.g., relative to U.S. gross domestic product, GDP). In most cases, estimating compliance costs is a sufficient proxy for changes in surplus.

Where multiple, interconnected markets are affected, or substantial international effects are anticipated, analysts might consider using computable general equilibrium analysis to estimate impacts. Such modeling may also be useful when a regulation is part of a larger suite of regulations that may have economy-wide, interactive effects. These models measure shifts in production and consumption resulting from compliance costs. In addition, they estimate how shifts in quantity or price in one market affect related markets. General equilibrium models are complex and generally require a significant amount of data to capture the effects of a regulation (see Berck and Hoffman 2002 and Lofgren et al. 2002). Such analysis requires working with a pre-existing model developed by one of several academic, government, or other institutions.[83]

[81] Because compliance costs serve as the basis for changes in the supply curve, analysts should not combine separate estimates of total compliance costs with estimates of changes in surplus. Adding these cost estimates together would result in double-counting.

[82] For example, for products where consumer demand is relatively inelastic, producers may have greater ability to pass compliance costs on to consumers in the form of higher prices.

[83] Examples of computable general equilibrium models used by Federal agencies to estimate impacts to the U.S. economy include the Global Trade Analysis Project (GTAP) model, the USAGE model, the Intertemporal General Equilibrium Model, and EMPAX-CGE.

Chapter 5

Account for Timing

The costs, benefits, and other impacts of regulations often accrue over several years, requiring that analysts take into account how affected individuals value impacts that occur in different time periods. In addition, RIAs generally involve applying data that reflects past rather than current price levels. Thus analysts must both inflate prices from prior years to the same dollar year, and discount future impacts back to the base year in which the regulation is first implemented.[84] Carrying out these steps involves distinguishing between inflation and real changes in value, and understanding how to appropriately account for time preferences. Below, we first discuss the underlying concepts and basic approach, then describe how to adjust for inflation, calculate discounted present values, and determine impacts on an annualized basis.

5.1 BASIC CONCEPTS AND APPROACH

Consider the four streams of payments in Table 5.1. If they represent the net benefits of different policy options in each year, how might we choose among them? Options A, B, and C sum to the same total over the 10 year period, but the net benefits vary across years. Under Option A, costs substantially exceed benefits for two years after which benefits exceed costs; under Option B, costs also initially exceed benefits but by lesser amounts and for a longer period; under Option C, benefits exceed costs by the same amount in all years. Option D sums to a smaller total with net benefits that decline over time. Comparing such streams of payments, regardless of whether they represent costs, benefits, or net benefits, requires (1) understanding whether they include the effects of inflation and (2) addressing time preferences through discounting. In combination, considering these issues allows us to determine which option is preferable.

TABLE 5.1. COMPARING UNDISCOUNTED ANNUAL NET BENEFITS

YEAR	0	1	2	3	4	5	6	7	8	9	TOTAL
Option A	**($2,000)**	**($1,000)**	$200	$300	$400	$500	$600	$600	$700	$700	$1,000
Option B	**($600)**	**($500)**	**($400)**	**($300)**	$100	$200	$300	$600	$700	$900	$1,000
Option C	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	$1,000
Option D	$200	$200	$200	$50	$50	$50	$50	$50	$50	$0	$900

The first question is whether values are measured in real or nominal dollars. Observed prices are measured in nominal (current-year) dollars. Because these prices may be affected by economy-wide inflation, values in different years are not necessarily comparable. If there is inflation, the quantity of goods one can buy for $1.00 decreases over time. Real (constant or inflation-adjusted) dollars net-out the effect of inflation so that dollars have equal purchasing power over time and are comparable across different periods.

To avoid misleading comparisons, regulatory analyses should always be conducted in constant (real, inflation-adjusted) dollars.[85] This approach has the advantage of allowing analysts to avoid the difficult task of attempting to project future inflation rates. As discussed in more detail in section 5.2, all values should be first converted to the same year dollars, then the analysis should be conducted in real dollars from that point forward. For example, a regulatory analysis prepared in 2015, which projects benefits and costs over the next 10 or 20 years,

[84] As discussed in more detail later, the dollar year is likely to differ from the base year used for discounting.

[85] For the remainder of this discussion, we assume that the values in Table 5.1 are undiscounted and expressed in real terms.

may be conducted in constant 2014 dollars. Generally, a dollar year should be selected that is reasonably close to the current year.[86]

The second question is how to weight real benefits and costs that accrue in different time periods. There are two interrelated reasons why values are not likely to be weighted equally over time. One is individual time preferences; people generally prefer to receive benefits as soon as possible and to defer costs. The other is opportunity costs; resources received today can be invested to yield a positive return while resources expended are no longer available for investment.[87]

Analysts account for the effects of timing by discounting future impacts to the *base* year of the analysis. This base year commonly reflects the first year in which the regulation is implemented, and is likely to differ from the *dollar* year selected for the analysis. For example, an analysis conducted in 2015 may express all values in 2014 dollars. However, if the rule will not be implemented until 2017, the analysts may use 2017 as the base year for discounting. The dollar year and the base year must be clearly identified throughout the analysis.

HOW SHOULD ANALYSTS ACCOUNT FOR THE EFFECTS OF TIMING?

Analysts should first select a common *dollar* year, and inflate all unit values to that year. They should then calculate the benefits, costs, and net benefits expected to accrue in each future year of the analysis, report the undiscounted stream of benefits and costs, and report their present value applying discount rates of 3 and 7 percent. Analysts should also report annualized values (calculated using each discount rate). The *base* year used when calculating present values should be the year in which the regulation is initially implemented, and may differ from the dollar year.

Although there are conceptual differences between a discount rate and an interest rate, they are closely related. An interest rate is the market rate at which money can be borrowed or loaned, and results from the interaction between market participants' willingness to save and demand for borrowing. The discount rate reflects preferences for receiving benefits or bearing costs at different dates, which may be influenced by the opportunity costs imposed by regulations or by similar actions that divert resources from other investments or consumption. In practice, discount rates are often based on market interest rates.

As in the case of prices, care must be taken to distinguish between nominal and real discount rates. Because regulatory analyses are conducted in real dollars, a real discount rate must be applied. Below, we first discuss how to adjust for inflation. Section 5.3 then discusses discounting in more detail, and Section 5.4 describes how to convert discounted amounts to annualized dollars.

5.2 ADJUSTING FOR INFLATION

In regulatory analysis, analysts often work with data from many different time periods; an analysis conducted this year is likely to rely on unit cost and benefit data collected in several previous years. Adjusting for inflation involves using an index to convert all dollar values to the same year dollars. Indices commonly used to reflect economy-wide trends are the Consumer Price Index (CPI), and the gross domestic product (GDP) implicit price deflator. Because the CPI is more easily accessible, it is more frequently applied.[88] In general, the two approaches yield similar estimates of the inflation rate.

[86] A year prior to the current year is generally used as the dollar year because the rate of inflation for the current year is not yet known.

[87] The two reasons are related. When real interest rates are positive, individuals can purchase more goods and services if they postpone those purchases by saving more or borrowing less. To maximize utility (well-being), they should allocate their spending over time such that their preference for incremental current over future spending equals the interest rate. Real interest rates are typically positive because individuals require compensation for deferring consumption.

[88] As discussed in Chapter 8, the GDP deflator must be used in preparing the accounting statement required under OMB *Circular A-4*. It is also used to determine the threshold for conducting analyses under the Unfunded Mandates Reform Act as discussed in Chapter 7 (see, for example, HHS 2015). However, within the analysis itself, the CPI (or more specialized indices) may be used instead of the GDP deflator to adjust benefits and costs to the same year dollars.

Other, more specialized indices are also available that reflect price trends in particular market segments (such as producer prices or medical services) or in particular geographic areas. In this section, we focus on the CPI and GDP deflator, since these are the indices most commonly used in regulatory analysis. However, in some cases analysts may instead apply more specialized indices. The inflation index or indices used, and the rationale for applying them, must be clearly documented in the RIA.

The CPI is developed by the Bureau of Labor Statistics within the U.S. Department of Labor. It measures the average change over time in the prices paid by urban consumers for a market basket of goods and services. (According to the Bureau of Labor Statistics, these urban consumers represent about 87 percent of the U.S. population.[89]) The CPI is based on detailed information on actual expenditures by a statistically-representative sample of individuals and families, including all consumption goods and services.

The CPI website includes an inflation calculator (http://www.bls.gov/data/inflation_calculator.htm) that can be easily used to convert values to the same year dollars, based on purchases of all goods and services nationally. If an analyst prefers to directly apply the index values from the CPI tables (for example, including these values in a spreadsheet used to calculate benefits and costs), the index values must be converted to reflect the rate of change, expressed as a proportion or percentage. For example, if the analyst wishes to inflate a value from dollar year "a," in which the index was 120, to a dollar year "b," in which the index was 140 (a 20 point difference), the increase would be (20/120) * 100 = 17 percent.[90] Thus a unit cost of $100 in year "a" dollars would become $117 if expressed as year "b" dollars.

More generally, to inflate a value from year "a" to year "b," the percentage change is calculated as:

$$\textit{Percent inflation (CPI)} =$$

$$((CPI_{year\ b} - CPI_{year\ a}) / CPI_{year\ a}) * 100$$

The GDP deflator is instead based on the value of all goods and services produced within the U.S. economy; it also can be calculated for subsectors of the economy. It is developed by the Bureau of Economic Analysis in the U.S. Department of Commerce, and includes personal consumption, domestic investment, net exports, and government consumption and investment.[91] It is not derived from a market basket of goods; rather it changes depending on investment and consumption patterns.

The GDP deflator is provided in Table 1.1.9 of the National Income and Product Accounts, which can be accessed through the Bureau of Economic Analysis website.[92] Again, as in the case of the CPI, the index values need to be converted to a proportional or percentage change to be applied in the analysis. This conversion follows the same formula as provided above for the CPI.

5.3 DETERMINING PRESENT VALUES

Once all unit benefits and costs are converted to the same dollar year (i.e., to constant dollars) and the year in which they occur is identified, the next step is to calculate their discounted present value. This value indicates how much dollars paid or received at a later time are worth in the base year (i.e., the year in which the regulation is first implemented), given time preferences and opportunity costs as discussed earlier.[93] For

[89] This and other basic information on the CPI is available at http://www.bls.gov/cpi/cpifaq.htm.

[90] The change can also be expressed as a multiplier, applying the formula $CPI_{year\ b}$ / $CPI_{year\ a}$ (140/120 = 1.17 percent in the example). In spreadsheet analysis, converting the proportion into a percentage is not necessary; the analyst may simply enter the proportion and multiply the year "a" value by the result.

[91] A glossary of related terms is available at: http://www.bea.gov/glossary/glossary.cfm; more information on the underlying concepts and methodology is available at: http://www.bea.gov/methodologies/.

[92] To access this table: (1) click on the "Interactive Data" tab at the top of http://www.bea.gov/; (2) select "GDP & Personal Income" under "National Data;" (3) click on "Begin Using the Data;" (4) under "National Income and Product Account Tables," click on Section 1, and select Table 1.1.9, "Implicit Price Deflators;" (5) click on the "Options" icon to choose the desired time period and to indicate annual as the frequency, then select "Update" to regenerate the table.

[93] In some cases, regulated entities may begin to respond to the regulation before it becomes effective, and related costs, benefits, and net benefits will need to be carried forward to the base year rather than discounted. In this case, their value will increase rather than decrease between the time when they are incurred and the base year.

regulatory analysis, the OMB guidance in *Circular A-4* (2003) requires agencies to report the results of their analyses applying discount rates of three and seven percent per year.[94] The use of two rates reflects uncertainty about whether regulation is likely to displace investment or consumption.[95] In a simple theoretical model, investment- and consumption-based discount rates would be equal, but in reality distortions such as taxes lead to differences.

The seven percent rate is intended to reflect the opportunity costs associated with displacing private investment, and was based on the estimated average before-tax rate of return to private capital in the U.S. economy at the time when the OMB guidance was developed. The three percent rate is intended to reflect the opportunity costs associated with displacing consumption (often referred to as the marginal "social rate of time preference"), and was based on the before-tax rate of return on long-term government debt to approximate the interest paid on savings. This approach assumes that the savings rate represents the average by which consumers discount future consumption. Both are real rates, consistent with the use of real dollars when estimating benefits and costs.

The formulae for calculating present values are provided in Figure 5.1.

FIGURE 5.1. CALCULATING PRESENT VALUES

If:

- PV = present value as of the base year
- FV_t = future value in the year (t) when the benefit or cost accrues
- NPV = net present value of benefits and costs combined across all time periods
- r = the discount rate
- t = the number of years in the future (measured from the base year) when the cost or benefit accrues
- n = the number of years included in the analysis

Then the discount factor for costs or benefits that accrue at the end of year t is:

$$1/(1+r)^t$$

The present value of a future cost or benefit that accrues in year t is:

$$PV = FV_t\,(1/(1+r)^t)$$

The net present value for a stream of future benefits and costs is:

$$NPV = V_{t=0} + (FV_{t=1}/(1+r)) + (FV_{t=2}/(1+r)^2) + (FV_{t=3}/(1+r)^3)...(FV_{t=n}/(1+r)^n)$$

Most spreadsheet programs automate these calculations, as do many calculators. In Excel, the function is NPV(r, [range or list of cells with flows ordered from "now" to the last period]).[96] Financial calculators typically have an NPV function into which you can enter a stream of costs, benefits, or net benefits as well as a discount (interest) rate. While in Excel r should be entered as a decimal (e.g., 0.03 if the discount rate is three percent), in many calculators r instead must be entered as a percentage (e.g., 3). The Excel function also has some optional arguments, such as whether the payments occur at the start or end of each period. While the end of the period

[94] While OMB allows agencies to apply other rates if justified, in practice agencies usually apply only the three and seven percent rates for intra-generational impacts. Discounting inter-generational impacts (for policies such as those addressing climate change or radioactive waste storage) raises several difficult issues related to forecasting future preferences and opportunity costs as well as inter-generational equity. HHS analysts rarely need to address these concerns because most HHS analyses cover shorter time periods; i.e., 10 to 20 years as noted earlier in this this guidance. OMB *Circular A-4* (2003) provides more discussion of these issues.

[95] On occasion, it may be informative to estimate the internal rate of return, which is the discount rate at which benefits equal costs (i.e., the net present value is zero). Calculating the internal rate of return is generally not useful for selecting among regulatory alternatives, however. A policy may have more than one internal rate of return if net benefits change from positive to negative (or vice-versa) more than once over the time period addressed. In addition, as is the case for both benefit-cost and cost-effectiveness ratios, the internal rate of return is not sensitive to scale. It does not indicate the amount by which benefits exceed costs, and hence does not provide information on which policy maximizes net benefits when policies differ in size.

[96] Excel also provides a present value function [PV(r, n, payment per period)] that is useful when the values are the same in each period.

is the Excel default, analysts often instead assume that payments occur at the beginning of each period, which means that the impacts in the base year (year "0" in the examples) are not discounted. In this case, a value of "1" must be entered into the Excel formula under "type," to change the default from the end to the beginning of each period.[97]

As discussed in Chapter 2, benefits and costs generally should be assessed over a 10-to-20 year period, consistent with the OMB guidance, unless the policy terminates sooner. Analysts should select a period that is adequate to encompass the time needed for the regulation to become fully effective, without requiring extrapolation so far into the future that predicting impacts become highly speculative given changes in the population, economy, technology, and other factors. Impacts further in the future often add relatively little to the present value of benefits and costs, given the effects of discounting, and are unlikely to alter the policy implications of the analysis. However, longer time periods may be considered if clearly justified.

We can use the streams of undiscounted net benefits in Table 5.1 to provide an example of this process. First, consistent with the OMB guidance in *Circular A-4*, analysts should present the stream of undiscounted costs, benefits, and net benefits (as illustrated for net benefits in Table 5.1), to aid decision-makers in understanding the timing. Presenting these graphically is often useful, as illustrated in Figure 5.2 for Option A from Table 5.1.

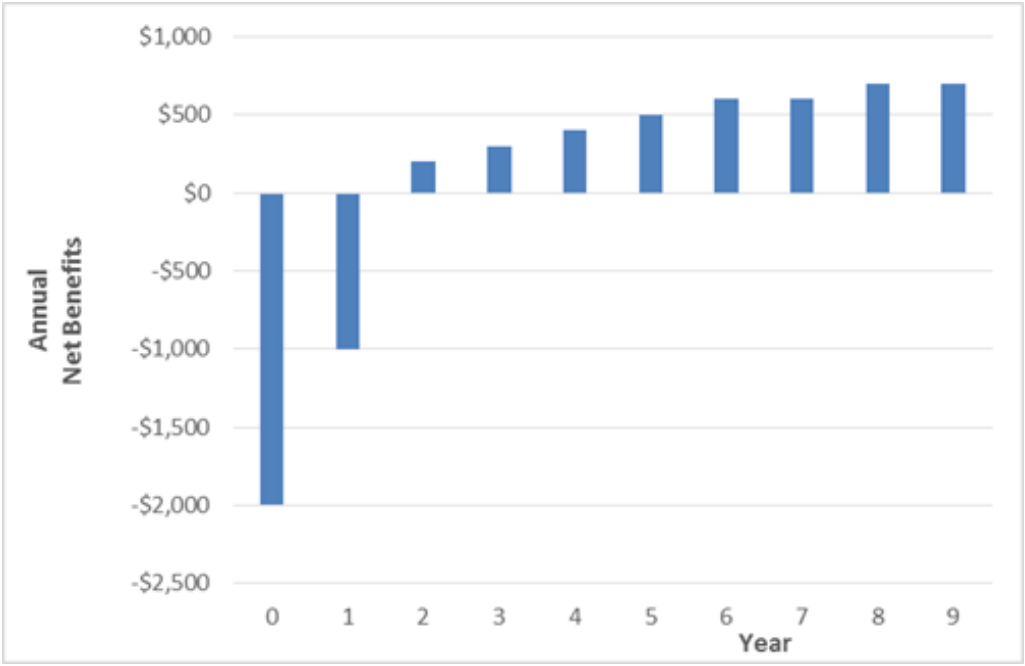


FIGURE 5.2. EXAMPLE PRESENTATION OF UNDISCOUNTED NET BENEFITS

Second, OMB requires that the results be presented using different discount rates, as illustrated in Table 5.2. This table presents the same four streams of net benefits as Table 5.1, undiscounted as well as discounted applying rates of the three and seven percent. Calculating present values makes it clear that the preferred option depends on the discount rate. Without discounting, Options A, B, and C all appear preferable to Option D. Discounted at a three percent rate, Option C is the best option. If the discount rate is seven percent, then Option D becomes best. At a seven percent rate, the net benefits of Option A also become negative. Thus at this rate, Option A would not be preferred to the "no action" baseline even if it were the only option being considered, since its costs exceed its benefits.

[97] While typically impacts incurred in the base year are not discounted, assuming payments occur at the beginning of each period, for some regulations analysts may find that it is more appropriate to assume end-of-period payments. In that case, base year impacts should be discounted and the Excel default assumption is appropriate. In the RIA, analysts should report the timing assumption used and the same assumption should be applied throughout the analysis.

TABLE 5.2. COMPARING DISCOUNTED NET BENEFITS

YEAR	0	1	2	3	4	5	6	7	8	9	NPV
Undiscounted											
Option A	**($2,000)**	**($1,000)**	$200	$300	$400	$500	$600	$600	$700	$700	$1,000
Option B	**($600)**	**($500)**	**($400)**	**($300)**	$100	$200	$300	$600	$700	$900	$1,000
Option C	$100	$100	$100	$100	$100	$100	$100	$100	$100	$100	$1,000
Option D	$200	$200	$200	$50	$50	$50	$50	$50	$50	$0	$900
Discounted to Year "0" at 3 Percent											
Option A	**($2,000)**	**($971)**	$189	$275	$355	$431	$502	$488	$553	$536	$358
Option B	**($600)**	**($485)**	**($377)**	**($275)**	$89	$173	$251	$488	$553	$690	$506
Option C	$100	$97	$94	$92	$89	$86	$84	$81	$79	$77	$879
Option D	$200	$194	$189	$46	$44	$43	$42	$41	$39	$0	$838
Discounted to Year "0" at 7 Percent											
Option A	**($2,000)**	**($935)**	$175	$245	$305	$356	$400	$374	$407	$381	**($292)**
Option B	**($600)**	**($467)**	**($349)**	**($245)**	$76	$143	$200	$374	$407	$490	$28
Option C	$100	$93	$87	$82	$76	$71	$67	$62	$58	$54	$752
Option D	$200	$187	$175	$41	$38	$36	$33	$31	$29	$0	$770

As demonstrated by Table 5.2, the choice of a discount rate can have a significant effect on the estimated net benefits. Whether the discount rate will affect the conclusions of the analysis will depend on the pattern of benefits and costs over time for each alternative considered. The option that provides the largest net benefits will depend on the magnitude of the impacts and their timing, as well as on the discount rate. Generally, the decision rule is that if only one policy is considered, then the policy should be implemented if the present value of net benefits is greater than zero. For regulatory analyses, which should consider multiple options (as discussed in Chapter 2 of this guidance), the option that is preferable in terms of economic efficiency will be the option with the largest net benefits, as long as the net present value is greater than zero.

5.4 ANNUALIZING IMPACTS

For regulatory analyses, OMB *Circular A-4* (2003) also requires that analysts present benefits, costs, and net benefits on an annualized basis to facilitate comparisons across analyses that cover different time periods. The annualized value of a stream of benefits, costs, or net benefits is the constant annual amount that, if maintained for the same number of years as the initial stream, has the same present value. In other words, annualization spreads the costs, benefits, or net benefits equally over the time period assessed, taking the discount rate into account. The concept is similar to amortization of a loan, in which the principal and interest are paid through a series of constant payments.

The formula for annualization is provided in Figure 5.3; the expression in brackets transforms a value into an annuity of n years at a discount rate r. Note that applying this formula requires first estimating the present value, following the formulae in Figure 5.1 as discussed in the preceding section.

FIGURE 5.3. CALCULATING ANNUALIZED VALUES

If:

- PV = net present value of costs, benefits, or net benefits
- r = the discount rate
- n = the number of years included in the analysis
- AV = annualized value

The annualized value is:

$$AV = PV * [(r * (1 + r)^{n}) / ((1 + r)^{n} - 1)]$$

Once a present value is calculated, it can be easily converted to an annualized value using spreadsheet software or a financial calculator. In Excel, the function is PMT (r, nper [number of periods], and PV). Because the PMT function is designed to calculate loan payments, it will provide a value with the opposite sign of the present value; simply reversing the sign will provide the correct amount for the purpose of regulatory analysis. OMB's 2011 Regulatory Impact Analysis: Frequently Asked Questions provides more detailed, step-by-step guidance on these calculations.

The annualized value is an alternative method for expressing the net benefits; the ranking of policies by annualized value will be the same as the ranking by present value net benefits when estimated over the same time period. To illustrate, in Table 5.3 we provide the results for the same streams of net benefits as assessed in Table 5.2. The conclusions are the same: Option C has the largest annualized value under a three percent rate; while Option D has the largest annualized value under a seven percent rate. If, however, these options were implemented over different time periods, the results could vary.

TABLE 5.3. COMPARING ANNUALIZED NET BENEFITS

OPTION	ANNUALIZED
Undiscounted	
Option A	$100
Option B	$100
Option C	$100
Option D	$90
Discounted at 3 Percent	
Option A	$41
Option B	$58
Option C	$100
Option D	$95
Discounted at 7 Percent	
Option A	**($39)**
Option B	$4
Option C	$100
Option D	$102

Because annualization provides a different perspective than the estimate of net present values, both annualized and present values should be reported in the RIA along with information on the time period over which these measures are calculated. The annualized value measures the average flow over the years included; the net present value measures the total. Annualized estimates are also needed to complete the accounting statement that must be submitted to OMB along with the RIA, as discussed in more detail in Chapter 8.

Chapter 6

Address Uncertainty and Nonquantifiable Effects

Any analysis involves uncertainties, including difficulties related to quantifying some potentially important effects. The challenge for the analyst is to determine how to best assess or quantify these uncertainties to support decision-making. The goal is to ensure that decision-makers and other stakeholders understand the extent to which key uncertainties – in the data, models, and assumptions – affect the main analytic conclusions.

For example, if the agency's best estimates suggest that benefits exceed costs for a particular regulatory option, how likely is it that this conclusion would be reversed given uncertainty about the magnitudes of the quantified effects and the potential impact of nonquantified effects? Might these uncertainties affect the relative rankings of the policy options? Answering these questions requires quantifying impacts to the greatest extent possible, and identifying key uncertainties and exploring them in both quantitative and qualitative terms. Over time, analysts should work to reduce these uncertainties and minimize the types of effects that cannot be quantified, by anticipating future analytic needs and investing in research that will be useful across a variety of regulatory analyses.

This chapter discusses strategies for characterizing the uncertainty in quantified effects as well as the potential impacts of nonquantified effects. It focuses on the benefit-cost analysis, as discussed in the prior chapters, but the approaches it describes are applicable to the supplemental analyses discussed later in this guidance as well. As with other analytic components, the uncertainty analysis is often iterative; the initial analysis may lead to decisions to conduct more research or to change the assumptions used, and perhaps to explore other policy options.

Although the assessment of uncertainty (including nonquantified effects) may be described along with the analytic methods when documenting the RIA (see Chapter 8), it is often helpful to summarize key uncertainties in a separate section. For example, the chapter describing the benefits analysis could first describe the analytic approach, then present the results, and conclude by discussing uncertainty and its implications. The executive summary, and the chapter that compares costs to benefits, could consolidate the most important findings from the individual chapters and describe how the uncertainties affect the overall conclusions.

6.1 CHARACTERIZING UNCERTAINTY IN QUANTIFIED EFFECTS

The data and models used to estimate costs, benefits, and other impacts inevitably involve limitations. These may relate to the quality of the methods used to collect the data, the extent to which the data address the same population, industries, or geographic area as the regulatory impacts, and the degree to which conditions may change between when the data were collected and when the regulation is implemented. In addition, the models used in the analysis, which may range from simple formulae to complex computer simulations, involve making assumptions about the relationships between various factors. All analyses require predicting how those affected will respond to the regulation, which adds to the uncertainty. The challenge for the analyst is to clearly describe (in qualitative and quantitative terms) the uncertainties related to the data, models, and assumptions in a way that aids decision-makers in understanding the confidence they should have in the results and the likely direction and magnitude of any bias.

6.1.1 BASIC CONCEPTS

Conceptually, one should distinguish uncertainty and variability. Variability refers to heterogeneity; for example, differences in the ages of those affected by a regulation. While variability can be described by statistical measures such as the standard deviation, it may be difficult to characterize precisely given that data may be

available for only a small (and perhaps non-representative) sample of those affected or for a limited geographic area or time period. The usual measure of uncertainty about a parameter when estimated from a sample of the population ("sampling variability") will be larger when there is more variability in the population (if there were no variability, even a small sample would yield an exact estimate of the parameter).[98]

In contrast, uncertainty describes lack of knowledge. For example, data on the relationship between exposure to a pathogen and the risk of mortality may be available for only a particular age group, and the agency may be uncertain whether individuals of different ages would respond similarly to the exposure. Variability is a characteristic of the real world that cannot be reduced by research (although research can lead to a better understanding of variability). In contrast, uncertainty concerns lack of knowledge and can be reduced by research.

Regulatory analysts often lack the time and resources needed to engage in substantial new primary research, and must determine how to best target their efforts. Such targeting requires using screening analysis (see Chapter 2) to identify areas where more work will have the most important implications for decision-making. Analysts must then determine how to best combine the available data with reasonable models and assumptions to characterize regulatory impacts. The limitations and uncertainties in these data, models, and assumptions must be clearly disclosed in the RIA.

The requirements in OMB *Circular A-4* (2003) encompass both variability and lack of knowledge when discussing treatment of uncertainty. OMB urges analysts to fully disclose any uncertainties inherent in the analysis and to evaluate and justify their analytical choices. OMB cautions that, at times, uncertainties may be significant enough to warrant delaying a decision until more information can be collected and assessed. This is especially true in situations where uncertainties have a significant effect on which regulatory decision appears to be best. When considering whether to recommend a delay, analysts must take into account both costs (e.g., of further data gathering efforts) and benefits (e.g., of the knowledge likely to be obtained from the new data). Delay may also have consequences for social welfare (for instance if it allows dangerous practices to continue), which must also be considered along with the impacts of any interim protective measures. If the timing of the regulation is determined by statute or court order, delay may not be possible.

6.1.2 GENERAL APPROACH

There are many options for addressing uncertainty in quantified effects. In *Circular A-4*, OMB outlines three approaches with increasing levels of complexity: qualitative discussion, numerical sensitivity analysis, and probabilistic analysis. These three methods are summarized in Table 6.1 and described in more detail below. Additional information on these approaches is provided in Morgan and Henrion (1990), Boardman et al. (2011), and other texts.

[98] Statistical or sampling variability is the variability in a statistical estimate that results when the estimate is calculated from a sample, not the full population. For example, the average height in the sample may not equal the average height in the population because a disproportionate number of tall people were sampled by chance.

TABLE 6.1. APPROACHES FOR ADDRESSING UNCERTAINTY IN QUANTIFIED EFFECTS

APPROACH	APPLICABILITY	CONDUCT
Qualitative Discussion	• For all analyses. • May suffice if: – the rule involves annual economic effects less than $1 billion; – the analyst is able to demonstrate that the results are robust to uncertainties; and, – the consequences of the rule are modest.	Disclose key assumptions and uncertainties and include information on the implications for decision-making.
Numerical Sensitivity Analysis	• For rules involving annual economic effects less than $1 billion, where: – the qualitative discussion raises questions about the robustness of the results; or, – the consequences of the rule are large.	Vary one or many parameters to calculate distinct sets of results for comparison.
Probabilistic Analysis	• For rules involving annual economic effects of $1 billion or more (required). • For rules with smaller impacts where numerical sensitivity analysis raises questions about the robustness of the results.	Develop distributions for the uncertain parameters and conduct Monte Carlo analysis to determine the distribution of the results.

Qualitative discussion of uncertainties: Qualitative discussion is the least rigorous approach, but is of significant importance. It should always be included in the RIA. This approach involves disclosing key assumptions and uncertainties and including information on the implications. To the greatest extent possible, the qualitative discussion should include both the likely direction of the potential bias (i.e., whether the assumption may lead to an under- or over-estimate of the impacts) and the likely magnitude of the effect (e.g., whether it is major or minor). Such information will help decision-makers and others better understand the implications of the analysis.

Numerical sensitivity analysis: Numerical sensitivity analysis allows the analyst to explore the effects of varying the values of key parameters and is often useful to determine whether uncertainty about particular components or assumptions may substantially affect the analytic result, as well as when data limitations or constrained resources prevent full probabilistic analysis. Sensitivity analysis can be conducted by: (1) by changing one variable or assumption at a time and calculating a new set of estimates (sometimes referred to as "partial sensitivity analysis"); or (2) by varying several variables simultaneously to learn more about the robustness of the results to widespread changes.

When conducting partial sensitivity analysis, it is generally infeasible to test all assumptions. Attention should be devoted to analyzing those assumptions or variables that are most important (in that they may have the greatest effect on the result) or are most uncertain. The analyst should vary key parameters one at a time using plausible alternative values while holding all other parameters constant. Partial sensitivity analysis can be conducted as a breakeven, or threshold, analysis; for example, where the analyst seeks to find the value of one key parameter at which quantified benefits equal costs (i.e., net benefits equal zero), as discussed later in this chapter.

Varying a combination of parameters simultaneously may obscure the effect that a single variable or assumption has on the estimates, but can be particularly useful when a group of parameters are closely related (e.g., changing demographics and participation in the labor market) or when conducting a bounding analysis. In a bounding analysis, the most- or least-favorable assumptions are selected to calculate best- or worst-case results. These two sets of results represent high-end and low-end estimates that bound the primary results of the analysis. However, care should be taken in conducting and interpreting this type of analysis, because it is

extremely unlikely that all of the parameters will simultaneously be at their highest or lowest values. Thus the outcome of an analysis that uses lower (or upper) bound estimates for all parameters is very improbable.

If the sign of the net benefits or the relative ranking of the regulatory alternatives does not change in response to sensitivity tests, analysts and decision-makers can conclude that the results are relatively robust and have greater confidence in them. Otherwise, the analyst should (1) further investigate whether it is likely that the alternative assumptions are more appropriate than the assumptions used in the original analysis; and (2) conduct more rigorous probabilistic analysis if possible.

Probabilistic analysis: Probabilistic analysis is generally most informative because it quantifies the likelihood that different results will occur. However, in some cases such analysis may not be warranted or feasible given data limitations and constrained time and resources. OMB *Circular A-4* indicates that probabilistic analysis "is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the $1 billion annual threshold" (OMB 2003, p. 41).

Probabilistic analysis often involves the use of simulation models to quantify the probability distributions of the effects. It provides decision-makers with information about the variance, or spread, of the statistical distribution of the impacts. This information may be particularly useful when the expected value of the net benefits is close to zero or similar across multiple policy alternatives. In such cases, decision-makers may feel more confident about the results if they have a smaller variance, because the realized results are more likely to be near the expected value.

To conduct a formal probabilistic analysis, analysts must determine the joint distribution of the uncertain parameters; i.e., the distribution of each parameter together with any dependencies among them. For some parameters, such as the average body mass index (BMI) of the population when BMI has been measured for a large representative sample, the distribution can be well estimated from the sample distribution. In other cases, the probability distribution may be estimated from other data (e.g., by regression analysis), or it may be necessary to assume a distribution (e.g., uniform or triangular between upper and lower bounds) and to test whether the results are very sensitive to the assumed distribution.

Even when data are limited, distributions can be developed through formal, structured expert elicitation. Such elicitation is designed to avoid well-known heuristics and biases that can lead to poor judgment, and may be worthwhile if (1) assumptions about the distribution are likely to significantly affect the analytic results; (2) additional primary data collection is not feasible or cost-effective; and (3) sufficient time and resources are available.

Conducting structured expert elicitation requires substantial effort. Researchers first develop a well-defined question to be addressed, as well as an extensive elicitation protocol designed to ensure that the experts each interpret the questions similarly and explain the bases for their responses. Experts are identified through a formal process intended to provide a range of perspectives. The elicitation often includes supplying the experts with background materials and holding a pre-elicitation workshop to share and critique information. The elicitation is then conducted with each expert individually, frequently through a lengthy interview following a pre-determined protocol. More information on this process can be found in the expert elicitation literature (e.g., Morgan and Henrion 1990, Cooke 1991, and O'Hagan et al. 2006).

Once the joint distribution of the key parameters is estimated, Monte Carlo simulation techniques are applied to derive a probability distribution of the outcome measure, which may be total costs, total benefits, net benefits, or another impact of concern. Monte Carlo analysis involves taking a random draw from the joint distribution of the uncertain parameters (or from the distributions for each parameter if they are independent) to produce a value for each parameter; these values are then used to calculate the outcome measure. This process is

repeated many times to produce a distribution of the outcome measure, the average of which provides an estimate of its expected value.

An advantage of Monte Carlo analysis is that it provides information on the full distribution of effects, from which one can determine how likely it is that the effect exceeds any particular threshold (e.g., zero). A limitation is that the results can be sensitive to the probability distributions that are used for the input parameters, and these are often not known with much accuracy.

In sum, HHS analysts should quantify the impacts of the regulatory alternatives to the greatest extent practical.[99] The analysis should be accompanied by clear discussion of the evidence of causality as well as the quality of the studies and the statistical rigor of the methods used. However, even if the available data are of low quality or inconsistent, the impact should be quantified and accompanied by an appropriate assessment of uncertainty that clearly communicates the limitations of the analysis.[100] When time and resource constraints restrict the extent to which less significant impacts can be quantified, the evidence used to support the analytic decision should be reported. Potentially significant effects should be left unquantified only when there is no feasible approach for quantifying them.

Regardless of which approach is used to assess uncertainty, analysts should take care to avoid the appearance of false precision. Calculations should be performed without any intermediate rounding, but the results should generally be rounded for presentation in the RIA. While a variety of conventions are used in different disciplines to determine the number of significant figures to present, generally the results should be rounded to reflect the number of significant digits in the input data. For example, total costs should not be reported to the penny if the unit costs used as an input are reported in tens or hundreds of dollars.

6.2 CHARACTERIZING NONQUANTIFIED EFFECTS

Another challenge is addressing outcomes that cannot be quantified but may have important implications for decision-making. For example, available data may suggest that a regulated hazard affects the risk of both mortality and morbidity, but may not be adequate to estimate the change in some types of morbidity risks associated with each regulatory option. Without quantification, it is difficult to appropriately balance the risk reductions associated with each option against its costs, or to determine the relative importance of these different types of benefits.[101]

Quantification with appropriate treatment of uncertainty is desired (as discussed above) because it provides a clearer indication of the likely direction and magnitude of the impacts. If quantification is not possible, analysts must determine how to best provide related information. Ignoring potentially important nonquantified effects may lead to poor decisions, but there is also a danger of overemphasizing them. In the absence of information, decision-makers and others may weight nonquantified effects in a manner consistent with their own (unarticulated and perhaps unconscious) beliefs, without sufficiently probing the rationale or the weighting. Clear presentation of the available evidence is needed to counterbalance this tendency.[102]

Thus analysts should first quantify regulatory impacts to the greatest degree possible, using tools such as sensitivity and probabilistic analysis to evaluate the effects of uncertainty as discussed previously. They then should determine how to best describe those effects that remain unquantifiable, to provide insights into their significance in comparison to each other and to the quantified impacts, as discussed below.

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[99] OMB *Circular A-4* states: "[t]o the extent feasible, you should quantify all potential incremental benefits and costs" (OMB 2003, p. 45).

[100] Determining how to best apply the available research requires careful review of the evidence and substantial professional judgment. A number of approaches, such as criteria-driven systematic review, meta-analysis, and structured expert elicitation, can be used to develop estimates in cases where the research varies in quality and provides inconsistent results. The benefit transfer framework, discussed in Chapter 3, also can be applied to other types of quantities to develop estimates from data on somewhat dissimilar effects.

[101] We use the term "quantification" to refer to the consequences of the regulation (generally measured in physical units, such as cases averted), and monetization to refer to the dollar value of those consequences.

[102] OMB *Circular A-4* (2003) indicates that nonquantified effects should be included in the summary table discussed in Chapter 8.

6.2.1 BASIC CONCEPTS

Analysts may be unable to estimate some potentially important regulatory impacts due to gaps in the available data, the nature of the impacts themselves, or the need to focus on assessing more significant effects due to time and resource constraints. For example, analysts may not have the data needed to estimate the effect of the regulation on disease incidence, even though the available research suggests that the disease is associated with the regulated hazard. In the case of costs, analysts may have evidence that the regulation will lead to significant innovation, but may not be able to predict or describe the likely innovations adequately to estimate the impacts in monetary terms.

Another example is information provision. Some regulations increase the type or quality of information available and its dissemination, but research may be lacking on how recipients are likely to respond. Thus while an intermediate measure may be available, such as the number of patients who receive information on potentially beneficial lifestyle changes, it may not be possible to translate this measure into a quantity that can be monetized to estimate benefits. The latter requires an estimate of the change in behavior that results and of how the behavioral change affects individual welfare; e.g., of the degree to which the risk of illness or death is reduced. While these types of deficiencies ideally would be remedied through additional primary research, such research may require more time and resources than immediately available. HHS agencies should, however, try to anticipate future analytic needs and invest in research that will be useful across several regulatory analyses.

In other cases, the lack of quantification may result because the effects are less tangible and more subject to normative judgment. They may involve important human values, such as dignity, equity, and privacy. While it may be difficult to quantify the change in these values attributable to a particular regulation, it may be possible to count the number of people affected or report other intermediate measures.

Any intermediate measures, such as these counts, should be presented in the analysis as indicators of potential costs or benefits. For example, if analysts have information on the number of organizations subject to a regulatory provision, but lack the information needed to estimate related costs, or they have information on the number of individuals affected, but lack the data needed to estimate a particular benefit, these counts should be reported. Such intermediate measures should also be reported when the resulting benefits and costs are fully quantified, to promote better understanding of the analytic results.

6.2.2 GENERAL APPROACH

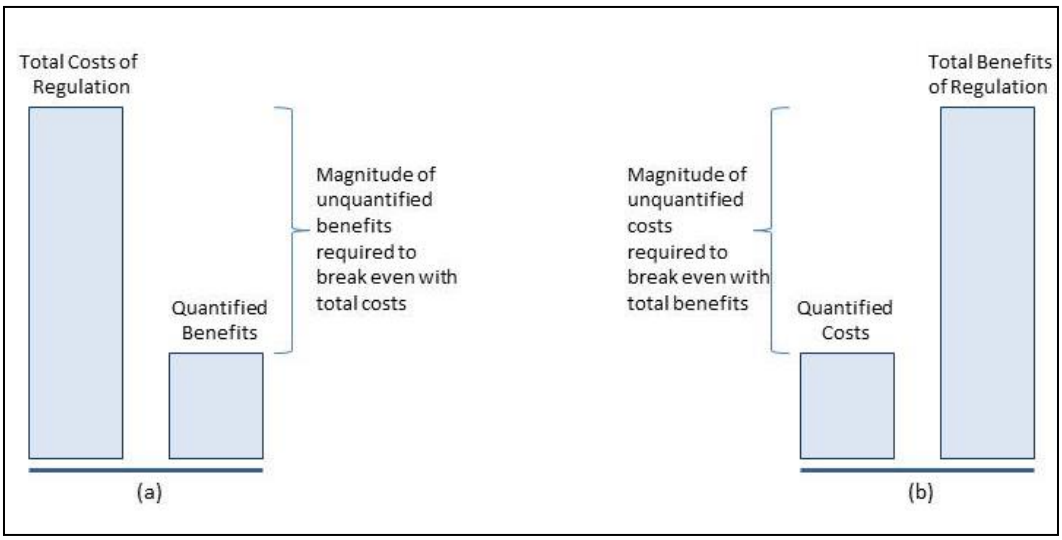
Options for incorporating nonquantified effects into the regulatory analysis depend on the available data and include both quantitative and qualitative approaches. Approaches that involve some calculation (and may be particularly useful when comparing benefits and costs) include breakeven, cost-effectiveness, and bounding analysis, but care must be taken to avoid misinterpretation of the results. More qualitative approaches include the use of tables and graphics as well as text discussions.

HOW SHOULD NONQUANTIFIABLE EFFECTS BE ADDRESSED?

If it is not possible to quantify an impact, analysts should consider using breakeven, cost-effectiveness, or bounding analysis, as well as tables and text, to illustrate the potential implications.

Breakeven analysis: Breakeven analysis, sometimes referred to as threshold analysis, asks the question "how large would the nonquantified effect(s) have to be, to bridge the gap between quantified benefits and costs?" Figure 6.1 provides an example of this concept. Part (a) shows the case where only some of the benefits can be quantified; part (b) illustrates the case where only some of the costs can be quantified.

FIGURE 6.1. BREAKEVEN ANALYSIS



Generally, breakeven analysis can only be conducted for a single quantity. Thus breakeven analysis is useful when analysts are particularly uncertain about one key parameter. For example, analysts may have information on the value of the effect (e.g., the VSL in the case of mortality risk reductions) but not the physical effects (e.g., the number of statistical cases averted). In this case, the breakeven analysis would be used to estimate the number of averted cases needed for benefits to exceed costs, given the VSL. Similarly, for costs, it may be possible to estimate the number of firms affected by a particular provision, but not the cost per firm. Breakeven analysis can be used to provide insight into how large the cost per firm would need to be for the costs to exceed the benefits of that provision. It can also be used to identify the breakeven probability of occurrence that would equalize costs and benefits.

Once the analysis is conducted, decision-makers and stakeholders can inspect the results to judge whether it is likely that the nonquantified effects are large enough to fill the gap. Breakeven analysis is most useful when some information is available on the potential magnitude of the impact, to provide a basis for judging whether the nonquantified effects can plausibly exceed the breakeven amount. It also may be informative when data are available but not public. For example, confidential information on the likelihood and consequences of terrorist attacks may be available to decision-makers but not to regulatory analysts or the general public. This information could provide context for decision-makers' review of the breakeven results for a regulation that addresses homeland security.

Cost-effectiveness analysis: Cost-effectiveness analysis is another approach that can provide insights when an impact can be quantified but cannot be assigned a monetary value (see Institute of Medicine 2006, Drummond et al. 2015). Under this approach, a monetary estimate of the costs (net of any monetized benefits) is divided by an effects measure to determine the cost per unit of effect. The effect could be the number of deaths averted, QALYs gained (see Chapter 3 and Appendix C), individuals treated, or another measure. Care must be taken, however, in interpreting the results. Cost-effectiveness ratios do not indicate whether an intervention is worth undertaking (i.e., whether the value of the benefits exceeds the costs), nor which option is likely to yield the largest net benefits.

Bounding or "what-if" analysis: Bounding analysis considers the extent to which benefits are likely to exceed costs based on lower- or upper-bound estimates of the magnitude of the nonquantified effects. For example, if the available data are sufficient to estimate that the mortality risk reductions associated with the regulation are unlikely to be greater than 1,000 statistical cases or fewer than 10 statistical cases, then the results could be presented using both estimates. "What if" analysis is similar, and involves investigating the impact of various hypothetical, but plausible, scenarios on the results. For example, the analyst could compare benefits and costs

for mortality risk reductions ranging from 10 to 1,000 statistical cases, if he or she believes that outcomes within this range are possible, and report the extent to which benefits exceed costs under each scenario.

The dividing line between these approaches and standard sensitivity analysis (discussed above) is somewhat vague. In concept, bounding or "what-if" analysis in this case would involve very wide ranges based on relatively little data or supporting evidence, and would be presented separately from the primary estimates of benefits and costs due to the high degree of speculation involved.

Tables and graphics: Tables and graphics are often useful for highlighting nonquantified effects, to ensure that they are not overlooked by decision-makers and others. One option is to simply list the effects in a table; however, the list is likely to be more useful if the effects can be categorized in a way that indicates the implications for decision-making. This categorization could include whether the effects are likely to be large or small, and to lead to over- or underestimates. Separate categories or exhibits could be used to report the strength of the evidence that links the effect to the regulation, the likelihood of its occurrence (e.g., high or low), or the extent to which it is reversible, as well as other attributes that will be salient for decision-making.

Table 6.2 below provides an example that uses symbols to highlight the potential magnitude of the impacts.[103] Alternatively or in addition, analysts could insert text into the table to provide more information than can be conveyed by a symbol. Such tables can also be used to separately indicate the effects on benefits and costs, rather than solely focusing on net benefits as in the example.

TABLE 6.2. EXAMPLE OF SUMMARY OF NONQUANTIFIED EFFECTS

EFFECT OF NONQUANTIFIED IMPACTS ON NET BENEFITS	POTENTIAL MAGNITUDE*
Analysis may overstate net benefits	
• impact "a"	
• impact "b"	
• etc.	
Analysis may understate net benefits	
• impact "c"	
• impact "d"	
• etc.	
Analysis may under- or overstate net benefits	
• impact "e"	
• impact "f"	
• etc.	
*Dashed vertical line indicates quantified net benefits.	

Text discussion: All of the approaches described above must be accompanied by text that clearly defines the nonquantified effects, explores the causal evidence that links them to the regulatory action, summarizes available information on their direction and magnitude, and discusses the conduct and interpretation of related analysis, including both the results and related uncertainties.

[103] Microsoft Excel and similar programs allow the user to represent quantities graphically; for example, to automatically size an arrow that represents the quantity "10" so that it is twice the size of an arrow that represents the quantity "5." While such features may be useful when analysts have some information on relative magnitudes, care should be taken to not mislead readers about the extent to which the size of the symbols represents evidence on the expected size of the effect.

In sum, the treatment of nonquantified impacts should be tailored to the characteristics of the effect (such as whether it involves intangibles or normative values), the extent to which relevant data are available, and the importance of the effect for decision-making. These impacts should be clearly defined and distinguished from the quantified impacts, to avoid the potential for double-counting.

At minimum, analysts should list significant nonquantified effects in a table and discuss them qualitatively. To the extent possible, the effects should be categorized or ranked in terms of their importance and implications for choosing among the regulatory alternatives (including the option of no action). Where some data exist, but are not sufficient to reasonably quantify the effect, analysts should consider whether breakeven, cost-effectiveness, or bounding analysis will provide useful insights. Intermediate measures, such as the number of individuals affected, should be reported where available. Where impacts can be monetized but not quantified, the monetary value per unit of impact (e.g., the value per averted statistical case in the case of health impacts) should be reported.

Chapter 7

Conduct Distributional and Other Supplementary Analyses

The previous chapters focus largely on the benefit-cost analysis that is the core of the RIA. However, agencies must also comply with a number of other analytic requirements. These include considering the distribution of benefits and costs across demographic or other population subgroups as well as complying with several other executive orders and statutes. In addition, for those regulations with impacts outside of the U.S., analysis of international impacts is required. These analyses should be reported in clearly labeled, separate sections of the regulatory analysis (see Chapter 8), which discuss the available evidence and related uncertainties as well as the implications for decision-making.

7.1 ASSESS DISTRIBUTION ACROSS DEMOGRAPHIC GROUPS

In addition to estimating the national net benefits of the policy options, HHS and other regulatory agencies are required to separately address how the benefits and costs of their economically significant regulations are distributed. The benefit-cost analysis discussed previously focuses on the net impact of the regulation on social welfare, while the distributional analysis focuses on the incidence of the benefits and costs.

In this section, we discuss the distribution of impacts across individuals with differing demographic or other characteristics. Such analysis is encouraged under Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011), as well as by OMB *Circular A-4* (2003), and includes analyses required by Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (Clinton 1997), and Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (Clinton 1994), where applicable.[104]

This analysis is intended to provide descriptive information for consideration by decision-makers and stakeholders; it should not assign values to reflect distributional preferences or make normative judgments related to the fairness or equity of the impacts. In many cases this analysis will be primarily qualitative or rely largely on simple screening; in those cases where distributional concerns are more significant, it will be more extensive and detailed.

7.1.1 BASIC CONCEPTS

The goal of distributional analysis is to provide information on how benefits and costs affect different groups, so as to make trade-offs between economic efficiency and distributional concerns more explicit. Decision-makers may choose the economically-efficient regulatory option that maximizes net benefits, or may choose a less efficient option to ameliorate distributional impacts or achieve other policy goals.

Generally, the distribution of both benefits and costs should be considered, so that decision-makers and others can consider the extent to which the impacts are counterbalancing for each group as well as the overall distribution of net benefits across groups. In addition to understanding the incremental effects of the regulation, analysts may wish to provide information on the distribution under the "without new regulation" baseline as well as on the distribution that results under each policy alternative.

The starting point for distributional analysis is the national assessment of social benefits and costs, discussed in Chapters 3 and 4. However, as noted in Chapter 4, transfer payments are generally not included in the benefit-cost analysis, but must be considered in the distributional analysis.

[104] See the National Archives website for a complete set of executive orders (http://www.archives.gov/federal-register/executive-orders/disposition.html).

A key step in the analysis involves identifying which population groups should be considered.[105] In some cases, groups of concern may be defined by statute. In addition, Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (Clinton 1994), requires agencies to identify and address "disproportionately high and adverse human health or environmental effects" on these groups. Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (Clinton 1997), requires agencies to identify and address risks that may disproportionately affect children. Other groups of concern may emerge in the course of the analysis. For example, analysts may find that the effects of the regulations are likely to be concentrated in certain geographic areas or among groups with particular characteristics, such as the homeless, the HIV-infected, or those with specific dietary habits.

It is often tempting to focus solely on adverse effects on disadvantaged groups. However, such focus is problematic because it leads analysts to ignore potential beneficial effects that may be of equal or greater importance. Any distributional effect involves both "from" and "to" sides of the equation; who gains may be as important as who loses. The benefits and costs of the regulation may be counterbalancing, or may differentially affect the advantaged and the disadvantaged.

When describing these effects, one option is to provide a table or graph that reports the percentage and value of the costs, benefits, and net benefits that accrue to individuals or households at different points in the distribution; e.g., to income quintiles. Other measures for describing inequality are available; their advantages and disadvantages are discussed in detail in several sources.[106]

7.1.2 GENERAL APPROACH

Assessing the distribution of regulatory benefits and costs, as well as net benefits, can be challenging. As noted earlier, the conduct of such analysis is likely to vary significantly depending on the nature of the regulation, the characteristics of its benefits and costs, the population groups of interest, and the data and other analytic resources available. Screening analysis (see Chapter 2) can be useful in determining how to best focus this effort. Below, we discuss some of the challenges related to assessing the distribution of regulatory costs and health-related benefits, which affect analysts' ability to address each independently as well as their net effect.

WHAT ARE THE REQUIREMENTS FOR DISTRIBUTIONAL ANALYSIS?

At minimum, analysts should include a short description of the likely distribution of benefits and costs across individuals or households in different population groups, including low income and minority groups and children as discussed in Executive Orders 12898 and 13045. Requirements for other types of distributional analysis are discussed in the next section.

Distribution of regulatory costs: In the case of regulatory costs (and off-setting savings), we are typically interested in the monetary expenditures needed to comply with the regulatory requirements (including transfers), measured in dollar terms, and the ultimate effect on the disposable income of the groups of concern. Where regulatory costs are borne directly by individuals and households, the main challenge is determining how the costs are distributed across those who belong to different groups, which may be identified, for example, by income quintile, minority status, or degree of health impairment.[107] Where the costs are borne initially by firms, assessing the effects on individuals and households in different groups requires additional steps.[108] We first need to know how regulatory costs imposed on these entities translate into changes in unit prices paid by

[105] OMB *Circular A-4* (2003) defines distributional effects broadly as including, for example, how regulatory impacts are divided across "income groups, race, sex, industrial sector, geography" as well as over time.

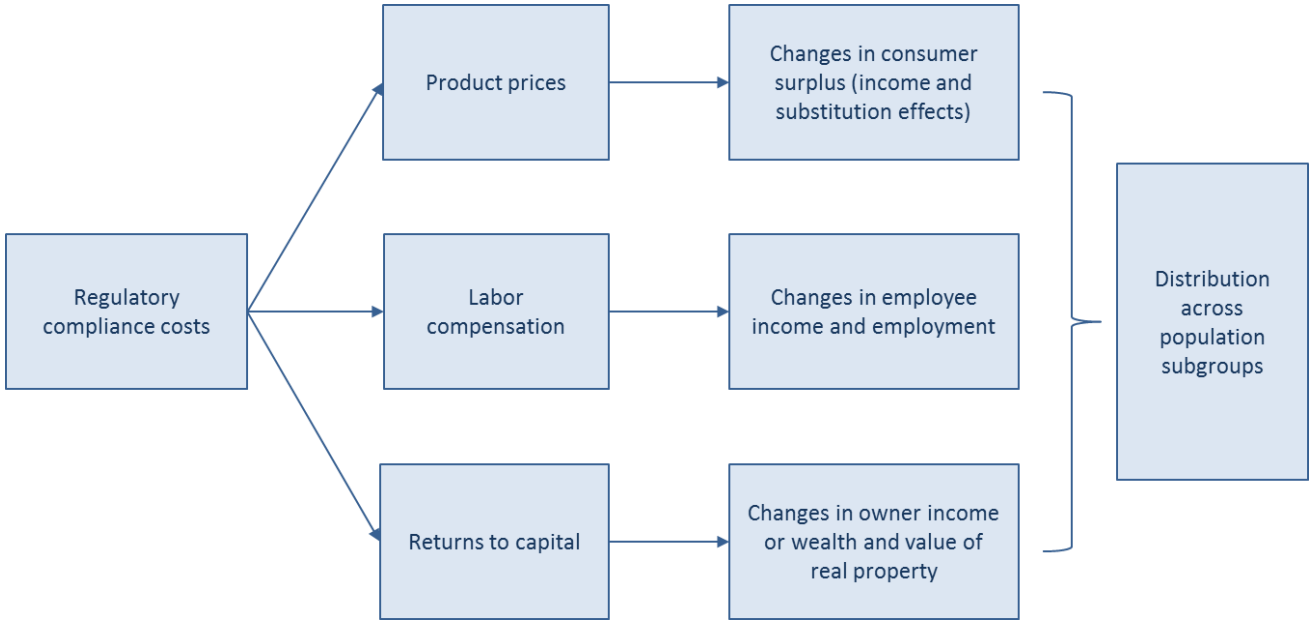
[106] For a general overview of options for addressing distributional concerns in policy analysis, see Weimer and Vining (2011), Chapter 7. For further discussion, see Boardman et al. (2011).

[107] Consumer behavior will also affect the distribution of these costs. For example, if the price of a food is increased, some may substitute an alternative food. This substitution may affect both the costs and the benefits incurred, and such behavioral responses may vary across population groups.

[108] If the organizations are not-for-profit, similar principles apply although the nature of the impacts may differ. If the costs are initially incurred by a government unit, then the analysis would address how that unit is funded; i.e., the distribution of taxes, users fees, or other revenue sources.

consumers (including both income and substitution effects), in wages paid to employees, and in returns to capital that accrue to owners, as illustrated in Figure 7.1.

FIGURE 7.1. DISTRIBUTION OF INDUSTRY COSTS ACROSS INDIVIDUALS AND HOUSEHOLDS



As in the benefit-cost analysis, the distributional analysis must clearly differentiate the impacts of the new policy from the impacts of other factors that should be reflected in the "no new regulation" baseline projections. At times, retrospective analysis may be available that addresses similar regulations and uses statistical tools to distinguish the effects of regulatory costs.[109] Interviews with members of the affected industry may also be useful. Otherwise, the extent to which each of the pathways in Figure 7.1 can be assessed will depend largely on the data available from the benefit-cost analysis. If only direct compliance costs are estimated, then it may be difficult to estimate how the costs are allocated across consumers and producers. If partial equilibrium modeling is included (which estimates changes in consumer and producer surplus), more sophisticated distributional analysis is possible. In a few cases, where regulations are expected to have significant impacts throughout the economy, results for model households from general equilibrium modeling may also be available. In all cases, the analysis of total social costs will exclude transfers, which will need to be estimated to assess the distribution of the impacts.

The allocation of costs across producers and consumers will also depend on the timeframe considered. Some costs that are fixed in the short run will be variable in the long run. For example, in the near term firms may not be able to make major changes in their physical plant (and some may close due to the costs of complying with the regulation), but such changes become more possible in the future, affecting how the costs are distributed.

Distribution of health benefits: In the case of benefits, some regulations may primarily provide savings in monetary costs, in which case the distributional analysis would proceed along the same lines as described above although the effects are likely to be in the opposite direction – savings potentially decrease prices, increase wages, and increase returns to capital. When the benefits involve reduced mortality and morbidity risks, there are several options for measuring the effects on each group. We can count the number of statistical cases averted (by multiplying the expected individual risk reduction by the number of people affected); we can use integrated measures (such as quality-adjusted life years, QALYs) to estimate the net effect on health-related

[109] For employment impacts, see Morgenstern (2013) for a comprehensive review.

quality of life and longevity; and we can use monetary measures that indicate the amount those affected would be willing to pay for the risk reductions (see Chapter 3).

In general, the distribution of health effect incidence is easier to calculate than the distribution of costs. The benefit analysis is likely to provide estimates of the number of people affected; the challenge is then to identify how the effects are allocated across the groups of concern.[110] In some cases, the characteristics of the regulation may aid in estimating this distribution. For example, if a food safety regulation affects the risks associated with drinking juice, and the distribution of juice drinking across groups (categorized by income, age, or other demographic attributes) is known, the analysis may be relatively straightforward. The risk assessment that supports the regulation will often provide related information. It typically summarizes or references available data on populations that may be particularly sensitive or vulnerable to the effects of the regulated hazard, including those who may be disproportionately affected due to health conditions, age, or socioeconomic status. In addition, HHS maintains several population databases that provide information on the characteristics of those who experience various types of health effects. Examples include the National Health Interview Survey and the Medical Expenditure Panel Survey.

In sum, the discussion above suggests that distributional analysis may be quite complex, and requires thinking carefully about what types of information will be most useful to decision-makers given the characteristics of the regulation and of those it is likely to affect. In some cases, the analysis may be primarily qualitative; in others more detailed quantitative assessment will be warranted. Analysts should follow a phased approach to ensure that the assessment is well-focused and useful for decision-making, using screening analysis as discussed in Chapter 2. Both gains and losses among advantaged and disadvantaged groups should be considered, to ensure that any counterbalancing or exacerbating impacts are taken into account.

7.2 CONDUCT SUPPLEMENTARY ANALYSES

Several other types of analysis are required by various statutes and executive orders. In general, all of these requirements should be addressed; however, the extent to which detailed analysis is required will depend on the characteristics of the specific rule. Table 7.1 summarizes these requirements and directs the analyst to additional guidance documents. The basic requirements are discussed in more detail below.

[110] As noted earlier, to the extent that people may alter their behavior in response to the regulation (e.g., taking less precaution in handling food when packaging is improved), any difference in this response can affect the distribution of benefits.

TABLE 7.1. REQUIREMENTS FOR SUPPLEMENTARY ANALYSES

REQUIREMENT	APPLICABILITY	GUIDANCE DOCUMENTS
Regulatory Flexibility Act: Requires agencies to consider the impact of regulatory actions on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment.	All regulations subject to notice and comment under section 553(b) of the Administrative Procedures Act. Note: a full regulatory flexibility analysis is not required if the agency can certify that the proposed rule will not "have a significant economic impact on a substantial number of small entities" (5 U.S.C. §605(b)). HHS provides guidance defining a "substantial number" and "significant effect" (see HHS 2003).	• *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (SBA 2012) • *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services* (HHS 2003)
Unfunded Mandates Reform Act: Requires agencies to assess the effects of regulatory actions on State, local, and tribal governments, and the private sector.	All "significant" rulemakings – defined as those likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year in 1995 dollars, adjusted for inflation.	• "Guidance for Implementing Title II of S.1" (OMB 1995) • Annual memorandum from HHS updating "significant rulemaking" threshold value (e.g., HHS 2014)
Executive Order 13132 ("Federalism"): Requires agencies to develop a process to ensure meaningful and timely input by State and local officials.	All policies that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."	None.
Paperwork Reduction Act: Requires agencies to estimate the information collection (reporting, recordkeeping, and third-party disclosure) burden associated with their actions.	All policies that require generation, maintenance, or provision of information to or for a Federal agency. Agencies must obtain approval from OMB prior to requesting the same information from 10 or more individuals.	• Paperwork Reduction Act Primer (Sunstein 2010b) • OMB's website Federal Collection of Information • HHS's website Frequently Asked Questions about PRA/Information Collection • Agency's designated PRA team

7.2.1 REGULATORY FLEXIBILITY ACT

The Regulatory Flexibility Act of 1980 (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) (5 U.S.C. 601, *et seq.*), "requires agencies to consider the impact of their regulatory proposals on small entities, analyze effective alternatives that minimize small entity impacts, and make their analyses available for public comment" (SBA 2012). Small entities include small businesses, not-for-profit organizations, and governmental jurisdictions, definitions of which can be found within Section 601 of the RFA. In addition, the U.S. Small Business Administration (SBA) has developed size standards to define small businesses, which can be found in 13 CFR 121.201. The RFA requirements have been extended to small rural hospitals through Section 1102(b) of the Social Security Act (42 U.S.C. §1302). Definitions of "small," "rural," and "hospital" are provided in the Medicare regulations at 42 CFR 412.

If a proposed rule is not expected to have a significant impact on a substantial number of small entities, the agency may certify that this is the case, and must provide a statement providing the factual basis for this determination. If the agency cannot provide this certification, or is uncertain about the rule's impact, it should prepare an Initial Regulatory Flexibility Analysis (IRFA) for publication with the proposed rule. Section 603 of the RFA lists the information that must be included in the IRFA.

For the final rule, if the agency cannot provide this certification or remains uncertain after reviewing public comment on the proposed rule, a Final Regulatory Flexibility Analysis (FRFA) should be prepared and published. The requirements for the FRFA are similar to those for the IRFA and are outlined in Section 604 of the RFA. When it prepares a FRFA, the agency must also publish one or more small entity compliance guides to inform small entities of their obligations and responsibilities under the rule.

Detailed guidance on compliance with the RFA and preparation of the regulatory flexibility analysis can be found in the SBA's *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act* (SBA 2012).[111] This document walks agencies through the process of preparing screening analyses and initial and final regulatory flexibility analyses. In addition, HHS's *Guidance on Proper Consideration of Small Entities in Rulemakings of the U.S. Department of Health and Human Services* (HHS 2003) supplements the SBA guidance, providing examples of issues that commonly arise in applying the RFA and SBREFA to HHS rulemakings.

7.2.2 UNFUNDED MANDATES REFORM ACT

The Unfunded Mandates Reform Act (UMRA) (2 U.S.C. §1501 *et seq.*) seeks to curb the practice of imposing unfunded Federal mandates on State and local governments. UMRA Section 1531 requires Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and the private sector. Section 1532 requires them to prepare a written statement that assesses the costs, benefits, and other effects of proposed or final rules for significant regulatory actions (2 U.S.C. §1532(a)). UMRA defines significant regulatory actions as those that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (in 1995 dollars) (2 U.S.C. §1532(a)). This threshold is adjusted each year for inflation.

Most of UMRA's requirements are fulfilled by the RIA that is prepared to comply with Executive Orders 12866 and 13563 (Clinton 1993, Obama 2011) and OMB *Circular A-4* (2003), as discussed in the earlier chapters of this guidance. Additional guidance on the preparation of written statements under UMRA can be found in OMB's 1995 "Guidance for Implementing Title II of S.1." In addition, HHS releases an annual memorandum updating the threshold value (adjusted for inflation) for a significant regulatory action (see, for example, HHS 2015).[112]

7.2.3 FEDERALISM

Executive Order 13132, "Federalism" (Clinton 1999), emphasizes consultations with State governments and enhanced sensitivity to their concerns in cases where regulatory or other policy actions impinge on their constitutionally established role as sovereign entities. It requires Federal agencies to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications." Section 1(a) defines policies that have federalism implications to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under Executive Order 13132, Federal agencies may not issue a regulation with Federalism implications that imposes substantial direct compliance costs and that is not required by statute unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments or the agency consults with State and local governments in the process of developing the proposed regulation. The agency also may not issue a regulation with Federalism implications that preempts a State law without consulting with State and local officials.

[111] This and other material related to implementation of the RFA is available on the Regulatory Flexibility Act (http://www.sba.gov/category/advocacy-navigation-structure/regulatory-flexibility-act) page of the SBA website.

[112] The method and sources used to update this threshold value are described in HHS (2015).

7.2.4 PAPERWORK REDUCTION ACT

The Paperwork Reduction Act (PRA) (44 U.S.C. §3501 *et seq.*) requires Federal agencies to estimate the information collection burden associated with all of their actions. The term "burden" means the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency. Agencies must obtain approval from OMB prior to requesting the same information from ten or more individuals. Thus, if a proposed regulation will impose such a burden (e.g., a regulation may require regular reporting of compliance data to HHS), the agency must prepare an information collection request (ICR) for review and approval by OMB.

Paperwork burdens or costs are a subset of the total costs of a regulation and should be included in those costs (see Chapter 4).[113] The paperwork burden of a regulation includes the incremental cost of required record keeping, reporting, and public disclosure. It includes only the incremental data collected as a result of the regulation; data collections required by the rule that are already undertaken for other purposes are considered part of the baseline and are not part of the collection burden under the PRA. For example, a rule requiring facilities to maintain records on health and safety-related maintenance practices may not result in an incremental collection burden if these records are already collected by the facility for other purposes, such as payroll. As with estimates of other compliance costs (see Chapter 4), it is important to isolate the incremental burden of the regulation when preparing the ICR.

7.3 ADDRESS INTERNATIONAL EFFECTS

The regulatory analysis should generally focus on benefits and costs that accrue to U.S. citizens and residents. However, regulations that address trade barriers and other market failures may have an effect on both the United States and its trading partners. In cases where regulations have impacts outside of the United States, they should be addressed in a supplementary analysis. Following the guidance in OMB *Circular A-4* (2003), these international effects should be reported separately from those occurring within the U.S.[114]

International effects may include direct economic impacts (e.g., related to increases or decreases in international trade) as well as any other potentially significant effects. For example, increasing safety requirements for U.S.-based food manufacturing may provide health benefits to countries that import this food; decreasing the transmission of disease in the U.S. is likely to decrease the risk of transmission to residents of other countries.

In general, analysis of international effects should include impacts on imports and exports. Partial equilibrium analysis using publicly available information on import supply and demand elasticities can be used to model how a regulation might change the flow of imports and exports. More complicated general equilibrium analysis may be required if an entire sector of the economy is affected. For additional information on these types of modeling, see Chapter 4.

The analysis of international effects may also include impacts on foreign entities whose U.S. operations are affected. It is often difficult to identify U.S. subsidiaries of foreign entities and report impacts to their operations separately from those to U.S.-based businesses. Therefore, impacts on U.S. subsidiaries are often included in the main analysis. If this is the case, and the analyst thinks that impacts on U.S. subsidiaries of foreign entities may be substantial, the analysis should include a qualitative discussion of the effect.

[113] There are important differences in the requirements of the PRA and the best practices for preparing RIAs as discussed in the prior chapters. For a detailed discussion of the PRA requirements, see the sources referenced in Table 7.1.

[114] Executive Order 13069 (Obama 2012) includes requirements for identifying regulations that may have significant international impacts.

For more information on how to address international effects, see OMB's *2008 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (OMB 2008) and the *Review of the Application of EU and US Regulatory Impact Assessment Guidelines on the Analysis of Impacts on International Trade and Investment* (OMB and the Secretariat General of the European Commission 2008).[115]

[115] OMB's reports to Congress are available on the OIRA Reports to Congress (http://www.whitehouse.gov/omb/inforeg_regpol_reports_congress/) page of its website.

Chapter 8
Communicate the Approach and Results

Regulatory analyses must be clearly and comprehensively documented in an RIA, which may be published in full in the preamble to the *Federal Register* notice for the proposed or final rule, or as a separate report, in which case it must be summarized in the preamble. The RIA must describe the rationale for the regulation, the options considered, the analytic approach, and the results, as well as the implications of uncertainties. For regulations with particularly large or complex impacts, it may be necessary to provide additional information in technical reports that supplement the main analysis.

Without clear communication, the RIA will not meet its intended goal of informing related decisions. This communication should address two audiences. First, it should be written so that members of the lay public can understand the analysis and conclusions. Second, it should provide enough detail so that competent analysts could ideally reconstruct the analysis, or at minimum explore the implications of changing key assumptions. This chapter briefly describes related practices.

8.1 DESCRIBE THE ANALYSIS AND RESULTS

The audience for the RIA is diverse and includes many who lack the technical expertise and knowledge of those who conducted the analysis. Given that the purpose of the analysis is to inform decision-makers and other stakeholders, it is critical that it be described in terms that can be easily understood by a lay audience. At the same time, the documentation must be sufficient to support future work, including replication, testing the effects of alternative assumptions, applying the same or similar approaches in a future analysis, or reconstructing the analysis as part of a retrospective assessment.

The main text should provide a succinct and clear summary of the analysis. Technical details should be provided in appendices or supporting documents. The main text may, for example, include the following major sections, reflecting the requirements in OMB *Circular A-4* (2003) as well as the requirements provided in this guidance document. Those sections that provide analytic results should also include a subsection that discusses the implications of uncertainties, as described in Chapter 6.

1) Executive Summary (see additional discussion below)
2) Statement of the need for the regulation
3) Characterization of the without-regulation baseline
4) Description of the regulatory alternatives (including the preferred alternative)[116]
5) Benefits of the regulatory alternatives
6) Costs of the regulatory alternatives
7) Comparison of benefits and costs
8) Supplementary analyses
    a) Distribution of benefits and costs
    b) Regulatory Flexibility Act analysis
    c) Unfunded Mandates Reform Act analysis
    d) Other analyses
    e) International effects

[116] These alternatives may include both regulatory and non-regulatory approaches, as described in Chapter 2.

In particular, the executive summary must use plain English and be designed to promote public understanding. OMB (2012) suggests that executive summaries include a statement of need for the regulation; a summary of the major provisions of the regulatory action; and, for economically significant rulemakings, a table summarizing the benefits and costs. For additional guidance on the format for Executive Summaries see "Clarifying Regulatory Requirements: Executive Summaries" (OMB 2012).

8.2 PROVIDE SUMMARY TABLES AND FIGURES

The RIA should include tables and figures that clearly convey the results of the analysis.

Key information to be summarized includes:

- Annual benefits and costs (undiscounted);
- Annualized and present value costs;
- Annualized and present value benefits;
- Net benefits (i.e., benefits minus costs) presented on an annualized basis and, as appropriate, in present value terms.

These quantified results should be accompanied by information on important nonquantified impacts.

In addition to "central" or "best" estimates, information on uncertainty must also be presented. When reporting annualized or present value impacts, analysts must indicate the time period over which impacts are estimated.[117] Results should be presented for discount rates of both three and seven percent.

Depending on the complexity of the analysis and the number of cost and benefit categories, the results may be summarized in a single or multiple tables or figures. Each should reference the information sources and note key assumptions. While such exhibits are essential to focus attention on key findings, analysts should keep in mind that some readers will skip over the more detailed technical information in the text. Thus clear labeling is needed to ensure that the contents of the tables and figures are not misinterpreted. Additionally, the associated text should interpret each table or figure for the reader. It may improve communication to supplement the results tables with charts and graphs that summarize and highlight key steps in the analysis as well as the major conclusions and their implications.

For economically significant rules, agencies are also required to provide OMB with an accounting statement that includes a standard table reporting benefit and cost estimates. Figure 8.1 provides a suggested format for this accounting statement, adapted from OMB *Circular A-4*. The accounting statement summarizes the information presented in the RIA and should include:

- Annualized incremental benefit and cost estimates, using real discount rates of three and seven percent, within the following three categories: monetized; quantified, but not monetized; and qualitative, but not quantified or monetized. The primary benefit and cost estimates should reflect the expected values. The minimum and maximum estimates should, if possible, reflect the 5th and 95th percent confidence bounds.
- Annualized incremental transfer estimates, which occur when wealth or income is redistributed without any direct change in aggregate social welfare.
- Information on the effects on State, local, and tribal governments, small businesses, wages, and economic growth.

[117] As discussed in Chapter 2, for meaningful comparison, benefits and costs should be measured over the same time period. When some impacts are assessed over longer periods than others to provide important information for decision-making, the results for the additional period should be reported separately to avoid misleading comparisons.

FIGURE 8.1. TEMPLATE FOR OMB ACCOUNTING STATEMENT

OMB #: **Agency/Program Office:**
Rule Title:
RIN#: **Date:**

Economic Data: Costs and Benefits Statement							
				Units			
Category	Primary Estimate	Low Estimate	High Estimate	Year Dollars	Discount Rate	Period Covered	Notes
Benefits							
Annualized Monetized $ millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative							
Costs							
Annualized Monetized $ millions/year					7%		
					3%		
Annualized Quantified					7%		
					3%		
Qualitative							
Transfers							
Federal Annualized Monetized $ millions/year					7%		
					3%		
From/To	From:			To:			
Other Annualized Monetized $ millions/year					7%		
					3%		
From/To	From:			To:			
Effects							
State, Local or Tribal Government:							
Small Business:							
Wages:							
Growth:							

In addition to the present value and annualized results, OMB *Circular A-4* suggests that the analyst include separate schedules of undiscounted monetized benefits and costs showing the type and timing of these effects, as discussed in Chapter 5. These undiscounted results should be presented in constant dollars for each year of the analytic time horizon. Again, this schedule could be presented in a table or as a bar chart or other graphic.

In sum, presenting the analysis so that it can be easily understood by decision-makers and stakeholders may require significant effort to clearly and concisely describe the options assessed, the analytic approach, and the results. Without such effort, the analysis may not play its intended role in the decision-making process, and may be misconstrued in ways that lead to significant and unnecessary controversy. Avoiding technical jargon, and using tables and graphics to illustrate key points, will aid in ensuring that the analysis is useful for decision-making.

Chapter 9
Conduct Retrospective Analysis

Executive Order 13563 directs each Federal agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive, or that can be modified to be more effective, efficient, flexible, and streamlined (Obama 2011, HHS 2011).[118] The initial HHS plan was finalized in August 2011 and has been subsequently updated.[119]

The plan describes HHS's approach for identifying regulations for review as part of an ongoing process and lists factors HHS routinely considers in this review (HHS 2011). The factors include many that can be evaluated qualitatively; for example, identifying redundant or obsolete regulations or requirements. While important for a broader program of retrospective review, such qualitative analysis is not the focus of this guidance. Rather, this chapter describes HHS's approach for quantitative retrospective analysis of the benefits and costs of selected economically significant regulations.

Quantitative retrospective benefit-cost analysis may serve several purposes, ranging from assessing the effectiveness of a single regulation to evaluating the overall use of benefit-cost analysis in the regulatory development process. The next section discusses the conceptual framework in greater detail. We follow with an overview of the approach to retrospective benefit-cost analysis, including a generalized discussion of analytic steps.

9.1 BASIC CONCEPTS

The general purpose of the prospective, or *ex ante*, analysis discussed in the previous chapters of this guidance is to determine whether the benefits of the regulation are likely to exceed costs (i.e., whether benefits minus costs, or net benefits, are positive) and to identify the regulatory alternative likely to generate the largest net benefits. Figure 9.1 identifies several ways in which subsequent retrospective, or *ex post*, analysis of benefits and costs may be useful.[120]

FIGURE 9.1. USES OF RETROSPECTIVE BENEFIT COST ANALYSIS

1. Evaluate whether existing regulations continue to be justified in economic terms (i.e., produce positive net benefits).
2. Support identification of changes to existing regulations that will decrease their costs or increase their benefits.
3. Provide insight into the accuracy of *ex ante* estimates of regulatory benefits and costs, particularly whether they tend to be over- or underestimated.
4. Identify ways to improve the accuracy of future cost-benefit analyses.

A primary goal is to assess whether the regulation has achieved the desired outcome. For example, if its purpose was to reduce new cases of heart disease, analysts would seek empirical evidence of this impact. While potentially difficult to obtain, this information is a necessary to determine whether net benefits are positive.

Additionally, retrospective benefit-cost analysis "can help identify specific regulations that are ripe for regulatory reform, since their benefit-cost balance may be more or less favorable than originally expected" (OMB 2005). Importantly, OMB notes that "a validation study designed to determine the accuracy of *ex ante*

[118] Aldy (2014) discusses the historical development of the retrospective review process within the Federal government and potential improvements.

[119] See the HHS website for the 2011 plan (http://www.hhs.gov/open/execorders/13563) as well as updates and an opportunity for public input regarding which regulations to review.

[120] This discussion is based largely on OMB (2005); more information is provided in subsequent reports such as OMB (2011c).

estimates does not by itself provide full guidance on the desirability of reforming the existing regulation" (OMB 2005, p. 41). For example, regulated entities may have incurred costs that will not be recovered if the regulation is retracted.[121]

Retrospective analysis may also inform the modification of an existing regulation with the goal of increasing its net benefits, regardless of whether net benefits are positive or negative as currently implemented. New information about key assumptions or inputs may suggest opportunities for optimizing the regulation.

After an agency has completed retrospective review of multiple regulations, it can identify whether it has a tendency to systematically over- or underestimate costs or benefits, and the extent to which over- or underestimation is attributable to various factors.[122] This information might highlight the need for additional uncertainty analysis, as well as ways in which future analyses can be improved.[123] It might also provide insight into how much weight should be granted to the cost-benefit analysis in the decision-making process as agencies promulgate new regulations (OMB 2005).

Finally, such information may identify ways to improve the accuracy of future *ex ante* analyses. For example, it may demonstrate that agencies routinely underestimate the ability of regulated entities to reduce costs as they gain experience with a particular regulation.[124] In certain cases, a regulation may motivate affected entities to go beyond the required compliance standards, resulting in additional health or other improvements not included in *ex ante* benefits estimates.[125] A better understanding of how affected entities respond to regulation will help improve the accuracy of future *ex ante* analysis.[126]

9.2 GENERAL APPROACH

In general, analysts should pursue retrospective benefit-cost analysis for those economically significant regulations identified in the HHS *Plan for Retrospective Review* where the need for regulatory reform is not obvious for other reasons (such as where the regulation requires obsolete technology) and where available data allow for meaningful assessment of impacts. Below, we first discuss challenges to estimating the effect of the regulation and addressing the time frame over which the impacts occurred, then describe the overall framework for the analysis.

9.2.1 ESTIMATING THE IMPACT OF THE REGULATION

The public or decision-makers may presume that retrospective analysis will be more accurate than prospective analysis because analysts can simply "tally" benefits and costs that have actually occurred. In other words, retrospective analysis may be perceived as a simple accounting exercise. However, correctly measuring incremental effects on a retrospective basis presents similar challenges to estimating impacts prospectively and is also subject to substantial uncertainty. The key challenge to *ex post* analysis is isolating the incremental effects

[121] Such incurred, or "sunk" costs have zero opportunity costs because these resources have already been used and cannot be used again. When the analytic goal is to determine whether to revise or vacate an existing regulation, and significant costs have been incurred, a prospective analysis of retracting the existing regulation may be more appropriate than a retrospective evaluation.

[122] An agency might also use retrospective review to better understand the cumulative effect of multiple regulations aimed at reducing the same risk.

[123] For review of the results of retrospective benefit-cost analyses of Federal regulations see, for example, Harrington et al. (2000), Harrington (2006), and Morgenstern (2015).

[124] A substantial body of literature on "learning by doing" examines declines in the per-unit cost of producing or using a new technology as experience with the technology increases over time, as discussed in Chapter 4 and EPA (2010).

[125] For example, in 2003, FDA promulgated a final regulation requiring that trans fatty acids be declared in the nutrition label of conventional foods and dietary supplements on a separate line immediately under the line for the declaration of saturated fatty acids. Subsequent review of industry compliance with the regulation revealed that the informational nature of the regulation and the desire to maintain market share for certain food products created incentives for the industry to find ways to reduce trans fatty acids in foods to a degree that exceeded FDA's expectations. As a result, *ex ante* estimates of costs and health benefits may have been understated.

[126] In addition to improving the accuracy of future *ex ante* analysis, a better understanding of how affected entities respond to regulations may identify more efficient methods of achieving similar policy objectives. For example, if analysts learn that assuming complete compliance with future regulations overstates actual compliance rates, they may determine that increasing enforcement resources for existing regulations will achieve better health outcomes for less cost than introducing additional regulations.

of the regulation. As with *ex ante* analysis, identifying incremental effects requires comparing two scenarios: the world with the regulation (the "incremental scenario") and the world without the regulation (the "baseline scenario" in *ex ante* analysis, as discussed in Chapter 2, or "counterfactual scenario" in *ex post* analysis).[127]

In *ex ante* analysis both scenarios occur in the future; neither is observed. Ideally, analysts do not assume that current conditions will persist in the future; the baseline is the evolution of the existing, observed world. Both the baseline and incremental scenarios are subject to significant uncertainty associated with assumptions about likely future health and economic conditions without the regulation, compliance with the regulation, and behavioral responses that may affect implementation (e.g., innovation by the regulated community).

In *ex post* analysis, uncertainty may be reduced because the world with the regulation (the incremental scenario) can be observed. What were included as probabilities or expected values in the *ex ante* analysis can be replaced with actual outcomes, to the extent that it is possible to separate the effects of the regulation from other factors. The agency may have data on compliance rates, or it may be able to obtain more accurate information on key assumptions, such as the number of units of a drug sold. In other cases, it may be difficult to separate the effects of the regulation from other factors. For example, the incidence of the health conditions addressed by the regulation may be rising or falling due to medical innovations, changing demographics, or other causes. The extent to which the regulation has accelerated a decrease in incidence, or offset what would have otherwise been an even larger increase, may be difficult to isolate, even using sophisticated statistical tools. Furthermore, analysts must still model the counterfactual scenario, which cannot be observed. Assumptions about what the world would have been like without the regulation introduce uncertainty to estimates of the incremental impacts.[128,129]

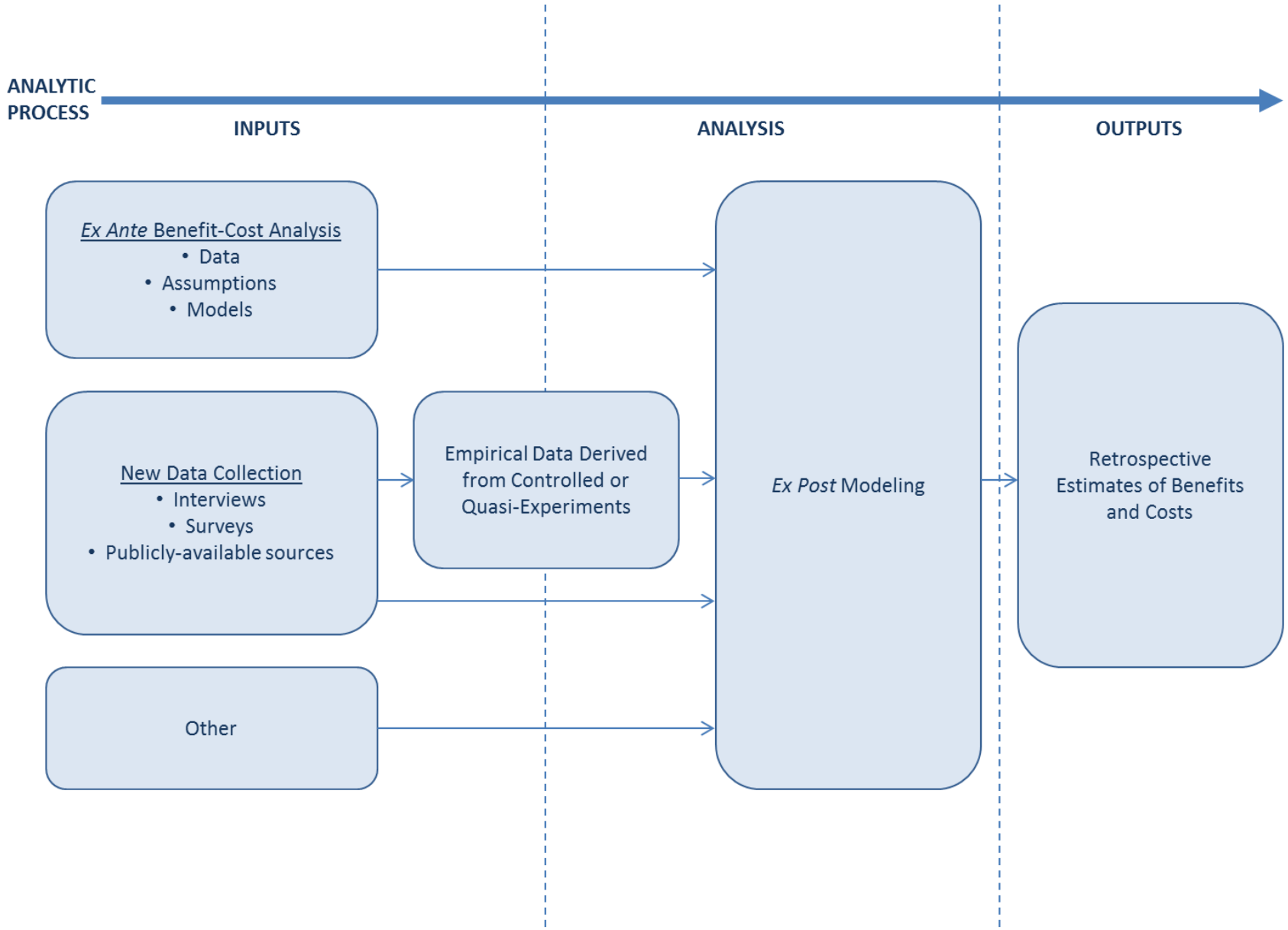
The major components of a retrospective benefit-cost analysis are the same as the RIA components illustrated in Figure 1.1. Figure 9.2 illustrates the process used to construct new models and highlights differences in the data and information potentially available for retrospective benefit-cost analysis. The process begins with the evaluation of existing information and the collection of new data. Relevant information may be obtained from a variety of sources, including the *ex ante* analysis previously developed in support of the regulation, newly available public information, surveys, or other sources. Retrospective analysis, like prospective analysis, is subject to the requirements of the PRA, which may limit an agency's ability to conveniently collect new data.

[127] The relevant comparison is the world with and without the regulation, not the world before and after the regulation is implemented. For example, a regulated entity's operating costs after a regulation takes effect may be influenced by market conditions or other factors unrelated to the regulation. Simply comparing costs before and after the regulation takes effect, without accounting for these other changes, could be misleading.

[128] *Ex ante* analysis estimates net benefits conditional on one or more sets of assumptions about the future, and sometimes uncertainty with regard to estimated net benefits may be aggregated over sets of future uncertain factors. In contrast, *ex post* analysis estimates net benefits conditional on specific realization of at least some of the *ex ante* uncertain factors. When using *ex post* analysis to judge the accuracy of *ex ante* estimates, this difference affects the interpretation and must be recognized.

[129] Many *ex ante* actions are undertaken to protect against uncertain adverse events. If the event does not occur, that does not necessarily mean that the regulation was unwarranted. For example, a vaccination policy does not necessarily have negative net benefits if the disease does not materialize; the insurance against possible disease provides its own benefit. Uncertainty about the likelihood of occurrence should be considered in the retrospective analysis as well as the prospective analysis.

FIGURE 9.2. RETROSPECTIVE ANALYSIS PROCESS



As indicated by the figure, data from two types of experiments might be available for these analyses: controlled or quasi-experiments. In the best case, the agency would design the regulation to allow for a controlled experiment, enabling analysts to empirically estimate the impact of the regulation with a high degree of confidence by comparing otherwise-identical treatment (i.e., subject to the regulation) and control (i.e., not subject to the regulation) groups.[130] This information on actual effects can replace assumptions about likely effects in the cost and benefit models. However, implementation of a controlled experiment is often at odds with regulatory design, which targets the populations in need of intervention or, for fairness, applies equally to everyone. Alternatively, in certain circumstances opportunities for natural or quasi-experimental designs, where natural randomization is exploited, may exist. For example, analysts may be able to identify unregulated comparison groups if (1) the regulation is phased in through time (new products are subject to the regulation while similar, older products are exempt); or (2) the regulation is not implemented uniformly across all geographic areas (e.g., implementation may differ across states).[131]

Such controlled or quasi-experiments may provide the best assessment of the actual effects of existing regulations because they are based on observed outcomes and data.[132] However, in practice, they may be too small in scale to be extrapolated to a national level, or the conditions necessary for successful experiments may be unavailable. For example, in many cases Federal regulations apply broadly to the general population. Thus, comparable control groups do not exist. Comparing populations through time may be more feasible; however, changes in underlying economic or health conditions may complicate such comparisons. Some of these challenges may be overcome using simple regression analysis or more sophisticated econometric modeling techniques.[133] In addition, regulations should be designed to ensure that monitoring or other data are available for use in future retrospective assessments.

The input data and additional analytic results are then used to update existing *ex ante* models or create new *ex post* models, as discussed in greater detail later in this chapter. At the conclusion of the process, decision-makers would use the results of the *ex post* modeling effort to evaluate the regulations. The process may be iterative as new data or insights are identified.

9.2.2 ADDRESSING THE TIMING OF THE IMPACTS

Below, we address two additional technical issues. They include defining the period of analysis and calculating present value and annualized impacts. While these issues are also relevant to prospective analysis, they may be addressed differently in retrospective analysis, depending on the period of interest.

Determining the time horizon: In retrospective analysis, defining the relevant time horizon is fairly simple. As with prospective analysis, the retrospective analysis should start in the year the impacts were first incurred, even if that period predates the effective date of the final regulation. For example, many regulated entities may incur costs in anticipation of upcoming regulations as they prepare to meet the regulation's effective date. These costs should be included in the analysis.

The end date is determined by the date when the retrospective analysis is undertaken or the most recent date for which retrospective data are available. To the extent that agencies wish to project impacts into the future based on new information collected in the retrospective analysis, additional prospective results should be clearly

[130] For a discussion of regulatory design intended to foster such experiments, see Greenstone (2009).

[131] For example, the National Traffic Highway Safety Administration (NHTSA) often issues standards applying only to new vehicles. Thus, it can estimate the efficacy of new safety equipment by comparing contemporaneous accident reports for new vehicles to similar records for older vehicles manufactured prior to the effective date of the final regulation (Lutter 2013).

[132] For two examples of these types of experiments conducted in the context of public health policy, see Newhouse and the Insurance Experiment Group (1996) and Baicker et al. (2013).

[133] For an informative discussion of the use of controlled and quasi-experiments in policy evaluation and the statistical analysis of such empirical data, see HM Treasury (2011), Chapter 9. For additional guidance on the design and conduct of such experiments, see Box et al. (2005).

separated and reported, as prospective analysis requires a different set of assumptions to address the future baseline and incremental scenarios.

Where the benefits and costs of a regulation are expected to occur unevenly through time, the analysts should consider the full time period over which the regulation was implemented. Longer timeframes may be particularly important when positive health impacts are not expected to be measurable until many years after the regulation goes into effect. In such cases, a longer timeframe ensures that all significant one-time benefits and costs are captured in the analysis. However, if benefits and costs are likely to remain constant through the period of the analysis, it may be sufficient to model impacts for a single year.[134]

Finally, if the agency wishes to compare the results of *ex ante* and *ex post* analyses, it must model the same time periods. However, this may not always be possible, particularly if the agency reviews the regulation within the first few years of implementation. In such cases, analysts should adjust *ex ante* estimates to exclude years not analyzed in the *ex post* analysis. Agencies should also ensure that the identical time periods are covered when comparing *ex ante* and *ex post* estimates of annualized impacts.

Calculating present value and annualized impacts: Regardless of whether impacts occur in the future or the past, time preferences matter. Resources allocated to compliance in prior years could have been used for other purposes. Benefits accrued earlier are generally more valuable than those accrued later. If analysts are interested in comparing the results of the retrospective analysis to the prospective analysis, they should report benefits and costs in present value terms using the same base year (see Chapter 5). Generally, the starting point (base year) is the year the regulation went into effect or the first year costs or benefits were incurred. Alternatively, impacts may be reported on an annualized basis. In either case, the stream of benefits and costs should also be reported by year and in constant, undiscounted dollars for those years.

9.2.3 FRAMING THE *EX POST* MODELING EFFORT

Earlier in this chapter, Figure 9.2 describes the general components of retrospective analysis, including inputs, analysis, and outputs. This section provides additional discussion of the choices analysts face during the analysis, particularly the *ex post* modeling effort. Generally, analysts should follow a phased approach to ensure that their work is carefully focused and useful for decision-making, following the steps listed in Figure 9.3 as discussed below.

Prior to initiating any retrospective modeling effort, analysts should consider the purpose of the effort, as the goal may affect the content of the analysis (see Figure 9.1). Based on that purpose, they should develop reasonable stopping rules to define the scope of the analysis. These rules are designed to focus analysts on answering the pertinent question related to a particular regulation, while avoiding unnecessary and expensive data collection and analysis.

Analysts should follow a stepwise progression: (1) simple screening analysis; (2) revisions to existing models developed for the *ex ante* regulatory analysis; and (3) entirely new modeling efforts, as indicated in greater detail in Figure 9.3. For example, if the purpose of the effort is to determine whether the benefits of a regulation exceed costs, and a simple screening analysis can answer this question, additional modeling efforts may not be necessary.

[134] Such a situation seems unlikely given continued changes in the size of the U.S. economy. But per capita effects might be roughly constant and reporting them would be perhaps as useful as reporting totals.

FIGURE 9.3. SUGGESTED STEPS FOR *EX POST* MODELING

LEVEL OF EFFORT	STEPS
Lowest ⇩	***Screening Analysis*** • Conduct case studies of incurred costs or benefits. • Conduct a simple bounding analysis with assumptions based on observed data.
⇩	***Adjust Existing Ex Ante Model Assumptions and Data*** In addition to the above screening tools, • Identify the key assumptions or data sources influencing the impact estimates in the *ex ante* model. • Focus retrospective research efforts on refining these assumptions and data, such as through natural or controlled experiments or other data collection efforts. • Update counterfactual and incremental scenarios using the existing model and this new information. • Evaluate the validity of existing models and whether they will achieve the goals of the retrospective analysis (e.g., whether they accurately depict the response of the regulated community).
⇩ **Highest**	***Construct a New Model*** In addition to, or in place of, adjustments to the *ex ante* model, • Use existing and new information to construct a new model of impacts. • Ensure the new model captures missing categories of benefits and costs or unanticipated responses by the affected community.

If analysts are interested not just in whether the regulation was effective, but also in the accuracy of the *ex ante* cost and benefit estimates, additional modeling may be required. They should first review the key assumptions or data sources driving the results of the *ex ante* analysis, particularly if the appropriateness of these is uncertain and they substantially affect the results. Analysts should focus their research on refining or updating these key factors.[135] Variations of the original *ex ante* models could be used to estimate the incremental change compared with the counterfactual scenario. However, such an approach assumes that the original models accurately characterize the implementation of the regulation and linkages to resulting benefits and costs.[136]

In some cases, through interviews with affected entities, additional data collection, or the results of controlled or quasi-experiments, analysts may determine that the *ex ante* models did not accurately characterize the impacts of the regulation. For example, compliance costs may be lower than anticipated if affected entities develop innovative methods of compliance, or improvements in overall productivity reduce all costs, including compliance costs. Or underlying market conditions may fundamentally change, making substitute sources of

[135] It is particularly helpful if the original *ex ante* analysis clearly identifies key assumptions and sources of uncertainty. Sensitivity analysis can be used to demonstrate the importance of each uncertain variable.

[136] A particularly well-known example of a regulation where the *ex ante* models did not accurately predict the behavioral response of the regulated community is the case of EPA's regulation of sulfur dioxide (SO_2) emissions. As described in Harrington et al. (2000), emissions reductions exceeded expectations for several reasons, including greater than expected efficacy of pollution control equipment, innovation by the regulated community, and changes in market conditions. The SO_2 regulation illustrates circumstances that would necessitate new cost and benefit modeling to accurately estimate the net benefits of the regulation.

goods or materials available to offset costs or benefits. In other cases, the agency may learn that key categories of benefits and costs were omitted from the original analysis. Based on this new information, analysts may decide to develop new models of benefits and costs.

In sum, conducting retrospective analysis requires thinking carefully about its goals. In some cases, revisiting the prospective analysis from an *ex post* perspective will provide important insights into the benefits and costs of the regulation. In other cases, prospective analysis of the benefits and costs of eliminating or modifying the regulation may be useful – instead of, or in addition to, the *ex post* analysis. In either case, the level of effort should be tailored to the purpose of the review.

Appendix A

Agency Checklist: Regulatory Impact Analysis (OMB 2010)

This appendix replicates OMB's 2010 Checklist, which is also available at: https://www.whitehouse.gov/omb/inforeg_regpol_agency_review.

With this document, the Office of Information and Regulatory Affairs is providing a checklist to assist agencies in producing RIAs, as required for economically significant rules by Executive Order 12866 and OMB *Circular A-4*.

Nothing herein alters, adds to, or reformulates existing requirements in any way. Moreover, this checklist is limited to the requirements of Executive Order 12866 and Circular A-4; it does not address requirements imposed by other authorities, such as the National Environmental Policy Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, the Paperwork Reduction Act, and various Executive Orders that require analysis. Executive Order 12866 and Circular A-4, as well as those other authorities, should be consulted for further information.

Checklist for Regulatory Impact Analysis:

- Does the RIA include a reasonably detailed description of the **need for the regulatory action**?[1,2]
- Does the RIA include an explanation of how the regulatory action will **meet that need**?[3]
- Does the RIA use an appropriate **baseline** (i.e., best assessment of how the world would look in the absence of the proposed action)?[4]
- Is the information in the RIA based on **the best reasonably obtainable scientific, technical, and economic information** and is it presented in an **accurate, clear, complete, and unbiased manner**?[5]
- Are the data, sources, and methods used in the RIA provided to the public **on the Internet** so that a qualified person can reproduce the analysis?[6]
- To the extent feasible, does the RIA quantify and monetize the anticipated **benefits** from the regulatory action?[7,8]
- To the extent feasible, does the RIA quantify and monetize the anticipated **costs**?[9]
- Does the RIA explain and support **a reasoned determination that the benefits of the intended regulation justify its costs** (recognizing that some benefits and costs are difficult to quantify)?[10]
- Does the RIA assess the **potentially effective and reasonably feasible alternatives**?[11]
    - Does the RIA assess the benefits and costs of different regulatory provisions separately if the rule includes a number of distinct provisions?[12]
    - Does the RIA assess at least one alternative that is less stringent and at least one alternative that is more stringent?[13]
    - Does the RIA consider setting different requirements for large and small firms?[14]
- Does the preferred option have the highest **net benefits** (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires a different approach? [15]
- Does the RIA include an explanation of why the planned regulatory action is **preferable** to the identified potential alternatives?[16]
- Does the RIA use appropriate **discount rates** for benefits and costs that are expected to occur in the future?[17]
- Does the RIA include, if and where relevant, an appropriate **uncertainty analysis**?[18]

- Does the RIA include, if and where relevant, a separate description of **distributive impacts** and **equity**?[19]
  - Does the RIA provide a description/accounting of transfer payments?[20]
  - Does the RIA analyze relevant effects on disadvantaged or vulnerable populations (e.g., disabled or poor)?[21]
- Does the analysis include a clear, plain-language **executive summary**, including an **accounting statement** that summarizes the benefit and cost estimates for the regulatory action under consideration, including the qualitative and non-monetized benefits and costs?[22]
- Does the analysis include a clear and transparent **table** presenting (to the extent feasible) anticipated benefits and costs (quantitative and qualitative)?[23]

NOTES

1. Required under Executive Order 12866, Section 6(a)(3)(B)(i): "The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need."
2. Circular A-4 states: "If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively." (P. 4)
3. See note 1 above.
4. Circular A-4 states: "You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action… In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline." (P. 15-16)
5. Circular A-4 states: "Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available… you should assure compliance with the Information Quality Guidelines for your agency and OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies..." (P. 17). The IQ Guidelines (paragraph V.3.a) define objectivity to include "whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner."
   http://www.whitehouse.gov/omb/assets/omb/fedreg/reproducible2.pdf
6. Circular A-4 states: "A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates. To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings." (P. 17). OMB IQ Guidelines (paragraph V.3.b.ii) further states: "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties."
7. Required under Executive Order 12866, Section 6(a)(3)(C)(i): "An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits."

8. Circular A-4 states: "You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information." (P. 19). Circular A-4 also offers a discussion of appropriate methods for monetizing benefits that might not easily be turned into monetary equivalents.

9. Required under Executive Order 12866, Section 6(a)(3)(C)(ii): "An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs;" See also note 6 above.

10. Executive Order 12866, Section 1(b)(6) states that to the extent permitted by law, "[e]ach agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." As Executive Order 12866 recognizes, a statute may require an agency to proceed with a regulation even if the benefits do not justify the costs; in such a case, the agency's analysis may not show any such justification.

11. Required under Executive Order 12866, Section 6(a)(3)(C)(iii): "An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions)..."

12. Circular A-4 states: "You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions." (P. 17)

13. Circular A-4 states: "you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option." (P. 16)

14. Circular A-4 states: "You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604)." (P. 8)

15. Executive Order 12866, Section 1(a) states: "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity) unless a statute requires another regulatory approach."

16. Required under Executive Order 12866, Section 6(a)(3)(C)(iii): "An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives."

17. Circular A-4 contains a detailed discussion, generally calling for discount rates of 7 percent and 3 percent for both benefits and costs. It states: "Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when they actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.... For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent.... If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent." (PP. 31, 34, 36)

18. Circular A-4 provides a detailed discussion. Among other things, it states: "Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes." (P. 40). Circular A-4 also states: "You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates." (P. 17)

19. Executive Order 12866, Section 1(b)(5) states; "When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, *distributive impacts*, and *equity*" (emphasis added). Circular A-4 states: "The term 'distributional effect' refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography)… Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency… Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups." (P. 14)

20. Circular A-4 states: "Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. . . . Transfer payments are monetary payments from one group to another that do not affect total resources available to society. . . . You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects." (P. 14)

21. Circular A-4 states: "Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups." (P. 14)

22. Circular A-4 states: "Your analysis should also have an executive summary, including a standardized accounting statement." (P. 3). OMB recommends that: "Regulatory analysis should be made as transparent as possible by a prominent and accessible executive summary—written in a "plain language" manner designed to be understandable to the public—that outlines the central judgments that support

regulations, including the key findings of the analysis (such as central assumptions and uncertainties)…If an agency has analyzed the costs and benefits of regulatory alternatives to the planned action (as is required for economically significant regulatory actions), the summary should include such information." See *2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, page 51. Available at: http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf

23. Circular A-4 states: "You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency." (P. 44). Circular A-4 includes an example of a format for agency consideration. OMB recommends "that agencies should clearly and prominently present, in the preamble and in the executive summary of the regulatory impact analysis, one or more tables summarizing the assessment of costs and benefits required under Executive Order 12866 Section 6(a)(3)(C)(i)-(iii). The tables should provide a transparent statement of both quantitative and qualitative benefits and costs of the proposed or planned action as well as of reasonable alternatives. The tables should include all relevant information that can be quantified and monetized, along with relevant information that can be described only in qualitative terms. It will often be useful to accompany a simple, clear table of aggregated costs and benefits with a separate table offering disaggregated figures, showing the components of the aggregate figures. To the extent feasible in light of the nature of the issue and the relevant data, all benefits and costs should be quantified and monetized. To communicate any uncertainties, we recommend that the table should offer a range of values, in addition to best estimates, and it should clearly indicate impacts that cannot be quantified or monetized. If nonquantifiable variables are involved, they should be clearly identified. Agencies should attempt, to the extent feasible, not merely to identify such variables but also to signify their importance." See *2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, page 51. Available at: http://www.whitehouse.gov/sites/default/files/omb/legislative/reports/2010_Benefit_Cost_Report.pdf

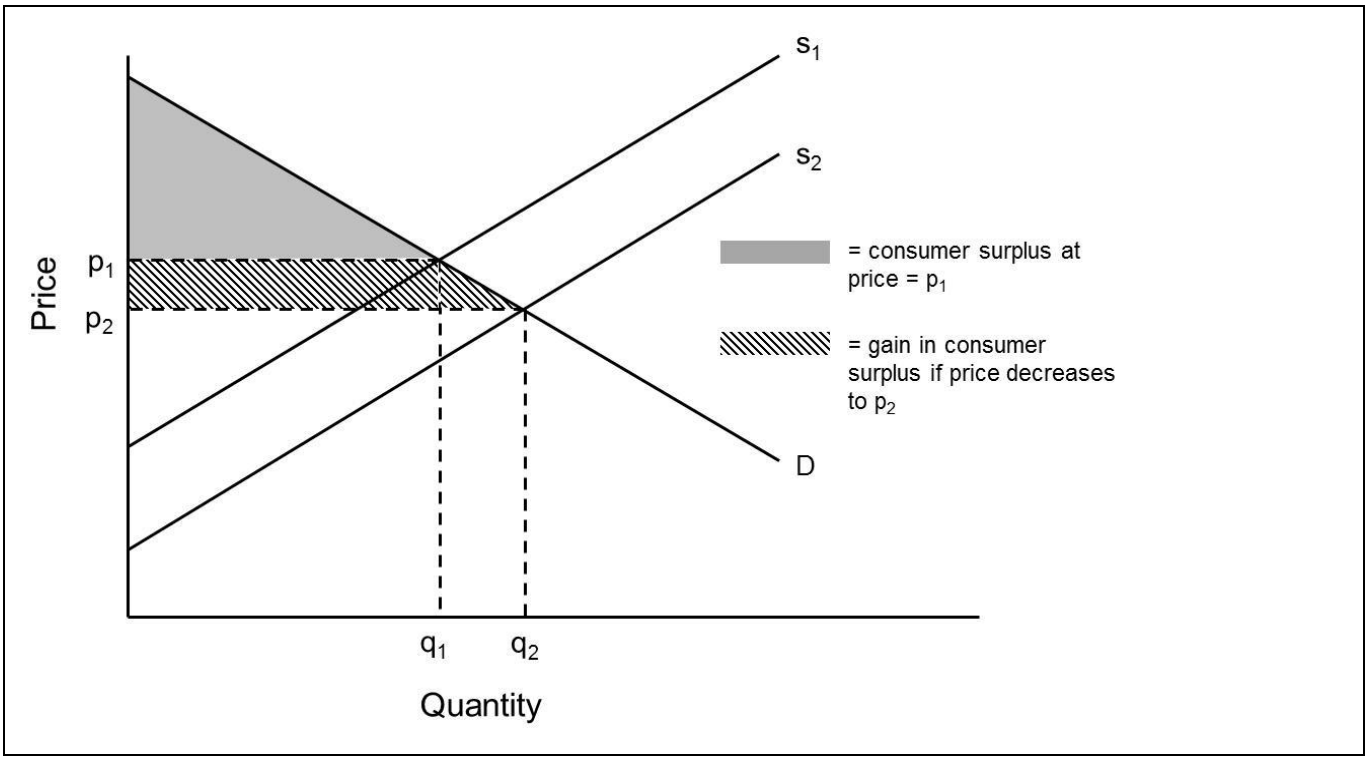
Appendix B

Consumer and Producer Surplus

As discussed in Chapter 3, a key assumption that underlies benefit-cost analysis is that benefit values are determined by the change in the amount by which aggregate WTP exceeds the market price, or "consumer surplus." When WTP exceeds price, the individual benefits from the fact that he or she can acquire the good or service for less than his or her willingness to pay. If price exceeds WTP, the individual would not purchase the good or service, choosing to use the money for other things. The difference between WTP and price can be aggregated across individuals to determine the consumer surplus associated with different price levels. Consumers generally benefit from price decreases, because WTP then exceeds price by a larger amount, and vice-versa.

This relationship is illustrated by Figure B.1. The horizontal axis represents the quantity of the good (q), the vertical axis represents its price (p). The market demand curve (D) indicates both consumers' WTP at each quantity and the quantity that would be purchased at each price.[137] Similarly, the supply curve (S) indicates both the marginal cost of supply at each quantity and the quantity that would be supplied at each price. The equilibrium market price is determined by where the two curves intersect. At this point, only consumers whose WTP exceeds the price purchase the good, and only producers whose cost of supply is less than the price produce it. For example, at price p_1, consumers would purchase quantity q_1. The shaded area above the price line and below the demand curve indicates the amount by which WTP exceeds price; i.e., consumer surplus at price p_1.

FIGURE B.1. CHANGE IN CONSUMER SURPLUS DUE TO A PRICE DECREASE



[137] Depending on the good or service, the prices represented in this schedule may reflect time costs or other factors that influence demand, in addition to the "sticker price" viewed by the consumer. Demand curves can also be developed for nonmarket goods, using the techniques described in Chapter 3 to estimate WTP.

If the price decreases, the quantity demanded rises as some consumers choose to purchase the good at the lower price rather than buying other goods or services. If changes in supply lead price to drop from p_1 to p_2, consumers would increase their purchases to quantity q_2.

When the price falls from p_1 to p_2, consumers benefit in two ways. First, they pay less for the q_1 units they continue to buy. Second, they buy $q_2 - q_1$ additional units for which WTP exceeds p_2 but does not exceed p_1. (The size of the increase in q is often summarized by the "demand elasticity," defined as the proportional change in q divided by the proportional change in p.) The area marked with diagonal lines indicates the gain in consumer surplus that results from the price decrease from p_1 to p_2.[138]

Similar concepts apply to producers. Regulatory compliance costs may affect the price and quantity of goods exchanged in the market, leading to changes in producer surplus. These relationships are illustrated by Figure B.2 for a competitive market.[139] In this case, we illustrate a cost increase that results from compliance with a new regulation. As in the earlier figure, the horizontal axis represents the quantity of the good (q) and the vertical axis represents its price (p); the market demand curve (D) indicates both consumers' WTP at each quantity and the quantity that would be purchased at each price; the supply curve (S) indicates both the marginal cost of supply at each quantity and the quantity that would be supplied at each price; and the equilibrium market price is determined by where the supply and demand curves intersect.

If the cost of supplying the good increases as a result of the regulation, the supply curve shifts upwards, from s_1 to s_2, reducing consumer surplus (the area between the demand curve and the price line). Producer surplus, which reflects the difference between the market price and supply costs (the area above the supply curve and below the price line), also decreases. For example, at price p_1 producers will supply quantity q_1. When supply costs increase, producers will provide a smaller quantity for each price and demand a higher price for each quantity. Thus the market price will increase to p_2 and the quantity sold will decrease to q_2.

The area bounded by the two supply curves and the new quantity line represents the increased cost of producing the quantity that is demanded at the new price.[140] In addition, the reduction in output results in a deadweight loss represented by the solid triangle, indicating forgone net benefits. This deadweight loss is part of the costs of the regulation.[141] Thus the net reduction in the total surplus (consumer plus producer) is a real cost to society. The question for analysts is whether these costs are greater or less than aggregate WTP for the regulation's benefits.

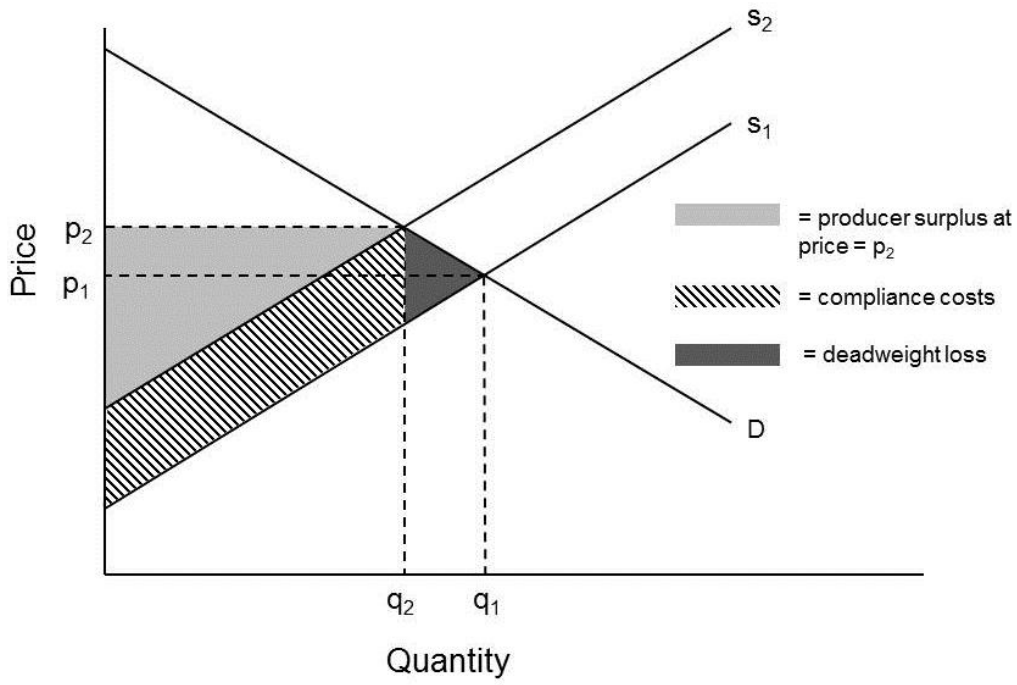
[138] When the price falls, some consumers who purchase the good at p_1 might purchase more units and some who do not purchase it at p_1 may purchase at the lower price p_2. In this case, the graph displays aggregate demand by all consumers; it does not indicate what quantity each consumer purchases. A similar graph could be drawn for an individual consumer.

[139] For a more detailed discussion of these concepts, see Boardman et al. (2011).

[140] As noted elsewhere, the real resource cost of producing a good may differ from the supply cost when the resource costs are not equal to the private costs, due to externalities, taxes, subsidies, or monopoly producers.

[141] Note that the deadweight loss results from changes in both producer and consumer surplus.

FIGURE B.2. CHANGE IN PRODUCER SURPLUS DUE TO A COST INCREASE



Appendix C
Methods for Estimating QALYs

As discussed in Chapter 3, estimating QALYs involves first determining the effect of a health state on HRQL, then multiplying HRQL by the duration of the health state. While the HRQL associated with a health state is likely to vary among individuals, in practice a common value is typically used for each state, representing a population average. This appendix introduces methods for estimating HRQL; more information on the implementation of these methods and their advantages and limitations is provided in Institute of Medicine (2006).

HRQL can be estimated directly or indirectly. Commonly used direct methods include the standard gamble, time tradeoff, and visual analog scale, administered in interviews or a survey. The standard gamble approach asks respondents to compare living the rest of their life (T years) in the health state of interest with a gamble between living the rest of their life in full health (with probability p) and immediate death (with probability 1 – p). The probability p* at which the individual is indifferent is his or her HRQL for that health state. This follows because living the rest of his or her life in the specified health state yields p* T QALYs (i.e., T years weighted by an HRQL of p*) and the gamble provides an expected value of p* T QALYs (i.e., a p* chance of T QALYs (T years weighted by an HRQL of 1) plus a complementary chance of zero QALYs (immediate death)).

The time tradeoff approach asks respondents to compare living the rest of their life (T years) in the health state of interest with living a shorter period (qT years) in full health, followed by death. The value q* at which the individual is indifferent is his or her HRQL for the health state. This follows because living T years with HRQL q* provides q* T QALYs, and living q* T years in full health also provides q* T QALYs.

The visual analog scale does not require a comparison of different future lives. It simply asks the individual to rate the health state of interest on a visual scale where one end is described as being as bad as dead and labeled 0, and the other is described as full health and labeled 100. (Alternatively, the individual may be asked to report a number between 0 and 100 rather than marking it on the scale.) HRQL is then defined as the response divided by 100.

An indirect method to estimate HRQL is to apply one of several generic HRQL indices, examples of which include the EurQol- (EQ)-5D, the Health Utilities Index (HUI), and the Quality of Well-Being (QWB) scale. Each describes health status by employing a classification system with several dimensions. In the case of the EQ-5D, these include mobility, self-care, usual activities, pain, and anxiety and depression. A particular health state is rated within each dimension; for example, as causing no, some, or extreme mobility problems. The HRQL associated with each health state is then calculated by applying a scoring function, developed by eliciting HRQL for some of the health states through a population survey using one of the direct methods described earlier. These indices have the advantage of standardizing the approach for describing each health state and providing a convenient method to calculate HRQL. The results will vary, however, depending on which index is applied, given differences in the attributes they include and in the scoring functions.

Once HRQL is determined for a particular health state, it is multiplied by the duration of that state to estimate the associated QALYs. The QALYs can then be summed across health states (e.g., acute and chronic phases) associated with a particular illness, and across the illnesses associated with a particular hazard. For regulatory analysis, health status with the regulation must be compared to health status in the absence of the regulation, which is likely to be less than full health. In particular, health status generally deteriorates with age, so that average HRQL for older individuals is generally less than 1.0 (see, for example, Hamner et al. 2006). Expected QALYs are calculated by weighting the HRQL experienced in each future year of life by the probability of living that year (i.e., by the survival curve). In addition, future QALYs are usually discounted using the same discount rates as for monetary values.

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Index

Glossary

Accounting Costs: Actual expenses plus depreciation of capital equipment (Chapter 4).

Annualized Value: The constant annual amount, which, if paid each year over a defined time period, has the same present value as a specified series of unequal payments over the same period (Chapter 5).

Baseline: Expected future conditions in the absence of a new regulation or other policy change (Chapter 2).

Benefits: For the purpose of HHS regulatory analysis, the value of the intended outcomes of a regulation or other policy, such as reductions in mortality or morbidity risks, as well as any countervailing effects on these outcomes, such as health risk increases. Note that analyses not subject to this guidance may use differing definitions when categorizing outcomes as benefits or costs (Chapter 2).

Benefit Transfer: The application of values from the available research to a policy context that differs in some respects from the context studied. Involves evaluating the quality of the research and its applicability to the policy context (Chapter 3).

Bounding Analysis: The application of reasonable high and low parameter values to determine the extent to which the analytic results might change given the likely variation in the values (Chapter 6).

Breakeven Analysis: The value of an unknown or uncertain parameter at which benefits and costs would be equal, indicating how large the value would need to be to bridge the gap between the quantified benefits and costs. Also referred to as “threshold” analysis (Chapter 6).

Capital Cost: The value of resources, including equipment, buildings, and land, that are not immediately consumed in the production process (Chapter 4).

Compliance Cost: The value of resources, including labor, capital, and materials, used to implement a regulation or other policy. Includes only those resources expended by the entities and individuals directly responsible for implementation; excludes impacts on prices or other market conditions (Chapter 4).

Consumer Price Index (CPI): An index maintained by the U.S. Bureau of Labor Statistics that indicates changes in the prices paid by consumers for a market basket of goods and services over time. May be used to adjust values measured in current dollars to a common dollar year so that analyses can be conducted in real dollars, avoiding the need to adjust for expected inflation (Chapter 5).

Consumer Surplus: The difference between the maximum an individual would be willing to pay for a good or service and the market price (Chapter 3, Appendix B).

Costs: For the purpose of HHS regulatory analysis, the value of the inputs required to implement a regulation or other policy, including labor, capital, and materials, as well as any offsetting savings. Note that analyses not subject to this guidance may use differing definitions when categorizing outcomes as benefits or costs (Chapter 2).

Deadweight Loss: The net loss in consumer and producer surplus that accrues when government intervention or other factors prevent the market from reaching a competitive equilibrium (Appendix B).

Discounting: The process for converting values that accrue in different years to their present value, to reflect individual time preferences and the value of investments forgone (Chapter 5).

Distribution: The allocation of benefits, costs, or net benefits across different population groups, defined, for example, by income level (Chapter 7).

Experiments: Comparison of outcomes across groups who are similar or identical except for their exposure to a regulation or other policy (Chapter 9).

Gross Domestic Product (GDP) Implicit Price Deflator: A measure reported by the U.S. Bureau of Economic Analysis that indicates the ratio of the market value of goods and services in current dollars to its the value in chained (constant) dollars. May be used to adjust values measured in current dollars to a common dollar year so that analyses can be conducted in real dollars, avoiding the need to adjust for expected inflation (Chapter 5).

General Equilibrium Models: Models that can be used to estimate the economy-wide impact of a regulation or other policy with large impacts (Chapter 4).

Health-Related Quality of Life (HRQL): A numerical indicator of health status estimated using a scale anchored at zero and one, where one corresponds to full health and zero corresponds to a state that is as bad as dead (Chapter 3, Appendix C).

Income Elasticity: The proportional change in price or quantity associated with a change in real income. When used in estimating the VSL, it indicates the proportional change in value (i.e., unit price) associated with an income change (Chapter 3).

Inflation: Economy-wide increases in prices (Chapter 5).

Net Benefits: The difference, benefits minus costs (Chapter 2).

Nominal Value: Values expressed in current-year dollars, reflecting the effects of both inflation and real changes in value over time (Chapter 5).

Opportunity Cost: The benefits of the best alternative use of specified resources, which is forgone when resources are used for one purpose and hence cannot be used for other purposes (Chapter 4).

Partial Equilibrium Models: Models that describe the effects of a regulation or other policy in one market, which can be used to estimate the impact on an industry or group of industries (Chapter 4).

Present Value: The value of a stream of benefits, costs, or net benefits discounted to reflect their value in a common year (Chapter 5).

Probabilistic Analysis: The use of distributions of parameter values to explore the effects of uncertainty on an analytic result. Often employs Monte Carlo simulation techniques, which involve taking multiple random draws from the distribution for each critical parameter, calculating the model output for each draw, and using the results to represent the distribution of the outcome measure (Chapter 6).

Producer Surplus: The difference between the revenue producers receive and their cost of production (Chapter 4, Appendix B).

Quality-Adjusted Life Year (QALY): A nonmonetary measure that integrates the duration and severity of illness. Calculated by multiplying the amount of time an individual spends in a health state by the HRQL associated with that state, and summing over health states (Chapter 3, Appendix C).

Real Value: Values adjusted to a common dollar year (constant dollars), removing the effects of inflation (Chapter 5).

Retrospective Analysis (*ex post*): Assessment of the impacts of a regulation or a policy after it has been implemented, looking back to compare its impacts to what might have otherwise occurred, in contrast to prospective (*ex ante*) analysis which involves predicting future impacts (Chapter 9).

Revealed Preference Methods: Estimation of values based on observed market prices or behaviors (Chapter 3).

Screening Analysis: Use of readily available information and simple assumptions to provide preliminary information on potential impacts; may aid in targeting future work (Chapter 2).

Sensitivity Analysis: Varying one or more key parameter values to explore the effects of uncertainty on the analytic results (Chapter 6).

Social cost: The sum of the opportunity costs associated with the implementation of a regulation or other policy (Chapter 4).

Standing: The definition of whose benefits and costs are to be counted in an analysis. For HHS regulatory analysis, generally includes all U.S. residents (Chapter 2).

Stated Preference Methods: Estimation of values based on surveys or other self-reported data (Chapter 3).

Statistical Cases: Risk changes summed over the affected population; for example, if 10,000 people each experience a risk reduction of 1 in 10,000, then one statistical case has been averted (Chapter 3).

Transfer Payment: Monetary payments between individuals or groups that do not affect the total resources available to society (Chapter 4).

Uncertainty: Lack of knowledge about a parameter value that could be addressed by more research (Chapter 6).

Value per Quality-Adjusted Life Year (QALY): The marginal rate of substitution between money in a defined period and health-adjusted life years remaining; often approximated by dividing a value per statistical life (VSL) estimate by expected remaining QALYs (Chapter 3).

Value per Statistical Life (VSL): The marginal rate of substitution between money in a defined time period and mortality risk; often approximated by dividing individual willingness to pay for a small risk change by the risk change (Chapter 3).

Value per Statistical Life Year (VSLY): The marginal rate of substitution between money in a defined period and life years remaining; often approximated by dividing a VSL estimate by remaining life expectancy (Chapter 3).

Variability: "Real world" heterogeneity of a parameter value (Chapter 6).

Willingness to Pay (WTP): The maximum amount of money an individual would exchange to obtain an improvement, given his or her budget constraints, such that his or her wellbeing is as good with the improvement and having made the payment as without (Chapter 3).

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO, Plaintiff, vs. ALEX M. AZAR II, et al., Defendants.	No. C 19-02405 WHA No. C 19-02769 WHA No. C 19-02916 WHA
STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA, Plaintiff, vs. ALEX M. AZAR, et al., Defendants.	**[PROPOSED] ORDER GRANTING PLAINTIFFS' JOINT MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**
COUNTY OF SANTA CLARA et al., Plaintiffs, vs. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Date: October 30, 2019 Time: 8:00 AM Courtroom: 12 Judge: Hon. William H. Alsup Action Filed: 5/2/2019

Having considered the cross motions for summary judgment and any oppositions, replies, and oral argument presented, it is HEREBY ORDERED that the Plaintiffs' joint motion for summary judgment is GRANTED.

The Court HEREBY DECLARES that the final rule, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 84 Fed. Reg. 23170 (May 21, 2019) (Rule) is arbitrary and capricious and not in accordance with law and that it violates the Spending Clause, Separation of Powers, the Establishment Clause, the Free Speech Clause, the Due Process Clause, and Equal Protection. The Court further DECLARES that Defendants acted in excess of statutory authority in promulgating the Rule.

The Court ORDERS that the Rule be vacated and set aside in accordance with the Administrative Procedure Act. 5 U.S.C. § 706(2).

The Court permanently ENJOINS Defendants U.S. Department of Health and Human Services (HHS), HHS Secretary Alex M. Azar II, Office for Civil Rights Director Roger Severino, and their officers, agents, servants, employees, attorneys, designees, subordinates, as well as any person acting in concert or participation with them, from implementing or enforcing the Rule, or taking any actions to enforce the underlying statutes in a manner contrary to the Court's opinion.

The Court ENJOINS Defendants HHS, HHS Secretary Alex M. Azar II, Office for Civil Rights Director Roger Severino, and their officers, agents, servants, employees, attorneys, designees, subordinates, as well as any person acting in concert or participation with them, from withholding, denying, suspending, or terminating federal funding from Plaintiffs in connection with the Rule, or otherwise unlawfully.

The Court awards costs, expenses, and reasonable attorneys' fees to Plaintiffs.

It is HEREBY FURTHER ORDERED that Defendants' motion to dismiss or, in the alternative, for summary judgment is DENIED.

IT IS SO ORDERED.

Dated: _____

_____
The Honorable William Alsup
United States District Judge

XAVIER BECERRA
Attorney General of California
KATHLEEN BOERGERS, State Bar No. 213530
NELI N. PALMA, State Bar No. 203374
KARLI EISENBERG, State Bar No. 281923
STEPHANIE T. YU, State Bar No. 294405
1300 I Street, Suite 125, P.O. Box 944255
Sacramento, CA 94244-2550
Tel: (916) 210-7522; Fax: (916) 322-8288
E-mail: Neli.Palma@doj.ca.gov
Attorneys for Plaintiff State of California, by and through Attorney General Xavier Becerra

JAMES R. WILLIAMS, State Bar No. 271253
County Counsel
GRETA S. HANSEN, State Bar No. 251471
LAURA S. TRICE, State Bar No. 284837
MARY E. HANNA-WEIR, State Bar No. 320011
SUSAN P. GREENBERG, State Bar No. 318055
H. LUKE EDWARDS, State Bar No. 313756
Office of the County Counsel, Co. of Santa Clara
70 West Hedding Street, East Wing, 9th Fl.
San José, CA 95110-1770
Tel: (408) 299-5900; Fax: (408) 292-7240
Email: mary.hanna-weir@cco.sccgov.org
Attorneys for Plaintiffs County of Santa Clara

DENNIS J. HERRERA, State Bar No. 139669
City Attorney
JESSE C. SMITH, State Bar No. 122517
Chief Assistant City Attorney
RONALD P. FLYNN, State Bar No. 184186
Chief Deputy City Attorney
YVONNE R. MERÉ, State Bar No. 173594
SARA J. EISENBERG, State Bar No. 269303
JAIME M. HULING DELAYE, State Bar No. 270784
Deputy City Attorneys
City Hall, Rm 234, 1 Dr. Carlton B. Goodlett Pl.
San Francisco, CA 94102-4602
Tel: (415) 554-4633, Fax: (415) 554-4715
E-Mail: Sara.Eisenberg@sfcityatty.org
Attorneys for Plaintiff City and County of San Francisco

LEE H. RUBIN, State Bar No. 141331
Mayer Brown LLP
3000 El Camino Real, Suite 300,
Palo Alto, CA 94306-2112
Tel: (650) 331-2000, Fax: (650) 331-2060
Email: lrubin@mayerbrown.com
Attorneys for Plaintiffs County of Santa Clara, et al.

**Additional Counsel Listed on Signature Pages*

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO,
Plaintiff,
vs.
ALEX M. AZAR II, et al.,
Defendants.

STATE OF CALIFORNIA, by and through ATTORNEY GENERAL XAVIER BECERRA,
Plaintiff,
vs.
ALEX M. AZAR, et al.,
Defendants.

COUNTY OF SANTA CLARA, et al.
Plaintiffs,
vs.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,
Defendants.

No. C 19-02405 WHA
No. C 19-02769 WHA
No. C 19-02916 WHA

CERTIFICATE OF SERVICE

Date: October 30, 2019
Time: 8:00 AM
Courtroom: 12
Judge: Hon. William H. Alsup
Action Filed: 5/2/2019

CERTIFICATE OF SERVICE

Case Name: **State of California v. Alex M. Azar, et al.** No. **3:19-cv-02769-WHA**

I hereby certify that on September 12, 2019, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT, WITH MEMORANDUM OF POINTS AND AUTHORITIES; AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

PLAINTIFFS' REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

[PROPOSED] ORDER GRANTING PLAINTIFFS' JOINT MOTION FOR SUMMARY JUDGMENT AND DENYING DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DAVID H. AIZUSS, M.D. IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF LOIS BACKUS, M.P.H., IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF ELIZABETH BARNES IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF ROBERT BOLAN, MD, CHIEF MEDICAL OFFICER, LA LGBT CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. BRAD BUCHMAN IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF JULIE BURKHART IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF MARI CANTWELL IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF WARD CARPENTER, MD, CO-DIRECTOR OF HEALTH SERVICES, LA LGBT CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF PETE CERVINKA IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF RANDIE C. CHANCE, PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF WENDY CHAVKIN, M.D., MPH IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. ALICE CHEN IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF SARA H. CODY, M.D., HEALTH Officer AND DIRECTOR OF COUNTY OF SANTA CLARA PUBLIC HEALTH DEPARTMENT, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. GRANT COLFAX IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. CHRISTOPHER COLWELL IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DARREL CUMMINGS, CHIEF OF STAFF OF THE LOS ANGELES LGBT CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. ELEANOR DREY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. RANDI C. ETTNER, PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

DECLARATION OF MARK GHALY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DEBRA HALLADAY, INTERIM CHIEF EXECUTIVE OFFICER OF VALLEY HEALTH PLAN, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF MARY E. HANNA-WEIR IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. JEANNE HARRIS-CALDWELL IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF SARAH HENN, MD, MPH, CHIEF HEALTH OFFICER, WHITMAN-WALKER HEALTH IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF BRUCE HINZE-WEIR IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF KEVIN KISH IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF RICARDO LARA IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF PAUL E. LORENZ, CHIEF EXECUTIVE OFFICER, SANTA CLARA VALLEY MEDICAL CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF ALECIA MANLEY, INTERIM CHIEF OPERATING OFFICER OF THE MAZZONI CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF COLLEEN P. MCNICHOLAS, D.O., M.S.C.I., F.A.C.O.G., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF KEN MILLER, M.D., PH.D. MEDICAL DIRECTOR OF COUNTY OF STANA CLARA EMS AGENCY, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF RICARDO LARA IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. JOSEPH MORRIS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF BRANDON NUNES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF NELI N. PALMA IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF SETH PARDO, PH.D. IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF FRANCES PARMELEE IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF RACHAEL PHELPS, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DENISE PINES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF STIRLING PRICE IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF RANDY PUMPHREY, D.MIN., LPC, BCC, SENIOR DIRECTOR OF BEHAVIORAL HEALTH, WHITMAN-WALKER HEALTH, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF BEN ROSENFIELD IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF NASEEMA SHAFI, CHIEF EXECUTIVE OFFICER, WHITMAN-WALKER HEALTH, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF ADRIAN SHANKER, FOUNDER AND EXECUTIVE DIRECTOR OF BRADBURY-SULLIVAN LGBT COMMUNITY CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF CHRISTINE SIADOR IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF NARINDER SINGH, PHARM. D., DIRECTOR OF PHARMACY FOR THE COUNTY OF SANTA CLARA, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF JILL SPROUL, R.N., CHIEF NURSING OFFICER OF SANTA CLARA VALLEY MEDICAL CENTER, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF JAY STURGES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DIANA TOCHE, D.D.S., IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF TONI TULLYS, M.P.A., DIRECTOR OF COUNTY OF SANTA CLARA BEHAVIORAL HEALTH SERVICES DEPARTMENT, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF MODESTO VALLE, CHIEF EXECUTIVE OFFICER OF CENTER ON HALSTED, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF HECTOR VARGAS, EXECUTIVE DIRECTOR OF GMLA: HEALTH PROFESSIONALS ADVANCING LGBTQ EQUALITY, IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF GREG WAGNER IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF RON WEIGELT IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF CHRISTOPHER M. ZAHN, MD IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

DECLARATION OF DR. BARRY ZEVIN IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF THEIR OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

CERTIFICATE OF SERVICE

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on September 12, 2019, at Sacramento, California.

Priscilla Lucas	*/s/ Priscilla Lucas*
Declarant	Signature

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