IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

ORAL ARGUMENT REQUESTED

MOTION FOR A PRELIMINARY INJUNCTION
OR, IN THE ALTERNATIVE, EXPEDITED SUMMARY JUDGMENT
AND SUPPORTING MEMORANDUM

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INTRODUCTION

The world is facing a global pandemic the likes of which it has not seen in over a century—the end of which is neither known nor in sight. As of shortly before this filing, over two million people in the United States were confirmed to have contracted the novel coronavirus,[1] and over 115,000 people were confirmed to have died from it. Americans are facing severe disruptions to everyday life, from social distancing and school closures to furloughs, layoffs, and collapsing businesses. As states reopen for business, and even with the best social distancing practices in place, some experts believe that the virus may resurge, and that the world will likely face a second wave of the pandemic in the fall or winter of 2020. Even optimistic projections predict that life will not approach normal until a vaccine is developed and distributed sometime in 2021 at the earliest.

During these difficult times, Americans need the security and peace of mind that affordable, high-quality health insurance coverage can offer. Congress enacted the Patient Protection and Affordable Care Act (the "Affordable Care Act" or "ACA") to provide that coverage. The ACA allows Americans to purchase insurance on Exchanges established by states or by the federal government operating in their stead, during either an annual open enrollment or during special enrollment periods ("SEPs") required by the statute and its implementing regulations. Among the various SEPs provided for by the ACA, an Exchange must provide an SEP when consumers are facing "exceptional circumstances"—a broad and inclusive term that certainly encompasses a once-in-a-century health crisis. Indeed, almost every state that runs its own Exchange has reached precisely that conclusion, establishing an SEP so that all of their

[1] For ease of reference, this brief uses "the novel coronavirus" to refer interchangeably to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), as well as the disease it causes, coronavirus disease 2019 (COVID-19).

residents can obtain access to ACA-compliant coverage. And the federal government itself has provided for SEPs in the context of Medicare Part D and group health insurance.

Yet the Trump Administration refused to provide a special enrollment period for the marketplaces administered by the federal government. Recognizing the gravity of the moment, the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") initially decided to provide an SEP, and had even gone so far as to communicate that decision to insurers. At the last minute, however, President Trump countermanded that decision for fear of "propping up" the ACA, Orbea Decl. Ex. B-4—an extraordinary about-face those close to the Administration characterized as "purely ideological" and "political," *id.* Ex. B-2. As President Trump has made clear, time and again, he intends to undermine the ACA to the point that Congress is forced to repeal it, or failing that, to effectively repeal it on his own through executive action and/or malign neglect. Defendants ultimately refused to open an SEP and, to date, have offered no cogent explanation for their decision.

Defendants' refusal is unlawful. The term "exceptional circumstances" plainly encompasses a global health crisis that has left millions of Americans in need of high-quality health insurance and could not have been anticipated during open enrollment. Defendants' conclusion to the contrary rests on an impermissible basis for action—the President's desire to sabotage a duly-enacted law. That desire offends the fundamental Constitutional principle that the Executive Branch "shall take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3, cl. 5. Even leaving that aside, however, Defendants' decision does not reflect the reasoned decisionmaking required by the Administrative Procedure Act, or any attempt to grapple with Americans' desperate need for comprehensive health coverage.

These violations are immensely consequential to Plaintiff the City of Chicago, not to mention millions of Americans. Uninsured and underinsured Americans, including Americans who have contracted the novel coronavirus, frequently do not seek necessary care until it is too late. That is a risk the City cannot afford at a time when encouraging its residents to seek adequate testing and treatment is essential to the City's response to the pandemic. Chicago also provides forms of health services to its residents regardless of insurance status, like ambulance services and free- or reduced-cost health clinics. However, Chicago often cannot recoup the cost of providing such services to uninsured individuals. That burden on the City has been unnecessarily increased by Defendants' decision to prevent Americans from enrolling in ACA-compliant coverage—at a time when the City's operations are already under extraordinary strain.

For these reasons, and as described more fully below, the Court should preliminarily enjoin Defendants to provide an SEP in response to the novel coronavirus for sixty days from the date of its order. That SEP should allow consumers to enroll in coverage that is effective as of the first date of the month in which the order is issued. In the alternative, Chicago respectfully requests that the Court convert this motion to a motion for summary judgment, expedite briefing and consideration of that motion, including the submission of an administrative record, enter judgment for Chicago, and grant such relief on a permanent basis. Simply put, Chicago and millions of Americans cannot wait for the relief that a special enrollment period would provide at this pivotal and fraught point in the Nation's history.

BACKGROUND[2]

A. Statutory and regulatory background

1. The Affordable Care Act

In 2010, Congress passed, and President Obama signed into law, the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *as amended*, Health Care Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010). One of the primary objectives of the ACA is "to expand coverage in the individual health insurance market." *King v. Burwell*, 135 S. Ct. 2480, 2485 (2015); *see also Maine Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1315 (2020) (explaining that the Act seeks "to improve national health-insurance markets and extend coverage to millions of people without adequate (or any) health insurance"); *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538 (2012) ("The Act aims to increase the number of Americans covered by health insurance and decrease the cost of health care."); *Doe #1 v. Trump*, 957 F.3d 1050, 1063 (9th Cir. 2020) (explaining that Congress aimed "[t]o incentivize the purchase of insurance plans through ACA marketplaces").

In enacting the ACA, Congress concluded that high uninsured and underinsured rates harm both individuals who lack adequate insurance and society as a whole. Specifically, Congress found that the uninsured suffer from "poorer health and shorter lifespan"; that the "cost of providing uncompensated care to the uninsured" is high; that "health care providers pass on the cost to private insurers, which pass on the cost to families" by "increas[ing] family premiums"; and that, because many "personal bankruptcies are caused in part by medical expenses," "significantly increasing health insurance coverage … will improve financial security for families." 42 U.S.C. § 18091(2)(E)-(G).

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[2] Chicago will refer to exhibits attached to its request for judicial notice as "RJN Ex. #" and to other declarations and exhibits as "LAST NAME Decl. ¶ # / Ex. #."

To further Congress's goal of expanding access to health coverage, the ACA imposed certain key reforms to the individual health insurance market, including:

- *Nondiscrimination on the basis of health status and health history.* The ACA requires "each health insurance issuer that offers health insurance coverage in the individual … market in a State [to] accept every … individual in the State that applies for such coverage," 42 U.S.C. § 300gg-1(a), and bars insurers from charging higher premiums on the basis of a person's health, *id.* § 300gg.

- *Coverage for essential health benefits.* Insurance for individuals and families sold on ACA Exchanges must cover "essential health benefits," *id.* § 300gg-6(a), and so-called "cost-sharing" payments—for example, deductibles and copayments—for such coverage are limited, *see id.* §§ 300gg-6(b), 18022(a)(2), (c).

- *Subsidized coverage.* The ACA "seeks to make insurance more affordable by giving refundable tax credits to individuals with household incomes between 100 percent and 400 percent of the federal poverty line." *King*, 135 S. Ct. at 2487 (citing 26 U.S.C. § 36B; 42 U.S.C. §§ 18081, 18082).

To help individuals learn about and enroll in the health insurance options that are available to them, the ACA "requires the creation of an 'Exchange' in each State where people can shop for insurance, usually online." *King*, 135 S. Ct. at 2487 (quoting 42 U.S.C. § 18031(b)(1)); *Maine Cmty. Health Options*, 140 S. Ct. at 1315 (explaining that the ACA "called for the creation of virtual health-insurance markets, or 'Health Benefit Exchanges,' in each State," to serve the "end" of increased coverage). These Exchanges, also known as health insurance marketplaces, enable people not eligible for Medicare or Medicaid to obtain adequate, affordable insurance independent of their jobs. The Exchanges therefore serve as "marketplace[s] that allow[] people to compare and purchase" ACA-compliant plans. *King*, 135 S. Ct. at 2485.

An Exchange may be established by the state in which it operates or, in states that have elected not to establish Exchanges, by the federal government. *See id.* at 2487 (citing 42 U.S.C. §§ 18031(b)(1), 18041(c)(1)); 45 C.F.R. § 155.105(f)). Twelve states and the District of Columbia operate "state-based Exchanges" or "SBEs" (operating their own websites rather than

using the federally run HealthCare.gov), thirty-two states rely principally on the federal government to run their "federally-facilitated Exchanges" or "FFEs" using HealthCare.gov, and six states have hybrid Exchanges that assume some, but not all, Exchange functions. RJN Ex. A-1. Illinois has a federally-facilitated Exchange, which, as is relevant here, means that Illinois must defer to the federal government's determinations regarding enrollment periods, although Illinois does exercise some plan certification functions. *Id.*

Exchanges may only offer quality health insurance plans, referred to as "qualified health plans" or "QHPs" under the Act. 42 U.S.C. § 18031(b)(1), (c); *see id*. § 18021(a). Such plans must cover preexisting conditions and essential health benefits and cannot impose annual or lifetime-dollar limits on core coverage. *See*, *e.g.*, *id*. §§ 300gg-3, -6, -11, 18022. Such coverage improves access to care and overall health and reduces financial burdens for individuals. *See, e.g.*, Young Decl. ¶ 5.

2. The enrollment process

Individuals may enroll in qualified health plans on an Exchange during a specified annual open enrollment period, typically at the end of the calendar year. 42 U.S.C. § 18031(c)(6). On federal Exchanges, open enrollment for 2020 lasted from November 1 to December 18, 2019, and open enrollment for 2021 is likely to have a similar range of dates. RJN Ex. A-2. Typically, plans selected during open enrollment start on January 1 of the next year. RJN Ex. A-3 at 14.

In addition to open enrollment, the ACA mandates that "[t]he Secretary *shall require* an Exchange to provide for ... (C) special enrollment periods specified in section 9801 of Title 26 and other special enrollment periods under circumstances similar to such periods under part D of title XVIII of the Social Security Act." 42 U.S.C. § 18031(c)(6) (emphasis added). Part D of title XVIII of the Social Security Act, colloquially known as Medicare Part D, provides for prescription drug coverage. Among the established Medicare Part D SEPs that the ACA

incorporates is one for "exceptional circumstances," defined as "such exceptional conditions as the Secretary may provide." 42 U.S.C. § 1395w-101(b)(3)(C); *see also* 42 C.F.R. § 423.38.

Pursuant to that statutory mandate, CMS's regulations require that an "Exchange *must* provide special enrollment periods … during which qualified individuals may enroll in QHPs and enrollees may change QHPs" when certain "triggering events" occur. 45 C.F.R. § 155.420(a)(1), (d) (emphasis added). And "the Exchange *must* allow a qualified individual or enrollee, and when specified … , his or her dependent to enroll in a QHP if one of the triggering events specified … occur." *Id.* § 155.420(a)(3) (emphasis added). Triggering events include circumstances such as an individual losing coverage, *id.* § 155.420(d)(1), gaining a dependent, *id*. § (2), enrolling unintentionally or erroneously, *id*. §§ (4), (12), experiencing changes in eligibility or access, *id*. §§ (3), (6), (7), or having a health insurer that violated its contract, *id*. § (5). CMS recently created a special enrollment period to promote access to so-called health reimbursement arrangements (employer-funded plans that reimburse certain health care expenses). *Id*. § (14).

As relevant here, another triggering event occurs if "[t]he qualified individual or enrollee, or his or her dependent, demonstrates to the Exchange, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Exchange may provide." *Id*. § (9). CMS has explained that the "flexibility afforded under § 155.420(d)(9) allows the Secretary to provide for additional special enrollment periods in the case of exceptional circumstances, as determined appropriate, and HHS will continue to exercise that authority through sub regulatory guidance." *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016*, 80 Fed. Reg. 10,750, 10,798 (Feb. 27, 2015).

CMS has set forth guidelines for the types of "exceptional circumstances" that warrant an SEP in sub-regulatory guidance, including in the FFE and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual. RJN Ex. A-3. The Manual identifies general types of "exceptional circumstances" that warrant an SEP, including circumstances that are "the result of an unforeseen event" or that "require[] that [an individual] obtain minimum essential coverage" along with "lack of access to his or her application or account." *Id*. at 100. The Manual does not address whether a pandemic or similarly catastrophic public health event would qualify as an "exceptional circumstance."

CMS has detailed many examples of "exceptional circumstances." On its website, for example, CMS lists circumstances where individuals suffer "[a]n unexpected hospitalization or temporary cognitive disability, or were otherwise incapacitated," or where "[a] natural disaster, such as an earthquake, massive flooding, or hurricane" prevents individuals from enrolling. RJN Ex. A-4. An "exceptional circumstance" can also include circumstances such as an individual being "a victim of a house fire [who] was displaced during [open enrollment]." RJN Ex. A-5.

CMS has also determined on multiple occasions that it has authority to issue blanket SEPs for "exceptional circumstances" affecting a large class of people. For example, in 2017, it allowed all individuals who, because of a hurricane, were unable to take advantage of other SEPs for which they would have qualified to access a blanket SEP. RJN Ex. A-6, A-7. In 2018, it allowed individuals affected by an emergency or major disaster formally recognized by FEMA that prevented them from enrolling to access an "exceptional circumstances" SEP. RJN Ex. A-5. CMS has also provided a blanket SEP for volunteers in Americorps and similar programs. RJN Ex. A-8. And CMS has even provided broad SEPs on an ad hoc basis in response to specific

requests, such as when it gave an "exceptional circumstances" SEP with retroactive coverage dates to a group of coal miners. *See* Orbea Decl. Ex. B-14.

Coverage selected during an SEP can begin as early as the first day of the month following enrollment, or can even be retroactive to a specific date, covering expenses incurred prior to enrollment. 45 C.F.R. § 155.420(b); RJN Ex. A-3 at 92. The regulations also provide that, for "exceptional circumstances" SEPs, "the Exchange must ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period." 45 C.F.R. § 155.420(b)(2)(iii). Indeed, the Manual provides that coverage effective dates for enrollment during an SEP will "[v]ary based on circumstances," RJN Ex. A-3 at 100, and can be retroactive in nature, *id.* at 129-30. CMS has therefore reiterated that, depending on the nature of the circumstances, "exceptional circumstances" SEPs may offer retroactive coverage dates. RJN Ex. A-4, A-5 at 2.

B. Factual background

1. The novel coronavirus

As of shortly before this, over two million people in the United States have been confirmed to have contracted the novel coronavirus, and over 115,000 people have been confirmed to have died from it. RJN Ex. A-9. "Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person." RJN Ex. A-10. "It is thought to spread mainly from person-to-person via respiratory droplets among close contacts." *Id.* The principal symptoms of the novel coronavirus "include fever, cough, difficulty breathing, and shortness of breath." *Id.* "Older adults and people of any age who have serious underlying medical conditions may be at higher risk for more severe illness," including death. RJN Ex. A-11.

In response to the pandemic, President Trump and HHS Secretary Azar declared states of emergency. *See* Proclamation No. 9994, *Declaring a National Emergency Concerning the Novel*

Coronavirus Disease (COVID-19) Outbreak, 85 Fed. Reg. 15,337 (Mar. 13, 2020); RJN Ex. A-12. Pursuant to guidance from federal authorities, state officials have ordered their residents to stay at home, forcing the closure of businesses, schools, and government offices. RJN Ex. A-13. As a result, the American economy is facing one of the worst downturns since the Great Depression, *see* RJN Ex. A-14, with unemployment rising to over 30 million people in April 2020, RJN Ex. A-15, and remaining high. That downturn has particularly harmed low-education and low-income workers. *Id.* Whether and when America will be able to fully reopen largely depends on when particular states meet a complicated set of gating criteria based on specific epidemiological thresholds. *See, e.g.*, RJN Ex. A-16 at 5.

It is crucial that Americans have access to comprehensive health insurance coverage amidst the pandemic. CDC has explained that "[e]xtensive, rapid, and widely available COVID-19 testing is essential." *Id.* at 3. It has also urged Americans to "[s]tay in touch with your doctor" and to "[f]ollow care instructions from your healthcare provider and local health department." RJN Ex. A-17. As Christen Linke Young, a fellow with the USC-Brookings Schaeffer Initiative for Health Policy, explains, "[t]hose without comprehensive health insurance coverage experience cost-related barriers to health care at higher rates than insured patients," which "may affect how they seek care and what services they receive, including for care related to COVID-19." Young Decl. ¶ 3. "[A]voidance or delay in seeking care could mean individuals delay seeking a COVID-19 test, resulting in a longer period of time during which a person is capable of infecting others," or "could result in individuals avoiding a test entirely." *Id.* ¶ 15. In comparison, the two legislatively-created funds that reimburse providers for COVID-19-related expenses are inadequate because they do not "provide the assurance of actual health coverage" and continue to expose patients and providers to significant costs. *Id.* ¶¶ 4, 18-36.

Allowing Americans to enroll in ACA-compliant coverage through a special enrollment period would provide relief to previously uninsured and underinsured individuals as well as individuals who have lost employer-provided health insurance as a result of the economic crisis caused by the pandemic. As Dr. Emily Gee, a health economist at the Center for American Progress, explains, "[t]he COVID-19 pandemic is expected to cause tens of millions of Americans to lose their current health insurance coverage." Gee Decl. ¶ 5. "Based on national enrollment figures and figures released by state Exchanges that have conducted their own special enrollment periods," Dr. Gee conservatively estimates that 422,000 to 667,000 Americans might enroll in ACA-compliant coverage during a national coronavirus SEP. *Id.* ¶ 6. As Dr. Gee notes, enrollment on a federal SEP could be even higher, *id.* ¶ 24; some estimates project that as many as 2.4 million Americans might seek to enroll, *id.* ¶ 25, and an SEP might also direct uninsured Americans to other programs, like Medicaid, *id.* ¶ 26. While individuals who lost employer-provided insurance may be eligible for a special enrollment period, the process of applying for such an SEP can be burdensome, and some individuals may already have missed their opportunity to do so. *Id*. ¶¶ 17-18.

For that reason, and often expressly invoking the "exceptional circumstances" provision, twelve of the thirteen state Exchanges have provided SEPs. RJN Ex. A-18 (Nevada: "Exceptional Circumstances"), A-19 (Washington: "exceptional circumstances"), A-20 (Connecticut: "exceptional circumstances"), A-21 (Rhode Island: "unexpected and exceptional circumstances"), A-22 (Colorado: "emergency"), A-23 (New York: "exceptional nature of the public health emergency"), A-24 (Vermont: "emergency"), A-25 (Massachusetts: "public health threat"), A-26 (California: "extraordinary"), A-27 (District of Columbia: "public health emergency"), A-28 (Maryland: "emergency"); A-29 (Minnesota: "emergency"). These SEPs

have resulted in significant gains in coverage. *See, e.g.*, Gee Decl. ¶¶ 20, 27; RJN Ex. A-20, A-22. The lone exception is Idaho, which is sparsely populated and has relatively few cases of the novel coronavirus. *See* RJN Ex. A-9.

2. Defendants' refusal to provide a special enrollment period

Although Members of Congress and others repeatedly asked Defendants to implement a special enrollment period on the 38 federally-facilitated and hybrid Exchanges, Defendants ultimately refused to do so. RJN Ex. A-45. On March 21, a CMS spokesperson confirmed that the Administration was "considering whether to create a special enrollment period for Obamacare coverage because of the coronavirus emergency." Orbea Decl. Ex. B-1. The planning for an SEP was sufficiently advanced that "by late March, administration officials sent word to insurers that the call would soon be official: They were reopening Obamacare." Orbea Decl. Ex. B-2. However, "the situation suddenly became 'fluid,' in the description of one executive," while "[a]nother described the administration as divided about whether to proceed, especially given the president's support for the lawsuit that would overturn the law." Orbea Decl. Ex. B-3; *see Texas v. United States*, 945 F.3d 355, 373 (5th Cir. 2019), *cert. granted*, 140 S. Ct. 1262 (2020).

Defendants' refusal to open an SEP ultimately rested on a political calculation made by the White House. "The president opposed reopening the Obamacare marketplaces when presented with the option." Orbea Decl. Ex. B-2. "In meetings at the White House in the time between his stated consideration and his announced rejection of the idea, Trump on multiple occasions … referred to Obamacare as 'a failure,' and questioned why the administration should bother helping to prop it up." Orbea Decl. Ex. B-4. A member of the President's party "close to the administration" characterized the decision as "purely ideological," while an administration official characterized it as "politiciz[ing] people's access to health services during a serious national health emergency." Orbea Decl. Ex. B-2. The decision "surprised even some officials in

the Health and Human Services Department, who believed the concept was still under consideration," and worried officials who "viewed the verdict as an unforced error in the middle of a historic pandemic." *Id.*

Defendants' refusal to open an SEP was first communicated on March 31, when a White House official told Politico that the Trump Administration had decided not to provide a special enrollment period. Orbea Decl. Ex. B-5. HHS Secretary Azar later defended the decision on the grounds that allowing providers to seek reimbursement through two legislatively-created funds is "better for … uninsured individuals" because it provides "disease-specific support of care to make sure that people get treatment." Orbea Decl. Ex. B-2. Defendants have not provided a written explanation of why the novel coronavirus pandemic did not qualify as an "exceptional circumstance," or why reopening the Exchanges would constitute bad policy.

Defendants' refusal is of a piece with President Trump's known hostility toward the Affordable Care Act and his repeated efforts to undermine it. For example:

- On January 25, 2017, President Trump stated, "[T]he best thing we could do is nothing for two years, let [the ACA] explode. And then we'll go in and we'll do a new plan and—and the Democrats will vote for it. Believe me … . So let it all come [due] because that's what's happening. It's all coming [due] in '17. We're gonna have an explosion. And to do it right, sit back, let it explode and let the Democrats come begging us to help them because it's on them." Orbea Decl. Ex. B-6.
- After Congress declined to repeal the Affordable Care Act on July 28, 2017, President Trump tweeted, "3 Republicans and 48 Democrats let the American people down. As I said from the beginning, let ObamaCare implode, then deal. Watch!" RJN Ex. A-30.
- On October 13, 2017, President Trump stated, "We're taking a little different route than we had hoped, because getting Congress—they forgot what their pledges were. … So we're going a little different route. But you know what? In the end, it's going to be just as effective, and maybe it will even be better." RJN Ex. A-31.
- In late April 2018, at a rally in Michigan, President Trump bragged, "Essentially, we are getting rid of Obamacare …. Some people would say, essentially, we have gotten rid of it." Orbea Decl. Ex. B-7.

- In signing a bill unrelated to the ACA on May 30, 2018, President Trump stated: "For the most part, we will have gotten rid of a majority of Obamacare." He went on to confirm that his Administration's objective is to achieve by executive action alone what Congress refused to do: "Could have had it done a little bit easier, but somebody decided not to vote for it, so it's one of those things." RJN Ex. A-32.
- At a rally on June 23, 2018, according to an observer, President Trump complained about Congress's decision not to repeal the ACA and told audience members that "it doesn't matter. We gutted it anyway." Orbea Decl. Ex. B-8.
- On August 1, 2018, President Trump returned to the same theme, stating that even though Congress declined to repeal the ACA, "I have just about ended Obamacare," but "we're doing it a different way. We have to go a different route." Orbea Decl. Ex. B-9.
- On October 2, 2018, President Trump referenced the ACA and stated, "We had it repealed and replaced. A little shock[] took place early in the morning. But the fact is, we didn't get one Democrat vote…. But we've pretty much dismantled it." Orbea Decl. Ex. B-10.
- On November 2, 2018, President Trump boasted that his Administration is "decimating [the ACA] strike by strike," Orbea Decl. Ex. B-11; "we've decimated Obamacare," *id.* Ex. B-12.
- On March 5, 2020, President Trump reiterated that he wanted to "totally kill" the Affordable Care Act. RJN Ex. A-33.
- After the Administration refused to open an SEP, on May 6, 2020, during a press availability in the Oval Office, President Trump declared that his Administration would continue arguing to invalidate the ACA, stating that "Obamacare is a disaster," that "[w]hat we want to do is terminate it," and that his Administration had "already pretty much killed it." Orbea Decl. Ex. B-13.
- On May 26, 2020, during a press availability in the Oval Office, President Trump claimed that "[w]e slashed Obamacare's crippling requirements," and that "essentially we got rid of Obamacare, if you want to know the truth. You can say that in the truest form." RJN Ex. A-34.

In other words, President Trump has repeatedly made plain his desire to, in effect, repeal the Affordable Care Act through executive action alone.

3. Chicago's injuries

Chicago is one of the cities across the country that is working to control the novel coronavirus and protect its residents. According to 2018 Census estimates, 11.9% of Chicago's population under the age of 65, or around 283,000 people, lack health insurance. Arwady Decl. ¶ 6; RJN Ex. A-35. That number has likely risen steeply as a result of the pandemic, which has

increased unemployment and thereby pushed individuals off their employer-provided insurance. Gee Decl. ¶¶ 5, 8. While the Bureau of Labor Statistics reports that the Chicago-Joliet-Naperville, Illinois metropolitan statistical area had 123,900 unemployed individuals in February 2020, it had spiked to 640,300 by April 2020. Arwady Decl. ¶¶ 7, 25; RJN Ex. A-36.

As a consequence of Defendants' refusal to open a special enrollment period, Chicago will face increased costs to provide health services to its residents. As noted above, in enacting the ACA, Congress found that the "cost of providing uncompensated care to the uninsured" is high. 42 U.S.C. § 18091(2)(E)-(G). Thus, as HHS has recognized, "uncompensated care costs will … fall substantially following major insurance coverage expansions." RJN Ex. A-37; *see also* RJN Ex. A-38 at 1-2. "Increasing comprehensive health insurance coverage, including through Exchange enrollment, would … help ensure that health care providers are paid for services they provide," as was the case with the expansion of Medicaid. Gee Decl. ¶ 12.

Chicago bears those costs in several ways. Chicago's Department of Public Health operates and partners with health clinics and other providers to provide certain services to uninsured and underinsured residents, Arwady Decl. ¶¶ 9-13, 15-17, and Chicago's Fire Department provides ambulance transport services to residents regardless of their ability to pay, *id.* ¶¶ 18-22. However, the more residents that lack adequate insurance, the more Chicago can expect to pay to operate many of these programs: "[t]he higher the uninsured and underinsured rate, the more that the clinics operated by the Chicago Department of Public Health and its community-based partners will necessarily have to provide free or reduced-cost care to patients," and "a higher number of uninsured or underinsured individuals or an increase in acute health needs will … result in more ambulance transports for which Chicago does not receive reimbursement." *Id.* ¶¶ 13, 22.

Defendants' refusal to open a special enrollment period also risks exacerbating the spread of the novel coronavirus in Chicago and across the nation. Chicago has mounted an aggressive response to the pandemic, directing its residents to community health centers to receive services during the pandemic (albeit through telemedicine, in many cases), and to city-supported testing centers. Arwady Decl. ¶¶ 28-34. It is essential to the City's health and well-being that City residents obtain testing and treatment if they contract the novel coronavirus: the more the pandemic spreads, the more the City faces increased strains on its budget, job and revenue losses, and impediments to its operations. *Id.* ¶¶ 35-40. But without comprehensive insurance coverage, individuals are less likely to seek out that testing and treatment. *Id.* ¶ 33; Young Decl. ¶¶ 3-4. That hurts those individuals and the City alike.

C. Procedural background

Chicago filed this lawsuit on June 15, 2020. ECF No. 1. Chicago raises three claims under the Administrative Procedure Act: (1) that Defendants' determination that the novel coronavirus does not constitute an "exceptional circumstance" is contrary to law, 5 U.S.C. § 706(2)(A); (2) that Defendants' refusal to provide a special enrollment period is arbitrary and capricious, *id.*; and (3), in the alternative, that Defendants have unlawfully withheld a special enrollment period, *id.* § 706(1). ECF No. 1 ¶¶ 177-87. Chicago asks the Court to declare that Defendants' decision not to provide a special enrollment period is unlawful, to vacate and set aside Defendants' decision, and to enjoin Defendants to provide a special enrollment period. *Id.* at 57-58.

Chicago now moves for a preliminary injunction or, in the alternative, expedited summary judgment.

LEGAL STANDARD

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Resources Def. Council, Inc.*, 555 U.S. 7, 20 (2008). In this Circuit, it remains an open question whether the "sliding-scale" approach to equitable relief—where "a strong showing on one factor could make up for a weaker showing on another"—still governs. *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011).

In resolving a motion for a preliminary injunction, "the court may advance the trial on the merits and consolidate it with the hearing." Fed. R. Civ. P. 65(a)(2). At that point, a movant is entitled to summary judgment if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Id*. 56(a). Generally, in cases under the Administrative Procedure Act, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Winder HMA LLC v. Burwell*, 206 F. Supp. 3d 22, 31 (D.D.C. 2016) (quotation omitted).

ARGUMENT

I. Defendants' decision not to provide a special enrollment period is unlawful.

Chicago is likely to prevail on the merits. Defendants concluded that a once-in-a-century pandemic did not constitute an "exceptional circumstance" warranting a special enrollment period.[3] That decision violates Defendants' nondiscretionary duty to provide an SEP in response

[3] Defendants' refusal constitutes final agency action subject to review under the APA. 5 U.S.C. § 704. It is agency action because it is the denial of a discrete proposed agency action—

to "exceptional circumstances." § I.A. Specifically, Defendants' refusal to provide a special enrollment period is contrary to any reasonable interpretation of the term "exceptional circumstances." § I.B. That decision was also arbitrary and capricious because Defendants were motivated by President Trump's opposition to the ACA, rather than any permissible and rational basis for agency action. § I.C. Alternatively, if Defendants' decision is instead understood as unlawfully withheld agency action, it violates their mandatory duty to provide an SEP in response to "exceptional circumstances." § I.D.

A. Defendants have a nondiscretionary duty to provide a special enrollment period in response to "exceptional circumstances."

Both the ACA and its implementing regulations require Exchanges to provide a special enrollment period in response to "exceptional circumstances." Specifically, the ACA mandates that "[t]he Secretary *shall require* an Exchange to provide for ... special enrollment periods … similar to such periods under [Medicare Part D]." 42 U.S.C. § 18031(c)(6) (emphasis added). In doing so, the ACA incorporates Medicare Part D's SEP for "exceptional circumstances." 42 U.S.C. § 1395w-101(b)(3)(C). The ACA's implementing regulations reflect this duty by requiring that Exchanges "*must provide* special enrollment periods," 45 C.F.R. § 155.420(a)(1) (emphasis added), when certain "triggering events" occur, *id.* § (d), like when an "individual meets other exceptional circumstances as the Exchange may provide," *id.* § (d)(9).

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namely, the denial of an order or provision for relief authorizing a blanket SEP in response to the pandemic—and one based, presumably, on an agency rule that the pandemic is not an "exceptional circumstance." *See* 5 U.S.C. § 551(14) ("'agency action' includes …. an agency rule, order, … relief, or the equivalent or denial thereof"); *see also Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (a denial "is the agency's act of saying no to a request"). That action is final within the meaning of the APA because it is the consummation of HHS's decisionmaking process, not a tentative or interlocutory decision, and because it determines rights and obligations and creates legal consequences, namely the lack of an SEP for uninsured individuals. *See Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).

"That language is mandatory, not precatory"—it imposes a duty that "admits of no discretion." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015). Indeed, "the mandatory 'shall[]' … normally creates an obligation impervious to judicial discretion." *Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 109 (2002).

That duty cannot be committed to Defendants' discretion by law. *See* 5 U.S.C. § 701(a)(2). As the Supreme Court recently explained:

> In order to give effect to the command that courts set aside agency action that is an abuse of discretion, and to honor the presumption of judicial review, we have read the § 701(a)(2) exception for action committed to agency discretion quite narrowly, restricting it to those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion. And we have generally limited the exception to certain categories of administrative decisions that courts traditionally have regarded as committed to agency discretion, such as a decision not to institute enforcement proceedings, or a decision by an intelligence agency to terminate an employee in the interest of national security.

Dep't of Commerce v. New York, 139 S. Ct. 2551, 2568 (2019) (quotations omitted). Neither of those narrow formulations apply here.

To start, the term "exceptional circumstances" provides a meaningful standard for reviewing courts to apply. Courts have routinely interpreted that language in other contexts. *See, e.g.*, *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 553 (2014) (patent law); *Open Am. v. Watergate Special Prosecution Force*, 547 F.2d 605, 611 (D.C. Cir. 1976) (FOIA); *United States v. Harris*, 2020 WL 1503444, at *5 (D.D.C. 2020) (prisoner release). And courts have applied similarly broad standards in the context of health care, like the requirement that a pilot project be "likely to assist in promoting the objectives" of Medicaid, *Gresham v. Azar*, 950 F.3d 93, 98-99 (D.C. Cir. 2020), and the requirement to provide "high quality and cost-effective" healthcare, *Cody v. Cox*, 509 F.3d 606, 610-11 (D.C. Cir. 2007); *see also Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1403-04 (D.C. Cir. 1995) (concluding that the phrase "in the

interest of justice" is not committed to agency discretion by law). Defendants' obligation to provide a special enrollment period is at least as administrable as these requirements, and certainly not couched in language that "provides absolutely no guidance as to how [the agency's] discretion is to be exercised." *Robbins v. Reagan*, 780 F.2d 37, 45 (D.C. Cir. 1985) (per curiam).

The purpose of the ACA and its implementing regulations adds further content to the meaning of "exceptional circumstances." As explained above, the ACA requires Defendants to administer Exchanges in a manner that provides Americans with access to needed comprehensive health coverage, a statutory purpose that informs what constitutes "exceptional circumstances" for triggering an SEP. Similarly, the Supreme Court recently relied on the purpose and structure of the Census Act in concluding that the Secretary of Commerce's authority to select census questions was not committed to his discretion, even though the Secretary was authorized to take the decennial census "in such form and content as he may determine." *New York*, 139 S. Ct. at 2568; *see also Marshall County Health Care Auth. v. Shalala*, 988 F.2d 1221, 1223-25 (D.C. Cir. 1993) (reviewing an agency's decision to provide exceptions "as the Secretary deems appropriate" because the statutory scheme provided sufficient standards to guide review).

The phrase "as the Exchange may provide," *see* 45 C.F.R. § 155.420(c)(9), does not commit Defendants' mandatory duty to their sole and unreviewable discretion, nor could it. *See Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Gen. Dynamics Land Sys. Div.*, 815 F.2d 1570, 1574 (D.C. Cir. 1987) ("[A] federal statute must always be superior to all other forms of law, including regulations."). That language simply reflects that the Exchange is charged with assessing, in the first instance, whether "exceptional circumstances" exist. To the extent the language gives the Exchange any discretion in making that determination, it plainly

does not give Defendants discretion to withhold an SEP where "exceptional circumstances" exist, or to define "exceptional circumstances" in an arbitrary or unreasonable manner.

In that respect, the regulation is akin to duties imposed by other laws that courts have held to be nondiscretionary. For example, the Supreme Court in *Weyerhaeuser Co. v. U.S. Fish & Wildlife Service* confronted a statute that imposed a "categorical requirement that the Secretary [of the Interior] take into consideration economic and other impacts" before designating an area as critical habitat, but then provided that the Secretary "*may* exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of designation." 139 S. Ct. 361, 371 (2018) (quotations and alterations omitted) (emphasis added). The statute therefore required the Secretary to engage in a reasoned cost-benefit analysis even though the Secretary had some discretion over the ultimate decision. *Id.* Put simply, while use of the word "may" confers "*some* discretion," it "does not mean the matter is *committed exclusively* to agency discretion." *Dickson*, 68 F.3d at 1401 (emphasis added); *see also Salazar v. King*, 822 F.3d 61, 80 (2d Cir. 2016) (explaining that even if an agency has "some discretion in making [an] initial triggering decision," that "discretion is not unfettered").

Finally, the administration of the ACA's Exchanges is hardly the kind of task "traditionally committed to agency discretion." *New York*, 139 S. Ct. at 2568. Those traditional domains have included quintessentially sensitive and unbounded decisions like "decision[s] not to institute enforcement proceedings" and "decision[s] by an intelligence agency to terminate an employee in the interest of national security." *Id.* (citing *Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985), and *Webster v. Doe*, 486 U.S. 592, 600-01 (1988)). In contrast, the ACA's Exchanges are governed quite specifically and extensively by the ACA and its implementing regulations. And courts can and have adjudicated many cases involving the meaning of those laws. *See, e.g.*,

Maine Cmty. Health Options, 140 S. Ct. 1308; *King*, 576 U.S. 988. This case therefore "involves the sort of routine dispute that federal courts regularly review: An agency issues an order," and a plaintiff "objects that the agency did not properly justify its determination under a standard set forth in the statute." *Weyerhaeuser*, 139 S. Ct. at 370.

Ultimately, the question before the Court is whether the novel coronavirus pandemic qualifies as an "exceptional circumstance" within the meaning of the ACA. If it does, Defendants have no discretion—they must provide an SEP to the public.

B. Defendants' determination that the pandemic is not an "exceptional circumstance" is contrary to the Affordable Care Act and its implementing regulations.

The pandemic is a national emergency that calls out for an aggressive response. There can be no question that it qualifies as an "exceptional circumstance" under any reasonable interpretation of the term. § I.B.1. That conclusion is reinforced by the ACA's fundamental purpose of providing access to affordable health insurance when it is needed the most. § I.B.2. And other relevant actors, including the state Exchanges and the federal government in other enrollment contexts, have reached this very conclusion. § I.B.3. Finally, issuing an SEP for the ACA's Exchanges would be consistent with CMS's own prior interpretations and practices. § I.B.4.

1. The pandemic is an "exceptional circumstance" under any reasonable interpretation of the term.

The pandemic is an "exceptional circumstance" that triggers the duty to provide an SEP. That term must be "construe[d] … in accordance with [its] ordinary meaning": "uncommon," "rare," or "not ordinary." *Octane Fitness*, 572 U.S. at 553 (quotations omitted); *see also Harris*, 2020 WL 1503444, at *5 (explaining that "exceptional … means clearly out of the ordinary, uncommon, or rare") (quotation omitted). While the term "exceptional circumstances" is

necessarily expansive, it includes, at a minimum, extraordinary, unpredictable events that dramatically increase the need for health insurance coverage and for enrollment flexibility.

There can be no question that our current circumstances are exceptional. On March 13, 2020, President Trump declared that "the COVID-19 outbreak in the United States constitutes a national emergency," and conferred authority on the HHS Secretary to waive or modify certain statutory and regulatory requirements. 85 Fed. Reg. at 15,337. Similarly, HHS Secretary Azar formally declared a "public health emergency," and CMS Administrator Verma referred to the pandemic as a "national emergency." RJN Exs. A-12, A-39. Courts, too, have referred to the pandemic as an "exceptional circumstance." *See, e.g.*, *United States v. Roeder*, 2020 WL 1545872, at *3 (3d Cir. 2020) (per curiam) (noting that "the COVID-19 pandemic has given rise to exceptional and exigent circumstances that require the prompt attention of the courts"); *Cassell v. Snyders*, 2020 WL 2112374, at *12 (N.D. Ill. 2020) ("In these exceptional circumstances, controlling the spread of COVID-19 counts as a compelling interest."); *Harris*, 2020 WL 1503444, at *5 ("[T]he Government (sensibly) does not dispute that COVID-19 constitutes 'exceptional' circumstances—at least in a 'broad sense.'").

Those determinations reflect reality. The novel coronavirus is a "severe acute respiratory illness that has killed … more than 100,000 nationwide," one which has "no known cure, no effective treatment, and no vaccine," and therefore presents an "extraordinary health emergency." *S. Bay United Pentecostal Church v. Newsom*, --- S. Ct. ----, 2020 WL 2813056, at *1 (2020) (Roberts, C.J., concurring); *see also* RJN Ex. A-9. In response to the pandemic, federal, state, and local governments have all imposed unprecedented limitations on Americans' ability to travel and congregate, physically closing schools, businesses, agencies, courts, houses of worship, entertainment venues, and others. RJN Ex. A-13; Arwady Decl. ¶ 24. As a result, the

economy faces a major economic crisis, and tens of millions of Americans have lost their jobs—with which often goes employer-provided insurance. RJN Ex. A-14, A-15.

If anything, a term like exceptional "seems too mild a word" for the pandemic, and but "a feeble description of the circumstances." *Taylor v. Milwaukee Election Comm'n*, 2020 WL 1695454, at *9 (E.D. Wis. 2020) (finding the pandemic "extraordinary"). The impacts of the pandemic are as severe and far more widespread than any of the natural disasters that CMS has previously determined to be "exceptional circumstances," much less the conclusion of service in AmeriCorps, another "exceptional circumstance." There is no basis to treat it any differently.

2. The ACA's purpose reinforces the conclusion that the pandemic is an "exceptional circumstance."

The conclusion that the pandemic is an "exceptional circumstance" is reinforced by the purpose of the ACA and its implementing regulations. "A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme ... because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *King*, 135 S. Ct. at 2492 (quoting *United Sav. Assn. of Tex. v. Timbers of Inwood Forest Associates, Ltd.*, 484 U.S. 365, 371 (1988)). Again, the ACA's raison d'être is "to expand coverage in the individual health insurance market," providing Americans with comprehensive coverage that reduces financial burdens. *King*, 135 S. Ct. at 2485; *see also Maine Cmty. Health Options*, 140 S. Ct. at 1315; *Nat'l Fed'n of Indep. Bus.*, 567 U.S. at 538; *Doe #1*, 957 F.3d at 1063. And that objective is buttressed by the Secretary's weighty responsibilities to aggressively respond to public health emergencies, including outbreaks of communicable diseases. *See, e.g.*, 42 U.S.C. §§ 243(a), (c)(1), 247d(a), 1320b-5.

Thus, to the extent there is any ambiguity as to whether "exceptional circumstances" includes an event like the current pandemic, these fundamental purposes compel the conclusion

that it does. *See King*, 135 S. Ct. at 2492-93 (concluding that the purpose and structure of the ACA compelled the rejection of an interpretation of an ambiguous term that would "destabilize the individual insurance market"). To stop the spread of the pandemic, CDC has explained that it is "essential" to encourage Americans to seek testing and treatment for the novel coronavirus. RJN Ex. A-16 at 3. It has also urged Americans to "[s]tay in touch with your doctor" and to "[f]ollow care instructions from your healthcare provider and local health department." RJN Ex. A-17. As Christen Linke Young has explained, providing Americans with comprehensive health insurance coverage through a special enrollment period is necessary to assure Americans that their care will be covered, and to allow them to seek care in ways that are both easy and safe to uninfected members of the public. *See, e.g.*, Young Decl. ¶¶ 3-4, 13-17. And, as Dr. Gee has estimated, a national coronavirus SEP could result in hundreds of thousands of Americans enrolling in such coverage, Gee Decl. ¶ 6, or potentially millions, *id.* ¶ 25.

Moreover, allowing Americans to obtain coverage through a special enrollment period would provide them with one measure of financial security in the face of the economic crisis that the novel coronavirus has unleashed. ACA-compliant coverage helps to ensure that individuals will not face steep medical bills for obtaining necessary health care. Young Decl. ¶¶ 6-10. Those who cannot afford such coverage may also be eligible for significant subsidies to defray the cost, or may be redirected to enroll in Medicaid if they qualify. Gee Decl. ¶¶ 9, 25, 26. At a time when many Americans are facing extraordinary hardship, lack of access to affordable health care should not exacerbate their challenges.

3. Both state Exchanges and the federal government in other contexts have recognized that the "exceptional circumstance" of the pandemic should trigger a special enrollment period.

Other relevant actors have overwhelmingly concluded that the novel coronavirus is an "exceptional circumstance." The state Exchanges are subject to the same statutes and regulations

regarding special enrollment periods as the federal government, including the same mandatory triggering events. 45 C.F.R. §§ 155.420(a)(1), (d)(9). Exercising their parallel authority, *twelve* of the thirteen state Exchanges have provided SEPs in response to the novel coronavirus. RJN Exs. A-18-29. In doing so, these Exchanges expressly referred to the pandemic as an "exceptional circumstance" or an "emergency," thereby basing their decision on the same SEP-triggering event at issue here. *See supra* pages 11-12. These virtually unanimous state decisions confirm that any reasonable reading of "exceptional circumstances" must encompass the pandemic.

Moreover, HHS, its subagencies, and other federal agencies have *themselves* recognized the gravity of the pandemic by issuing special enrollment periods in other enrollment contexts—just not the ACA's Exchanges. Specifically, CMS has announced that, in the context of Medicare Advantage and Medicare Part D, it would interpret the "exceptional conditions Special Enrollment Period (SEP)" to apply to "beneficiaries who were eligible for—but unable to make—an election because they were affected by the COVID-19 pandemic." RJN Ex. A-40 at 1-2. For other Medicare parts, CMS has announced that it will retroactively provide "equitable relief" to "eligible individuals who could not submit a timely enrollment," allowing them to enroll in coverage effective as of when they would have originally been able to enroll, without requiring such individuals to "show proof they were impacted." RJN Ex. A-41 at 1. The fact that CMS has nonetheless decided to treat the ACA's Exchanges differently is flatly contrary to the underlying statute, which mandates "special enrollment periods … under circumstances similar to such periods under part D." 42 U.S.C. § 18031(c)(6)(C).

Citing the "national emergency" posed by the pandemic, the IRS and the Employee Benefits Security Administration also extended deadlines for enrolling in group health plans and

other benefit plans until 60 days after the end of the pandemic, as well as for enrolling in COBRA continuation coverage. *Extension of Certain Timeframes for Employee Benefit Plans, Participants, and Beneficiaries Affected by the COVID-19 Outbreak*, 85 Fed. Reg. 26,351 (May 4, 2020). In doing so, those agencies recognized the need to "take steps to minimize the possibility of individuals losing benefits because of a failure to comply with certain pre-established timeframes." *Id.* HHS reviewed and expressly concurred with that decision. *Id.*; RJN Ex. A-49. There is nothing that distinguishes those contexts from this one—except, of course, President Trump's well-known distaste for the ACA.

Separately, HHS has issued a number of waivers designed to alleviate regulatory burdens on insurers, providers, and other major companies. RJN Exs. A-42-A-44. In issuing one set of such waivers, CMS Administrator Verma referenced "President Trump declar[ing] the rapidly evolving COVID-19 situation a national emergency"; asserted that "it remains vital that our healthcare system be equipped to respond effectively to the additional cases that do arise," and "that federal requirements designed for periods of relative calm do not hinder measures needed in an emergency"; and characterized the pandemic as "the rarest of situations." RJN Ex. A-39. Those seeking to enroll should receive the same flexibility as regulated industries.

4. CMS's own prior interpretations and practices confirm that the pandemic is an "exceptional circumstance."

CMS has repeatedly recognized that the "exceptional circumstances" event is designed to address unanticipated events and resulting health insurance needs. As CMS has explained: "The exceptional circumstances special enrollment period provides an important avenue to coverage for consumers who experience or are affected by *unanticipated events, often outside of their control*." *Patient Protection and Affordable Care Act; Market Stabilization*, 82 Fed. Reg. 18,346, 18,366 (Apr. 18, 2017) (emphasis added). Similarly, in the context of Medicare Part D, CMS has

concluded that "the Secretary's authority to establish SEPs for exceptional circumstances should be reserved for situations that are not specifically contemplated in the statute and … exercised on a case-by-case basis depending on the circumstances of a particular situation." *Medicare Program; Medicare Prescription Drug Benefit*, 70 Fed. Reg. 4,194, 4,437 (Jan. 28, 2005). And CMS has recognized that "exceptional circumstances" can result from a personal event or an event with widespread consequences, such as a natural disaster. RJN Ex. A-4; RJN Ex. A-5 at 2.

These descriptions fit the novel coronavirus like a glove. A global pandemic is quintessentially an "unanticipated event … outside of [consumers'] control." 82 Fed. Reg. at 13,866. By no fault of their own, families across the country are now forced to face the pandemic without adequate coverage. They could not possibly have predicted the outbreak of the pandemic during 2020 open enrollment. Nothing of the sort had occurred in recent memory, and so Americans reasonably made enrollment decisions based on their existing and expected future health needs, rather than the potential long-tail risk of a pandemic. There is therefore no basis for holding consumers to decisions they made months before they could have known of the risk.

While CMS's guidelines focus on circumstances that limit an individual's ability to enroll in health insurance in the first instance, like natural disasters, they do not restrict the term to only those events, nor could they reasonably do so. To the contrary, CMS itself has explained that an "exceptional circumstances" SEP "should be granted as consistently as possible based on established criteria, *while still allowing enough flexibility to account for the inherent unpredictability* of exceptional circumstances." 82 Fed. Reg. at 18,366 (emphasis added). And in the context of Medicare Part D, which guides the ACA's SEP-triggering events, CMS has explained that there may be unanticipated situations where it is in the "best interest of the beneficiary to have an enrollment (or disenrollment) opportunity," and so examples of

"exceptional circumstances" are "not meant to be exhaustive." *Medicare and Medicaid Programs*, 85 Fed. Reg. 9,002, 9,120 (Feb. 18, 2020).

Moreover, the regulatory text does not limit the meaning of "exceptional circumstances." *See* 45 C.F.R. § 155.420(d)(9). If Defendants wish to impose a narrower or higher standard, they must formally amend the regulation, not "ignore [its] plain language." *Clean Air Project v. EPA*, 752 F.3d 999, 1011 (D.C. Cir. 2014) (quotation omitted). Where Congress or an agency has limited the circumstances that qualify as exceptional, they have done so expressly. *See, e.g.*, 5 U.S.C. § 552 ("[T]he term 'exceptional circumstances' does not include a delay that results from a predictable agency workload."); 8 U.S.C. § 1229a(e)(1) ("The term 'exceptional circumstances' refers to exceptional circumstances … beyond the control of the alien."); 5 C.F.R. § 831.1715(h)(2) ("[O]nly in rare and exceptional circumstances meeting all of the following conditions."); 26 C.F.R. § 301.7701-13A ("For this purpose, transactions necessitated by an excess of demand for loans over savings capital in the association's area are not to be deemed to be necessitated by exceptional circumstances."); 32 C.F.R. § 651.29(b) ("Extraordinary circumstances that preclude the use of a CX are…."); 37 C.F.R. § 401.3 ("In exceptional circumstances when …."); 42 C.F.R. § 421.214(j) ("[U]nder the following exceptional conditions…."). No such limitations appear here.

Even assuming that "exceptional circumstances" means only events that prevented individuals from enrolling when they would have otherwise been eligible, an SEP is required. Many individuals, including those that lost employer-related insurance, have encountered or will encounter difficulties in establishing eligibility and applying for special enrollment periods for which they qualify. Gee Decl. ¶¶ 17-18. In providing an SEP for Medicare Part D, for example, CMS expressly analogized the novel coronavirus to a natural disaster, recognizing that

individuals may have been "unable to and did not make an election during another valid election period as a result of the emergency," and that individuals may also "rely on help making healthcare decisions from friends or family members" who were affected. RJN Ex. A-40 at 1. Thus, extending a blanket SEP without any documentation requirements would be consistent with what CMS has done in past circumstances.

C. Defendants' refusal to provide a special enrollment period is arbitrary and capricious.

Even if Defendants' decision were permissible under the governing statutes and regulations, it was arbitrary and capricious. Under the APA, the Court "shall … hold unlawful and set aside agency action … found to be arbitrary [or] capricious." 5 U.S.C. § 706(2)(A). An agency's action is invalid if it "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before [it], or [if it] is so implausible that [the decision] could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Defendants' decision was arbitrary and capricious for two principal reasons: it relied on an impermissible basis for action—President Trump's bare desire to sabotage the ACA, § I.C.1—and it is irrational and unjustified, in light of the threat posed by the pandemic and HHS's other efforts to give enrollment flexibility, § I.C.2.

1. Defendants refused to open a special enrollment period to prevent Americans from enrolling in ACA-compliant coverage.

By definition, President Trump's desire to undermine a duly-enacted statute cannot be a "factor[] Congress … intended [the agency] to consider." *State Farm*, 463 U.S. at 43. It is fundamental that "the President and federal agencies may not ignore statutory mandates or prohibitions merely because of policy disagreement with Congress." *In re Aiken Cty.*, 725 F.3d

255, 260 (D.C. Cir. 2013). Were it otherwise, the executive branch's obligation to "take Care that the Laws be faithfully executed" would be a nullity. U.S. Const. art. II, § 3.

Indeed, "[a]gencies are … 'bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Colorado River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139 (D.C. Cir. 2006) (quoting *MCI Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994)). Thus, while the executive branch's "power of executing the laws necessarily includes both authority and responsibility to resolve some questions left open by Congress that arise during the law's administration," *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 327 (2014), the President may not "refrain from executing laws duly enacted by the Congress," *Nat'l Treasury Emps. Union v. Nixon*, 492 F.2d 587, 604 (D.C. Cir. 1974).

The D.C. Circuit's recent decision in *Gresham v. Azar* illustrates these principles. In *Gresham*, residents of Kentucky and Arkansas challenged a series of Medicaid work requirements implemented by those states and approved by the HHS Secretary. 950 F.3d 93, 96-97 (D.C. Cir. 2020). At the outset, the Court noted that "[t]he district court is indisputably correct that the principal objective of Medicaid is providing health care coverage," a goal it described as consonant with "the Affordable Care Act's expansion of health care coverage to a larger group of Americans." *Id.* at 100-01. The Secretary had impermissibly focused instead on "three alternative objectives" directed toward "better health outcomes," a goal the statute does not mention. *Id.* at 101.

The D.C. Circuit then considered whether the Secretary had adequately considered the risk that the work requirements would lead to lost coverage. It determined that "estimates and concerns raised in the comments were enough to alert the Secretary that coverage loss was an

important aspect of the problem," but that the Secretary had simply "dismiss[ed] them in a conclusory manner." *Id.* at 103. That, the Court explained, was arbitrary and capricious: "[w]hile we have held that it is not arbitrary or capricious to prioritize one statutorily identified objective over another, it is an entirely different matter to prioritize non-statutory objectives to the exclusion of the statutory purpose." *Id.* at 104. The Court therefore vacated the Secretary's approval of the requirements.

Defendants' last-minute decision not to open a special enrollment period was, if anything, more egregious than in *Gresham*. Not only did Defendants prioritize a non-statutory objective, as in *Gresham*, but that objective was to sabotage the statute itself. After considering an SEP for several weeks, Orbea Decl. Ex. B-1, CMS officials went so far as informing insurers that the Administration intended to open one, Orbea Decl. Ex. B-2. Yet Defendants reversed that decision on direction from the White House. *Id*. This decision came after President Trump "referred to Obamacare as 'a failure,' and questioned why the administration should bother helping to prop it up." Orbea Decl. Ex. B-4. Administration officials also thought an SEP might conflict with "the president's support for the lawsuit that would overturn the law." Orbea Decl. Ex. B-3. Administration officials and others characterized the decision as "purely ideological" and "politic[al]." Orbea Decl. Ex. B-2.

That decision is part and parcel of the Administration's other efforts to sabotage the Affordable Care Act. Beginning with his inauguration, President Trump has repeatedly said that he would like the ACA to "explode" to force Congress to make a "new plan" with him. After the ACA did not, in fact, explode, and Congress declined to repeal the law, President Trump instead took unilateral executive action to, in his words, "get[] rid of Obamacare"; "gut[] it anyway"; "end[] Obamacare"; "dismantle[]," and "decimate[] it"; and "totally kill" it. Indeed, when asked

about his support for the lawsuit seeking to invalidate the ACA less than a month ago, and after the Administration decided not to open an SEP, President Trump confirmed: "Obamacare is a disaster," "[w]hat we want to do is terminate it," and his Administration had "already pretty much killed it" (or at least tried to do so). *See supra* pages 12-14.

Defendants' refusal to open a special enrollment period therefore placed the President's political interests in sabotaging the ACA over any reasoned analysis of whether the current circumstances are exceptional or the ACA's purpose. Any other explanation the agency might offer for the decision not to open an SEP would only be a pretext—an "explanation for agency action … incongruent with what the record reveals about the agency's priorities and decisionmaking process." *New York*, 139 S. Ct at 2575.

2. Defendants' refusal was unreasonable.

Assuming, for the sake of argument, that Defendants decided not to open a special enrollment period for a reason other than to sabotage the ACA, that decision was irrational. In reviewing agency action, the Court cannot "defer to the agency's conclusory or unsupported suppositions," *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (quotation omitted). "[T]he mere fact that there is some rational basis within the knowledge and experience" of the agency, "under which [it] might have" justified its conclusion, "will not suffice to validate [its] decisionmaking," *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 627 (1986) (quotation omitted). And the agency's appeal to its "expert judgment" is unavailing where it failed "to point … to any data of the sort it would have considered if it had considered [the issue] in any meaningful way." *Nat'l Treasury Emps. Union*, 854 F.2d at 499.

Defendants have not provided any rational basis for their refusal to open an SEP. In their public statements regarding the decision, Defendants have not explained how they interpret the term "extraordinary circumstances" or why they concluded that a once-in-a-century pandemic

does not qualify. Nor have they explained how the decision is consistent with the ACA's goal of expanding access to needed health coverage. Instead, all Defendants have said is that refusing to provide an SEP and instead allowing providers to seek reimbursement for novel coronavirus-related expenses through the two legislatively-created funds is "better for … uninsured individuals" because it provides "disease-specific support of care to make sure that people get treatment." Orbea Decl. Ex. B-2; *see also id.* Ex. B-4.

For the reasons explained above, that rationale is plainly not the whole story. But it is also wrong. As Christen Linke Young explains, those funds "do not provide the assurance of actual health coverage" to uninsured patients. Young Decl. ¶ 4. For example, the testing fund cannot be accessed if a provider does not ultimately order a test, *id.* ¶ 20; other services cannot be reimbursed, *id.* ¶ 21, including the cost of a hospital admission, *id.* ¶ 22; and uninsured individuals cannot access the fund directly, *id.* ¶ 23. The treatment fund suffers from many of the same shortcomings, but also can only be used if COVID-19 is the primary diagnosis, *id.* ¶ 30, cannot be used for related services or illnesses, *id.* ¶¶ 30-33, and may have been exhausted by the time an individual seeks treatment, *id.* ¶ 34. Given these gaps, these funds do not provide the same reassurance as comprehensive coverage. *Id.* ¶ 36.

Defendants also "failed to consider [other] important aspect[s] of the problem." *State Farm*, 463 U.S. at 43. Specifically, Defendants apparently did not consider the regulatory text or the overarching purpose of the ACA. Nor have they considered the experiences of states that have operated their own SEPs and seen significant enrollment. There is a reason that support for an SEP has been virtually unanimous among the affected community, including among insurers that might otherwise be expected to voice concerns that permitting special enrollment would lead to adverse selection problems, RJN Ex. A-46-A-47, as well over 200 non-profits, including

provider groups. RJN Ex. A-48. These are serious policy questions that require reasoned deliberation, explanation, and evidentiary support—not the back of the hand.

Finally, Defendants' explanation cannot be squared with Defendants' other efforts to give enrollment flexibility. As explained above, HHS and CMS have assented to special enrollment periods in the context of Medicare, RJN Ex. A-40 at 1-2, A-41 at 1, and for group health plans, 85 Fed. Reg. at 26,351. There is no reason, in Defendants' professed explanation or in logic, why the individuals who were permitted to enroll by virtue of these actions could not also have resorted to the testing and treatment funds. Nor have Defendants explained why the circumstances are so exigent that they need to give extraordinary flexibility to regulated industries, but not consumers. RJN Exs. A-42-A-44. These fundamental inconsistencies further illustrate the arbitrariness in Defendants' refusal to provide an SEP.

D. In the alternative, Defendants have unlawfully withheld a special enrollment period.

Defendant's decision not to provide a special enrollment period is best understood as a denial of agency action or as a rule that the novel coronavirus does not constitute an exceptional circumstance. *See supra* note 3. "A 'failure to act' is not the same thing as a 'denial.' The latter is the agency's act of saying no to a request; the former is simply the omission of an action without formally rejecting a request." *S. Utah Wilderness All.*, 542 U.S. at 63.

However, to the extent Defendants' decision is instead characterized as the unlawful withholding of agency action, Chicago remains entitled to relief. The APA requires a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). A plaintiff may sue under Section 706(1) where they assert that "an agency failed to take a *discrete* agency action that it is *required* to take," *S. Utah Wilderness All.*, 542 U.S. at 64—*i.e.*, where "a federal agency has a 'ministerial or non-discretionary' duty amounting to 'a

specific, unequivocal command.'" *Anglers Conservation Network v. Pritzker*, 809 F.3d 664, 670 (D.C. Cir. 2016) (quoting *id.* at 63-64).

Those standards are met here. In seeking a special enrollment period, Chicago asks for a "discrete agency action," and does not mount a "broad programmatic attack." *S. Utah Wilderness All.*, 542 U.S. at 64. And, as explained above, Defendants have no discretion in determining whether to provide an SEP in response to "exceptional circumstances." The only question is, again, whether "exceptional circumstances" exist; they do, for the reasons described above. Defendants' failure to provide an SEP therefore constitutes unlawfully withheld agency action.

II. Defendants' decision not to provide a special enrollment period irreparably harms Chicago.

Chicago also meets the other preliminary injunction factors. Defendants' decision exacerbates the spread of a deadly pandemic and places additional demand on the already-strained uncompensated care services that Chicago provides. Those are injuries that are "certain and great, actual and not theoretical, beyond remediation, and of such *imminence* that there is a clear and present need for equitable relief to prevent irreparable harm." *Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 555 (D.C. Cir. 2015) (quotation omitted). And they are irreparable: "there can be no do over and no redress" if Chicago prevails at a delayed final judgment. *League of Women Voters v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016).[4]

Courts across the country have recognized that "the escalating spread of COVID-19," and the government's "critical interest in protecting the public health," present harms that are both

[4] Because Chicago is suffering irreparable harm, it has also suffered injury for purposes of Article III standing. *See League of Women Voters*, 838 F.3d at 9 (holding that the same harms provided "injury for purposes both of standing and irreparable harm"); *In re Navy Chaplaincy*, 516 F. Supp. 2d 119, 125 (D.D.C. 2007) ("In the bulk of cases, a finding of an irreparable injury *a fortiori* signals the existence of an injury-in-fact sufficient to confer standing."), *aff'd*, 534 F.3d 756 (D.C. Cir. 2008).

substantial and irreparable. *In re Abbott*, 954 F.3d 772, 778 (5th Cir. 2020); *see also, e.g.*, *Altman v. Santa Clara*, 2020 WL 2850291, at *19 (N.D. Cal. 2020) ("the government's—and the public's—interest in controlling the spread of a dangerous pandemic"); *Bayley's Campground Inc. v. Mills*, 2020 WL 2791797, at *13 (D. Me. 2020) ("upset[ting] the bedrock of the state's public health response to COVID-19"); *Benner v. Wolf*, 2020 WL 2564920, at *9 (M.D. Pa. 2020) ("grave harms that could result to all Pennsylvanians from a widespread COVID-19 outbreak"); *Antietam Battlefield KOA v. Hogan*, 2020 WL 2556496, at *17 (D. Md. 2020) ("more transmissions of COVID-19 and more cases of serious illness and death"); *Elim Romanian Pentecostal Church v. Pritzker*, 2020 WL 2468194, at *6 (N.D. Ill. 2020) ("the health and safety of the public"), *injunction pending appeal denied*, Order, No. 20-1811 (7th Cir. May 16, 2020) ("extraordinary public health emergency"); *Calvary Chapel of Bangor v. Mills*, --- F. Supp. 3d ----, 2020 WL 2310913, at *10 (D. Me. 2020) ("If the prevalence of COVID-19 pulses up within a community, it puts lives … at risk."); *SH3 Health Consulting, LLC v. Page*, 2020 WL 2308444, at *11 (E.D. Mo. 2020) ("the severe harm the residents of the City and County could suffer"); *Legacy Church, Inc. v. Kunkel*, 2020 WL 1905586, at *44 (D.N.M. 2020) ("[t]he public's interest in limiting the COVID-19 outbreak in the state"). And with good reason: the pandemic is inflicting incalculable damage on state and local governments and their residents.

If Chicago's residents cannot enroll in affordable, ACA-compliant health insurance coverage, they will be less likely to seek medical care, further spreading the novel coronavirus. As Dr. Gee estimates, the consequence of Defendants' decision is that several hundred thousand Americans—and potentially millions—will not obtain affordable, high-quality health insurance, Gee Decl. ¶¶ 5, 25, many of whom reside in the City. And, as explained above, Americans who lack health insurance coverage are less willing to seek critical testing and treatment from places

that charge, including for the novel coronavirus. That conclusion has been confirmed by study after study, including those conducted by federal agencies, as well as recent polling about Americans' reactions to the novel coronavirus. Young Decl. ¶¶ 6-14. Uninsured and underinsured individuals also delay care, allowing conditions to worsen, *id.* ¶ 15; seek care from emergency services, like the ambulance services provided by the City, *id.* ¶ 16; and are less able to obtain care at home, forcing them to go places where they might infect others, *id.* ¶ 17. Increased funding for testing and treatment, and non-ACA-compliant coverage, simply cannot provide uninsured and underinsured Americans with the peace of mind needed to encourage them to seek care. *Id.* ¶¶ 18-40; Gee Decl. ¶¶ 11, 13.

The spread of the novel coronavirus, in turn, places additional strain on the city's health and other systems. If more City residents become sick, more City residents will seek forms of free- or reduced-cost care from clinics and community health centers, call ambulance services when their conditions worsen, and the like. The continued spread of the pandemic also requires Chicago to further stretch its emergency response capabilities, including the support it provides with respect to testing, tracking, and personal protective equipment. Arwady Decl. ¶¶ 14, 29-34. And it will continue to harm the City's operations, impacting City offices and programs and sickening City employees. *Id*. ¶ 38. That's not to mention the downstream harm to a City's health, productivity, and liveliness that comes from the continued threat posed by the pandemic. *Id.* ¶ 36. The two reimbursement funds, which suffer from serious shortcomings and cannot substitute for widespread coverage, do not cure these injuries. Young Decl. ¶¶ 4, 18-36.

Even forgetting for a moment that a once-in-a-century pandemic is ravaging the Nation, there is a close relationship between the uninsured and underinsured rate in a given jurisdiction and the cost of uncompensated care paid for by local authorities. Arwady Decl. ¶¶ 10-13, 20-22;

RJN Exs. A-37, 38; Gee Decl. ¶ 12. All things equal, Chicago would prefer that as many of its residents as possible have health insurance, so that they will not need to resort to the City's uncompensated care programs. But when they do, Chicago is committed to providing those services, often at significant cost. To take one example, Chicago recovers, on average, about 2-3% of what it bills for providing ambulance transports to uninsured individuals, yielding a shortfall in the tens of millions. Arwady Decl. ¶ 21. Thus, even in normal times, Defendants' decision to limit the ability of Chicagoans to enroll in health coverage predictably increases the burden on Chicago's uncompensated care services.

To be clear, Chicago's interests in fighting the spread of the pandemic, ensuring that its residents can get the care they need, and preventing City health systems from being overburdened, are not easily reducible to mere dollars-and-cents. To the contrary, Chicago's specific "expenditures are merely a symptom of [its] programmatic injury." *League of Women Voters*, 838 F.3d at 9. What Chicago faces is a series of profound disruptions to its health, its economy, and its way of life, harming the City's overall ability to function.

To the extent those injuries have a financial component to them, however, they qualify as irreparable all the same. "Economic loss sustained due to a federal administrative action is typically 'uncompensable' in the sense that federal agencies enjoy sovereign immunity, and the waiver of sovereign immunity in the APA does not reach damages claims," so long as it is particularly "serious." *Cal. Ass'n of Private Postsecondary Schs. v. DeVos*, 344 F. Supp. 3d 158, 170 (D.D.C. 2018). Should Chicago prevail at final judgment, it obviously "will not be able to recover from CMS for any economic loss [it] suffer[s]." *Northport Health Servs. of Arkansas, LLC v. HHS*, 2020 WL 2091796, at *3 (W.D. Ark. 2020). Those losses are significant; as explained above, the increased strain on Chicago's operations comes at a time when the City can

least afford to bear it. That is all the more true where "COVID-19 and the public health measures necessary to combat the novel coronavirus have … creat[ed] a crisis in funding" for many jurisdictions, including Chicago (which faces at least a $700 million budget shortfall, Arwady Decl. ¶ 39). *Confederated Tribes of Chehalis Reservation v. Mnuchin*, 2020 WL 1984297, at *8 (D.D.C. 2020); *cf. Asante v. Azar*, 2020 WL 1930263, at *4 (D.D.C. 2020) (declining "to disrupt funding to California hospitals during this national emergency").

At the end of the day, thousands of Chicago residents lack health insurance when they could otherwise have it. Chicago's resulting injuries are irreparable and significant and therefore warrant preliminary relief.

III. The balance of equities and the public interest favor a preliminary injunction.

The balance of the equities and public interest factors "merge when the Government is the opposing party." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 10 (D.C. Cir. 2019). In considering whether to grant a preliminary injunction, the Court must "balance the competing claims of injury and ... consider the effect on each party of the granting or withholding of the requested relief." *Jacinto-Castanon de Nolasco v. ICE*, 319 F. Supp. 3d 491, 503 (D.D.C. 2018) (quoting *Texas Child. Hosp. v. Burwell*, 76 F. Supp. 3d 224, 245 (D.D.C. 2014)). That balance here favors a preliminary injunction.

First, for all the reasons explained above, a special enrollment period is essential to ensuring that uninsured and underinsured individuals can access health coverage amidst a global pandemic. That coverage is, in turn, key to limiting the spread of the pandemic, and to reducing the strain on health care providers. In this respect, Chicago's injuries are emblematic of those faced by city and state governments, as well as private entities like privately owned hospitals, health clinics, and EMS services, in every state with a federally-facilitated or hybrid Exchange.

Indeed, many of the cases cited above recognize the *public's* interest in abating the effects of the pandemic.

Second, Chicago has shown that Defendants' decision contravenes the Administrative Procedure Act as well as the Affordable Care Act and its implementing regulations. The D.C. Circuit has emphasized that "there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" *League of Women Voters*, 838 F.3d at 12 (citation omitted); *Jacksonville Port Auth. v. Adams*, 556 F.2d 52, 58-59 (D.C. Cir. 1977) (recognizing that "there is an overriding public interest … in the general importance of an agency's faithful adherence to its statutory mandate"). In particular, "[t]he public interest is served when administrative agencies comply with their obligations under the APA." *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 21 (D.D.C. 2009). Defendants did not do so here.

And ***third***, Defendants cannot point to any harm that would result from providing a special enrollment period. The only cost that Defendants might face is the expense necessary to adapt Healthcare.Gov to facilitate an enrollment period. Nor would opening an SEP harm any private parties, a conclusion reinforced by the manifest insurer and provider support for doing so. RJN Exs. A-46-47. Indeed, twelve of thirteen state Exchanges already have, RJN Exs. A-18-29, with no indication that doing so resulted in any problems for insurers or providers. Thus, the public interest and the balance of the equities plainly point toward allowing uninsured and underinsured Americans to purchase high-quality, affordable coverage under the ACA when the need for such coverage simply could not be greater.

IV. In the alternative, the Court should convert Chicago's motion to a motion for summary judgment, expedite consideration of that motion, and enter judgment for Chicago.

For the reasons explained above, Chicago is likely to prevail on the merits, and its injuries tip the scales toward relief. Nevertheless, if the Court concludes that Chicago is not entitled to a preliminary injunction, or believes that summary judgment would be a more efficient way of resolving this case, Chicago respectfully requests that the Court convert this motion to a motion for summary judgment, expedite briefing and consideration of that motion, including the submission of an administrative record, and enter judgment for Chicago.

Such expedited consideration is consistent with the federal rules. "Before or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing." Fed. R. Civ. P. 65(a)(2). And "a party may file a motion for summary judgment at any time until 30 days after the close of all discovery." *Id.* 56(b); *see also* 28 U.S.C.A. § 1657 ("[T]he court shall expedite the consideration of any action … if good cause therefor is shown."). "In APA cases early summary judgment motions are often appropriate, as '[t]he entire case on review is a question of law, and only a question of law.'" *Am. Hosp. Ass'n v. HHS*, 2018 WL 5777397, at *2 (D.D.C. 2018) (quoting *Marshall Cty. Health Care Auth. v. Shalala*, 988 F. 2d 1221, 1226 (D.C. Cir. 1993)). Courts therefore can and do adjudicate APA cases on the basis of expedited cross-motions for summary judgment where there is reason for expedition. *See, e.g.*, *L.M.-M. v. Cuccinelli*, --- F. Supp. 3d ----, 2020 WL 985376, at *8 (D.D.C. 2020); *Policy & Research, LLC v. HHS*, 313 F. Supp. 3d 62, 71 (D.D.C. 2018); *Clean Water Action v. Pruitt*, 2017 WL 8292486, at *1 (D.D.C. 2017); *Sierra Club v. Pruitt*, 238 F. Supp. 3d 87, 89 (D.D.C. 2017).

Expedition is warranted here. For the reasons explained above, Defendants' decision not to provide a special enrollment period has prevented, and is preventing, Americans from

enrolling in ACA-compliant health coverage amidst a global pandemic. Those individuals are less likely to seek testing and treatment for the novel coronavirus, allowing it to spread. And Chicago and other governments are bearing the cost with every day that passes. The legal issues raised by Chicago's lawsuit can be addressed quickly and efficiently through briefing on dispositive cross-motions.

Chicago is likewise entitled to judgment for the reasons explained above. And if the Court enters judgment for Chicago, it should vacate Defendants' decision not to provide a special enrollment period and enjoin them to do so. Defendants' decision is contrary to the governing statutes and regulations, and given that the agency had already decided to provide an SEP before that decision was countermanded based on impermissible and unreasoned grounds, there is not a "serious possibility" that the agency will be able to "substantiate its decision on remand." *Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993). Moreover, "the Court should not turn a blind eye to the danger of leaving the current rule in place," *Conservation Law Found. v. Pritzker*, 37 F. Supp. 3d 254, 271 (D.D.C. 2014)—*i.e.*, preventing people from obtaining coverage when they need it the most. The Court should therefore require Defendants to provide an SEP rather than permit them to continue to deny that desperately needed relief to the public.

CONCLUSION

Plaintiffs' motion for a preliminary injunction or, in the alternative, expedited summary judgment should be granted.

Dated: June 15, 2020

Respectfully submitted,

/s/ John T. Lewis
John T. Lewis (D.C. Bar No. 1033826)
Robin F. Thurston (D.C. Bar No. 1531399)
Benjamin Seel (D.C. Bar No. 1035286)
Sean A. Lev (D.C. Bar No. 449936)
Democracy Forward Foundation
1333 H Street NW
Washington, DC 20005
(202) 448-9090
jlewis@democracyforward.org
rthurston@democracyforward.org
bseel@democracyforward.org
slev@democracyforward.org

Mark A. Flessner
Stephen J. Kane
Rebecca Hirsch
Affirmative Litigation Division
City of Chicago Department of Law
121 N. LaSalle St., Room 600
Chicago, IL 60602
mark.flessner@cityofchicago.org
stephen.kane@cityofchicago.org
rebecca.hirsch2@cityofchicago.org

Counsel for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

DECLARATION OF DR. ALLISON ARWADY

I, Dr. Allison Arwady, declare under penalty of perjury as prescribed in 28 U.S.C. § 1746:

1. The facts contained in this declaration are known personally to me and, if called as a witness, I could and would testify competently thereto under oath. I submit this sworn declaration in support of the City of Chicago's motion for a preliminary injunction or, in the alternative, expedited summary judgment.

2. I started at the Chicago Department of Public Health (CDPH) in 2015 and served as Chief Medical Officer before being confirmed by the City Council as Commissioner in January, 2020. As Chief Medical Officer, I oversaw the disease control, environmental health, emergency preparedness, and behavioral health divisions. I have worked on disease outbreaks, immunization promotion, tuberculosis response, lead poisoning prevention, substance misuse, and more. Prior to CDPH, I worked for the U.S. Centers for Disease Control and Prevention as an Epidemic Intelligence Service officer. In that role, I focused on outbreak response, including international work on Ebola and Middle East Respiratory Syndrome. While based at the Illinois

Department of Public Health, I responded to disease outbreaks across the state. I have a bachelor's degree from Harvard University, a master's degree in public health from Columbia University, and I completed medical school and clinical training at Yale University. I am a board-certified internal medicine physician and pediatrician and continue to see primary care patients weekly.

The City of Chicago

3. Chicago, located in Cook County, is the largest city in Illinois and the third largest city in the United States.

4. The United States Census Bureau's statistics are the best available means for determining the population of Chicago and its demographic characteristics. Those statistics are available at https://www.census.gov/quickfacts/chicagocityillinois.

5. According to 2019 Census estimates, Chicago has nearly 2.7 million residents. Of those residents, 88%, or 2.38 million people, are under the age of 65. 6.9% of Chicago's population, or around 186,000 people, have a disability.

6. 2019 Census estimates for the proportion of Chicago's population without health insurance are unavailable. According to 2018 Census estimates, 11.9% of Chicago's population under the age of 65, or around 283,000 people, lack health insurance. Those same estimates show that 19.5% of Chicago's population, or around 526,500 people, live in poverty.

7. The Bureau of Labor Statistics reports that, in February 2020, the Chicago-Joliet-Naperville, Illinois metropolitan statistical area had 123,900 unemployed individuals.[1]

[1] *Economy at a Glance, Chicago-Joliet-Naperville, IL*, U.S. Bureau of Labor Statistics, https://www.bls.gov/eag/eag.il_chicago_md.htm (last visited June 14, 2020).

8. As a major American city, Chicago provides a wide range of services on behalf of its residents, including, as relevant here, health services, public assistance through human and social services, and emergency medical care.

The City's Health Infrastructure

9. Chicago has a Department of Public Health that generally seeks to promote and improve the health of city residents. The Department has an annual budget of around $221 million and is staffed by over 600 full-time employees.[2]

10. The Chicago Department of Public Health operates free clinics. Specifically, the Department operates five clinics that provide free vaccinations;[3] five clinics that provide mental-health services at no cost for uninsured and underinsured Chicago residents;[4] and three clinics that provide free testing and treatment for sexually transmitted infections.[5] The City also provides certain at-home or in-field health programs, such as nursing home support for pregnant women and newborn babies and directly observed therapy for tuberculosis. Collectively, these clinics and services serve thousands of uninsured and underinsured city residents and, in particular, provide services that may not be covered by non-ACA-compliant health coverage.

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[2] *2020 Budget Overview*, City of Chicago 126, https://www.chicago.gov/content/dam/city/depts/obm/supp_info/2020Budget/2020BudgetOverview.pdf.

[3] *Walk-In Immunization Clinics*, City of Chicago, https://www.chicago.gov/city/en/depts/cdph/supp_info/health-protection/immunizations_walk-inclinics.html.

[4] *Mental Health Centers*, City of Chicago, https://www.cityofchicago.org/city/en/depts/cdph/supp_info/behavioral-health/mental_health_centers.html.

[5] *STI/HIV Testing and STI Treatment*, City of Chicago, https://www.cityofchicago.org/city/en/depts/cdph/provdrs/health_services/svcs/get_yourself_evaluatedforstihivaids.html.

11. Each of these clinics faces greater demand when there is an increase in either the health needs of Chicago residents or in the number of uninsured or underinsured individuals who cannot obtain those services or other forms of health care elsewhere.

12. The Chicago Department of Public Health also partners with, and provides funding to, community-based health centers to offer a wide array of medical services, including for uninsured and underinsured patients.[6]

13. The higher the uninsured and underinsured rate, the more that the clinics operated by the Chicago Department of Public Health and its community-based partners will necessarily have to provide forms of free or reduced-cost care to patients.[7] In that event, Chicago either must provide the Department and its partners with more funding, or the Department and its partners must decrease the services that they provide.

14. The Department of Public Health also conducts citywide surveillance and response efforts for communicable and vaccine-preventable diseases, including 31 employees and around $3.5 million for communicable disease, 32 employees and around $11.5 million for vaccine-preventable disease, 44 employees and around $28.5 million for emergency preparedness, and 25 employees and around $5 million for epidemiology and IT/informatics.[8]

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[6] *Health Services*, City of Chicago, https://www.cityofchicago.org/city/en/depts/cdph/provdrs/health_services.html.

[7] *See, e.g.*, John Holahan & Bowen Garnett, *The Cost of Uncompensated Care With and Without Health Reform*, Urban Inst. 4 (Mar. 2010), https://www.urban.org/sites/default/files/publication/28431/412045-The-Cost-of-Uncompensated-Care-with-and-without-Health-Reform.PDF (A higher "number of uninsured and … amount of uncompensated care …. will translate into increased pressure on state and local government to finance the growing cost of the uninsured."); Erin F. Taylor et al., *Community Approaches to Providing Care for the Uninsured*, 25 Health Aff. 173, 173 (2006), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.w173 ("Increases in the number of uninsured people often strain local safety nets and health systems.").

[8] *2020 Chicago Budget Overview* at 126-28.

15. The Department of Public Health also partners with all hospitals and healthcare organizations in the City of Chicago through the Healthcare System Preparedness Program, which supports the Chicago Health System Coalition for Preparedness and Response.[9] This program includes coordination of all thirty five acute care and specialty hospitals, 110 long term care facilities, 50 dialysis centers, all Federally Qualified Healthcare Centers, and other organizations that provide health care services within the City.

16. This program includes safety net hospitals which, as part of their participation, demonstrate their ability to react to patient surges and complete accreditation requirements. Safety net hospitals provide healthcare for individuals regardless of their insurance status or ability to pay, and typically serve a higher proportion of uninsured, low-income, and other vulnerable individuals than do other hospitals.

17. Chicago's partnership with these hospitals includes financial support such as situational awareness communication, support for data collection and reporting, disaster exercises, clinical trainings, and providing supplies, such as personal protective equipment, mechanical ventilators, and radios. In particular, this program benefits patients during surge events, like the novel coronavirus pandemic.

18. The Chicago Fire Department provides ambulance transportation services to its residents, including its uninsured and underinsured residents. The Department receives around $94 million in annual funding for emergency medical services, employing more than 800 people to provide those services.[10]

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[9] *Healthcare System Preparedness Program*, City of Chicago, https://www.chicago.gov/city/en/depts/cdph/supp_info/health-protection/healthcare-system-preparedness-program.html (last visited June 14, 2020).

[10] *2020 Chicago Budget Overview* at 120.

19. Based on my review of the Department's records, the Department's paramedics provide ambulance-transportation services approximately 250,000 times per year, with over 260,000 in 2019.

20. The Chicago Fire Department provides ambulance services regardless of the patient's income or insurance status. Chicago generally seeks reimbursement for ambulance services from the patient or, if applicable, the patient's insurer.[11]

21. However, Chicago usually does not receive full reimbursement for ambulance services from its uninsured and underinsured residents. Based on my review of the Department's records, in 2018, for example, the Chicago Fire Department provided ambulance services to 60,007 patients for whom no insurance was identified. Chicago charged these patients $63,717,638 for ambulance services but collected just $1,028,713—a loss of $62,688,925. These numbers increased in 2019, during which the Chicago Fire Department provided ambulance services to 61,377 patients for whom no insurance was identified. Chicago charged these patients $65,970,368 for ambulance services but collected just $1,564,799—a loss of $64,958,819.[12]

22. In Chicago's experience, the uninsured and underinsured disproportionately rely on ambulance service for transport to the emergency department.[13] A higher number of

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[11] *Ambulance Bills*, City of Chicago, https://www.cityofchicago.org/city/en/depts/fin/supp_info/revenue/ambulance_bills.html (last visited June 14, 2020).

[12] Because efforts to collect for 2019 are ongoing, these figures may change with time.

[13] *See, e.g.*, Benjamin T. Squire et al., *At-Risk Populations and the Critically Ill Rely Disproportionately on Ambulance Transport to Emergency Departments*, 56(4) Annals of Emergency Med. 341, 347 (2010), https://www.ncbi.nlm.nih.gov/pubmed/20554351; *see also* Zachary F. Meisel et al., *Variations in Ambulance Use in the United States: The Role of Health Insurance*, 18(10) Acad. Emergency Med. 1036, 1041 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3196627/pdf/nihms314403.pdf ("EMS use is higher among those who historically have had difficulty accessing routine medical care, specifically poor and uninsured patients.").

uninsured and underinsured individuals or an increase in acute health needs will therefore result in more ambulance transports for which Chicago does not receive reimbursement and thus must make up for the shortfall in its budget.

The Novel Coronavirus Pandemic in Chicago

23. As of June 14, 2020, over 49,000 people have been confirmed to have been diagnosed with the novel coronavirus in the City of Chicago, and over 2,300 people have been confirmed to have died from it.[14]

24. Chicago has been subject to the State of Illinois's stay at home orders and has issued its own coronavirus-related guidance, which generally provides that City residents "should practice physical distancing, wear a face covering and wash their hands often."[15] The Department of Public Health has issued several COVID 19-related Executives Orders and guidance available on the City's website,[16] as well as disseminated guidance to health care providers through the Department of Public Health's Health Alert Network.

25. As a result of the economic crisis caused by the novel coronavirus, the Chicago-Joliet-Naperville area's unemployment rate spiked to 640,300 in April 2020, an increase of 516,400, or roughly ~416%.[17] More recent statistics are unavailable, but given national trends, that rate has likely remained high.

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[14] *Coronavirus Response Center*, City of Chicago, https://www.chicago.gov/city/en/sites/covid-19/home.html (last updated June 14, 2020).

[15] *Latest Guidance*, City of Chicago, https://www.chicago.gov/city/en/sites/covid-19/home/latest-guidance.html (last visited June 14, 2020). As of June 14, 2020, Chicago was in Phase 3, which permits certain additional industries to reopen cautiously, following specific safety guidelines. *Phase III Cautiously Reopen: Industry Guidelines for Reopening*, City of Chicago, https://www.chicago.gov/city/en/sites/covid-19/home/reopening-business-portal.html (last visited June 14, 2020).

[16] *Id.*

[17] *Economy at a Glance.*

26. Similarly, while more recent uninsured rate statistics are unavailable, the uninsured rate described above is now likely much higher, given that many individuals who have lost their employment have also lost their employer-provided health insurance as a result.[18]

27. At the same time, the pandemic has necessarily created a new and widespread need for health care services.

The City's Response to the Pandemic

28. In response to the novel coronavirus, Chicago has mounted a comprehensive effort to connect city residents to necessary health, food, housing, financial, and other resources.[19]

29. Specifically, Chicago has directed its uninsured and underinsured residents to its clinics and other community health centers to receive necessary health services during the pandemic.[20] Where in-person services are not possible or are unnecessary, Chicago is committed to using telemedicine and technology to continue the health services it provides directly to Chicago residents (*e.g.*, mental health services, nursing home services, and WIC support).

30. Chicago also supports seven coronavirus testing sites within the City, operated by the nonprofit CORE Foundation, and which are available to symptomatic residents, asymptomatic residents with known exposure to the novel coronavirus, and asymptomatic frontline workers.[21] The City provides the funding for all testing kits and lab work for these sites.

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[18] Selena Simmons-Duffin, *Millions Of Americans Have Lost Health Insurance As Unemployment Soars*, NPR (May 24, 2020), https://www.npr.org/2020/05/13/855096156/millions-of-americans-have-lost-health-insurance-as-unemployment-soars.

[19] *See Coronavirus Response Center*.

[20] *Managing Your Health*, City of Chicago, https://www.chicago.gov/city/en/sites/covid-19/home/managing-your-health.html?#tab-shouldtest.

[21] *Managing Your Health.*

31. The Department of Public Health operates a mobile app, Chi COVID Coach, which "allows people who have coronavirus questions—or symptoms—to connect with trained public health employees who can answer questions about symptoms, quarantine, testing locations and more."[22] It has also established a call center and email address to take questions from the public.[23]

32. Although Chicago advises that individuals isolate themselves at home and receive telephonic medical care, individuals who believe they have contracted the novel coronavirus and/or are in medical distress sometimes use ambulance services to receive necessary care.[24] If those individuals are uninsured or underinsured, the City will provide transport but, for the reasons explained above, is unlikely to receive reimbursement for the expense.

33. Even though Chicago provides certain forms of care to its uninsured and underinsured residents, Chicago is concerned that those residents may be less likely to obtain necessary testing and treatment for the novel coronavirus. In the City's experience, uninsured and underinsured individuals are more likely to skip or postpone needed care due to cost.[25]

34. As of May 8, 2020, Chicago has distributed over 7 million pieces of personal protective equipment, including over 4 million gloves and over 3 million masks.[26]

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[22] Kelly Bauer, *City's New Chi COVID Coach App Lets You Sign Up For Vaccine Alerts, Testing Information And More*, Block Club Chi. (Apr. 27, 2020), https://blockclubchicago.org/2020/04/27/citys-new-chi-covid-coach-app-lets-you-sign-up-for-vaccine-alerts-testing-information-and-more/.

[23] *Resources.*

[24] *See* Mark Guarino, *This Hospital Was Built for A Pandemic*, Wash. Post (Apr. 9, 2020), https://www.washingtonpost.com/health/2020/04/09/rush-hospital-coronavirus/.

[25] *See, e.g.*, *The Chicago Health Care Access Puzzle*, City of Chicago 8 (Nov. 2008), https://www.chicago.gov/dam/city/depts/cdph/policy_planning/PP_ChgoHealthCareAccessRpt-1-.pdf.

[26] *Health Care Workers*, City of Chicago, https://www.chicago.gov/city/en/sites/health-care-workers/home.html (last updated May 8, 2020).

Overall Impact on the City

35. Chicago has a strong interest in ensuring that its residents can obtain adequate medical care. The City would prefer that those residents obtain affordable, ACA-compliant coverage, so that they can seek comprehensive care for all of their medical needs. However, Chicago is committed to caring for its uninsured and underinsured residents.

36. In ordinary times, Chicago is harmed as a whole when its residents feel they cannot obtain necessary medical care. A population that cannot obtain medical care is necessarily sicker, less productive, and less able to participate in the community and civic life.

37. However, amidst the current pandemic, it is an absolute necessity that Chicago residents be able to obtain care, including testing and treatment for the novel coronavirus. The more uninsured and underinsured individuals that do not seek care, the more the novel coronavirus will spread, further harming the City, its budget, its economy, and its well-being.

38. Ultimately, the pandemic has had effects across all of Chicago's programs. Many City agencies and programs are closed or only offering telephonic services as a result of the pandemic, and have had to redirect their personnel and resources and adjust their operations in response. For example, Chicago's clinics that provide vaccinations and treat sexually-transmitted infections have been closed since mid-March, and the staff at those clinics diverted to Chicago's pandemic response. Some City employees have also contracted the novel coronavirus, making it harder for the City to operate effectively.

39. Chicago expects to face a budget shortfall of at least $700 million, in part as a result of the pandemic.[27] That "conservative" figure "depend[s] on how long it takes for

[27] Gregory Pratt & John Byrne, *Mayor Lori Lightfoot: Chicago's Coronavirus Budget Shortfall at Least $700 Million*, Chicago Trib. (June 9, 2020), https://www.chicagotribune.com/politics/ct-

consumers to regain confidence and whether coronavirus cases surge again."[28] Specifically, Chicago faces hundreds of millions of dollars in lost revenue.[29] At the same time, Chicago is facing extraordinary strain on its health, emergency response, and other services.[30]

40. It is not clear when Chicago, or other cities, will be able to fully reopen, or whether they will need to impose restrictions again in the face of another wave of the novel coronavirus.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 15, 2020

Chicago, Illinois

Dr. Allison Arwady

coronavirus-chicago-budget-shortfall-lori-lightfoot-20200609-d6pb4n7drje6xfe4tzaioesrgu-story.html.

[28] Fran Spielman, *Estimated 2020 Budget Shortfall Is $700 Million, Says Mayor, Who Won't Rule Out Property Tax Increase*, Chicago Sun-Times (June 9, 2020), https://chicago.suntimes.com/city-hall/2020/6/9/21285650/chicago-city-budget-shortfall-700-million-coronavirus-federal-help-lightfoot.

[29] *Id.*

[30] Becky Vevea, *How COVID-19 Could Hit Chicago's Budget*, NPR (May 8, 2020), https://www.npr.org/local/309/2020/05/08/852760731/how-c-o-v-i-d-19-could-hit-chicago-s-budget.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

DECLARATION OF CHRISTEN LINKE YOUNG

I, Christen Linke Young, declare under penalty of perjury as prescribed in 28 U.S.C. § 1746:

1. The facts contained in this declaration are known personally to me and, if called as a witness, I could and would testify competently thereto under oath. I submit this sworn declaration in support of the City of Chicago's motion for a preliminary injunction or, in the alternative, expedited summary judgment.

2. I am a fellow with the USC-Brookings Schaeffer Initiative for Health Policy, a research center within the Economic Studies division of the Brookings Institution. My research concerns how Americans get health care coverage, how that coverage is financed, and how the health care system can be improved to make coverage affordable and accessible to more people. I have published many pieces of scholarly analysis on these topics. I have testified before Congress and before state legislatures, and my work is frequently cited in national media. My full curriculum vitae, including a list of publications, appears as an Appendix to this declaration.

I. Summary of observations and opinions.

3. Those without comprehensive health insurance coverage experience cost-related barriers to health care at higher rates than insured patients. These barriers may affect how they seek care and what services they receive, including for care related to COVID-19.

4. Current policy provides some protection for uninsured individuals who need COVID-19 care, but it is not comprehensive insurance coverage. Specifically, the two free-standing "funds" that reimburse providers for COVID-19 costs for uninsured patients do not provide the assurance of actual health coverage, and short-term insurance products may expose consumers to significant costs if they become seriously ill.

II. Uninsurance is associated with cost barriers to care.

5. A very large body of evidence, from both before and after implementation of the Patient Protection and Affordable Care Act (ACA),[1] demonstrates that health insurance coverage is associated with a greater likelihood that individuals will seek and receive needed care. As described below, research indicates that uninsured individuals are more likely to delay or forgo care because of costs and less likely to have reliable access to the health care system, as compared to those with comprehensive forms of health insurance coverage.

A. Uninsured individuals are more likely to go without care because of costs.

6. Evidence consistently reflects that uninsured individuals are more likely to go without needed health care services because of costs. Analysis of results from the National Health Interview Survey[2] administered by the Centers for Disease Control and Prevention (CDC)

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[1] Pub. L. No. 111-148, 124 Stat. 119 (2010), *as amended*, Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

[2] *National Health Interview Survey*, CDC, https://www.cdc.gov/nchs/nhis/index.htm (last viewed May 27, 2020).

demonstrates that in 2017, uninsured adults were five times more likely to report that they had gone without health care "because of costs" in the previous twelve months (20% versus 4%).[3] When including individuals who delayed care, and not just those who avoided it altogether, that figure rises to 28% of the uninsured (compared to only 7% of the insured).[4] That is, in the relatively recent past more than a quarter of uninsured adults reported that costs had affected their ability to seek care in a twelve month period.

7. Indeed, CDC data reflect that in every year since 1998, uninsured individuals have been far more likely than the insured to report that they delayed or went without care due to cost. Implementation of the ACA was associated with a decrease in the rate at which uninsured individuals reported cost barriers to care, but the disparity between insured and uninsured individuals remain large.[5] Because uninsured individuals differ from the insured in many ways, including the fact that they are disproportionately low-income, these data cannot be used to infer that uninsurance is the only factor behind these disparities in cost-related barriers to care, but the data are consistent with insurance status playing an important role.

8. Researchers using a variety of data sources covering varying time periods have reached the same conclusion. To consider just a few examples: Gallup's Health and Healthcare poll reveals that the uninsured are more likely than the insured to delay care because of costs over the entire time horizon of the survey; nearly two thirds (across all insurance statuses) of

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[3] Gary Claxton et al., *How Does Cost Affect Access to Care?*, Kaiser Family Found. (Jan. 22, 2019), https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care. For survey question wording, see *NHIS Data, Questionnaires and Related Documentation*, CDC, https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm (last visited May 27, 2020).

[4] *How Does Cost Affect Access to Care*.

[5] *See id.*

those delaying care report that care is associated with a "serious condition."[6] Another news organization survey in 2005 found that 51% of the uninsured (compared to 25% of the insured) reported that a member of their household "skipped medical treatment, cut pills or did not fill a prescription in the past year because of the cost."[7] Analyzing 1997 and 1998 data from a different CDC survey, the Behavioral Health Risk Factor Surveillance Survey,[8] researchers found that 39% of adults who had been uninsured for one year and only 7% of insured adults reported that they could not see a physician due to costs in the prior year.[9]

9. Analysis of the impact of the ACA's Medicaid expansion reveals the same pattern. A review by the Kaiser Family Foundation identifies 91 different studies that find Medicaid expansion and the associated increase in insurance coverage is associated with better utilization of care and 55 studies showing improved access to care.[10] For example, Medicaid

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6 Lydia Saad, *Delaying Care a Healthcare Strategy for Three in 10 Americans*, Gallup (Dec. 17, 2018), https://news.gallup.com/poll/245486/delaying-care-healthcare-strategy-three-americans.aspx.

7 *Health Care Costs Survey*, USA Today, Kaiser Family Found. & Harv. Sch. of Pub. Health (Aug. 2005), https://www.kff.org/wp-content/uploads/2013/01/7371.pdf.

8 *See Behavioral Risk Factor Surveillance System*, CDC, https://www.cdc.gov/brfss/index.html (last updated Nov. 5, 2019).

9 *See* John Z. Ayanian et al., *Unmet Health Needs of Uninsured Adults in the United States*, 284(16) J. Am. Med. Ass'n 2061 (2000), https://jamanetwork.com/journals/jama/fullarticle/193207.

10 *See* Madeline Guth et al., *The Effects of Medicaid Expansion under the ACA: Updated Findings from a Literature Review*, Kaiser Family Found. 8 fig. 4 (Mar. 17, 2020), https://www.kff.org/report-section/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review-report/. The review identifies a small number of studies that are inconclusive on each of these metrics, which the authors conclude is generally because "early studies using 2014 data" are limited by the fact that "changes in utilization may take more than one year to materialize." *Id.*

expansion is associated with statistically significant decreases in the rate at which individuals report being unable to afford care, including follow-up and specialist care.[11]

10. Some research indicates that cost-related barriers deter uninsured individuals from receiving care specifically for acute conditions. One study of "health shocks"—injuries or newly emerging chronic conditions—found that uninsured individuals were less likely to receive any care at all (79% versus 89%). Moreover, they were about twice as likely to go without needed follow-up care because of costs (19% versus 9% for injuries, or 9% versus 4% for a new chronic condition), and were in worse health several months after the shock had occurred.[12]

B. Uninsured individuals are less likely to have a usual source of care.

11. Uninsured individuals are also far less likely to report having a usual source of care compared to insured people, meaning that treatable conditions may be detected later and when treatment is more expensive. National Health Interview Survey data reflect that in 2017, half (50%) of uninsured people reported that they did not have a place that they would "usually go to if [they were] sick and need health care," compared to just 11% of the privately insured.[13]

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[11] *See, e.g.*, Sarah Miller & Laura R. Wherry, *Four Years Later: Insurance Coverage and Access to Care Continue to Diverge Between ACA Medicaid Expansion and Non-Expansion States*, 109 Am. Econ. Ass'n Papers & Proceedings 327, 327 (2019), https://pubs.aeaweb.org/doi/pdfplus/10.1257/pandp.20191046.

[12] *See* Jack Hadley, *Insurance Coverage, Medical Care Use, and Short-Term Health Changes Following an Unintentional Injury or the Onset of a Chronic Condition*, 297(16) J. Am. Med. Ass'n 1073 (2007), https://pubmed.ncbi.nlm.nih.gov/17356028/.

[13] Rachel Garfield et al., *The Uninsured and the ACA: A Primer*, Kaiser Family Found. (Jan. 25, 2019), https://www.kff.org/report-section/the-uninsured-and-the-aca-a-primer-key-facts-about-health-insurance-and-the-uninsured-amidst-changes-to-the-affordable-care-act-how-does-lack-of-insurance-affect-access-to-care/; *NHIS Data, Questionnaires and Related Documentation*; *see also, e.g.*, *How Does Cost Affect Access to Care*; Catherine Hoffman & Julia Paradise, *Health Insurance and Access to Health Care in the United States*, 1136 Annals of the N.Y. Acad. of Scis. 149 (2008), https://nyaspubs.onlinelibrary.wiley.com/doi/full/10.1196/annals.1425.007; *Summary Health Statistics for U.S. Adults: National Health Interview Survey, 2006*, CDC 12-13 (Dec. 2007), https://www.cdc.gov/nchs/data/series/sr_10/sr10_235.pdf.

12. Other research demonstrates that those who gained coverage in the first several months of the ACA's implementation were far less likely to be without a usual source of care than those who remain uninsured. Researchers found that 39% of the newly insured in the fall of 2014, compared to 57% of those who remained uninsured, did not have a regular source of health care services.[14]

C. These cost barriers may affect COVID-19 care.

13. Together, these data suggest that cost-related barriers to care for the uninsured can impact COVID-19 treatment. Delays in seeking care and foregone care because of costs are common for the uninsured in general, and these obstacles are likely to continue to apply in the COVID-19 context.

14. Indeed, an April 2020 Gallup poll found that 14% of Americans (insured and uninsured alike) would "avoid seeking treatment due to concerns about the cost of care" if they experienced COVID-19 symptoms. Further, 9% indicated they would avoid care because of costs even if they suspected COVID-19 infection.[15] Given the wide disparities between the rate at which insured and uninsured individuals report delaying or foregoing care because of costs, it is probable that uninsured individuals would be more likely to avoid COVID-19 care.

15. This avoidance or delay in seeking care could mean individuals delay seeking a COVID-19 test, resulting in a longer period of time during which a person is capable of infecting others, but not aware of their infection. It could result in individuals avoiding a test entirely. It

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[14] Rachel Garfield et al., *Access to Care for the Insured and Remaining Uninsured: A Look at California During Year One of ACA Implementation*, Kaiser Family Found. fig. 1 (May 28, 2015), https://www.kff.org/report-section/access-to-care-for-the-insured-and-remaining-uninsured-issue-brief/.

[15] *See* Dan Witters, *In U.S., 14% With Likely COVID-19 to Avoid Care Due to Cost*, Gallup (Apr. 28, 2020), https://news.gallup.com/poll/309224/avoid-care-likely-covid-due-cost.aspx.

could also mean that individuals who become very ill may ultimately enter care at a later point in the trajectory of the disease.

16. Insurance status may also affect how individuals seek care if they ultimately decide to do so. Because the uninsured disproportionately lack a usual source of care, many will not have any connection to primary care. And because they lack insurance coverage, they also face difficulty obtaining care in advance of a serious illness or before an existing illness becomes more severe. As a result, they may be more likely to seek care in high acuity settings like an emergency room or other emergency services.

17. Insurance status may also affect the nature and extent of care. For example, coverage for prescription drugs and physician visits makes it more likely that people experiencing illness will be able to stay home, seek diagnosis, and obtain treatment without coming to the hospital. That reduces the demands placed on a hospital system that may face resource constraints during the current pandemic. Patients who have comprehensive insurance also retain coverage across treatment settings, enabling ongoing care.

III. Current policy does not provide the protection of insurance coverage.

18. Some new programs have been established to address COVID-19-related care for uninsured patients, but they differ from actual health insurance in important ways and are unlikely to provide the same access to the health care system that comprehensive coverage would provide. Specifically, two government-administered funds are available to cover some costs related to COVID-19 *testing* and COVID-19 *treatment*, respectively, but there are major gaps in these programs compared to comprehensive coverage. Short-term health insurance plans also leave consumers exposed to potentially large bills. A national special enrollment period allowing uninsured Americans to enroll in marketplace coverage would create a comprehensive alternative.

A. Current testing funding is less protective than comprehensive coverage.

19. In the Families First Coronavirus Relief Act, Congress provided $1 billion to reimburse health care providers for the COVID-19 testing for the uninsured,[16] and Congress has since added an additional $1 billion to the fund.[17] This funding can be used to pay for specific health care services delivered to an uninsured patient. Specifically, the fund will reimburse providers for "in vitro diagnostic products" that test for COVID-19, and for the cost of health care services delivered during a visit to a health care provider (such as a doctor's office or emergency department), but only if the visit "result[s] in an order" for a COVID-19 test and if the services "relate to" the test.[18]

20. This is a limited benefit that will not pay for many services that may be delivered, even in the case of an uninsured individual presenting with the intention of getting a COVID-19 test. For example, if an uninsured person sees a health care provider seeking a COVID-19 test, but for whatever reason no test is ultimately ordered by the provider, the fund cannot be accessed for any of the services received and the patient may be responsible for payment.[19]

21. Even if a test is ordered, other services that may be obtained by the patient during the visit—like a flu test or imaging services for more serious cases—cannot be reimbursed from the fund and may be billed to the patient.[20]

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[16] Pub. L. No. 116-127, 134 Stat. 178 (2020).

[17] Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020).

[18] Families First Coronavirus Relief Act, § 6001.

[19] *See, e.g.*, Kirk Siegler, *Many Who Need Testing For COVID-19 Fail To Get Access*, NPR (Apr. 3, 2020), https://www.npr.org/2020/04/03/826044608/many-who-need-testing-for-covid-19-fail-to-get-access (describing cases where patients did not have a COVID-19 test ordered, despite their concerns about COVID-19).

[20] *See* Sabrina Corlette, *Expanded Coverage for COVID-19 Testing is an Important Step, But Loopholes Expose All of Us to Greater Risk*, Ctr. on Health Insurance Reforms (Apr. 6, 2020), http://chirblog.org/expanded-coverage-for-covid-19-testing/.

22. In addition, if a COVID-19 test occurs during a hospital admission, then the provider may not be reimbursed for the visit from the testing fund.[21] If the patient ultimately tests positive for COVID-19, some costs can be reimbursed from the treatment fund, as described below, but if the test is negative those costs may be billed to the patient.

23. Further, individual uninsured patients do not have any direct access to fund dollars, even if the services they received qualify for reimbursement. Providers can submit claims to the Department of Health and Human Services (HHS).[22] However, there is nothing an individual can do to seek protection from the fund; it is entirely at the discretion of the provider whether to ask for reimbursement. If the provider does not do so—either because they are unaware of the option or they simply elect not to—then uninsured individuals can be, and have been, billed for the services, even if they would otherwise qualify for reimbursement.[23]

24. These gaps mean that an uninsured individual who may wish to obtain a COVID-19 test has no meaningful assurance that their health care costs will be covered by the fund—and

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[21] *See Frequently Asked Questions for the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured*, Health Resources & Servs. Admin., https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions (last visited May 27, 2020) ("The testing-related visit (the admission) would not be eligible for reimbursement because the care setting is not an office visit, telehealth visit, urgent care or emergency room and is not separately billable with applicable CPT/HCPCS codes on the inpatient claim. Unless COVID-19 is the primary diagnosis for the admission, no portion of this claim would be eligible for reimbursement under the program since the primary reason for treatment is not COVID-19.") ("*Frequently Asked Questions*").

[22] *See COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured*, Health Resources & Servs. Admin., https://www.hrsa.gov/CovidUninsauredClaim (last updated May 2020).

[23] *See, e.g.*, Kimberly Leonard, *Trump and Congress Tried to Make Coronavirus Testing and Treatment Free, but People Are Still Getting Big Bills When They Go to the Hospital*, Bus. Insider (May 21, 2020), https://www.businessinsider.com/coronavirus-patients-medical-bills-hospitals-doctors-insurance-2020-5 (describing cases where individual patients received bills despite the fact that the services provided qualified for reimbursement); *see also Expanded Coverage for COVID-19 Testing*.

no way to obtain that assurance. To be sure, the testing fund will relieve some financial burden that would otherwise fall upon uninsured consumers, and will compensate providers for some care that might otherwise have been uncompensated. But because a consumer cannot rely on the fund, it does not serve the same role as health insurance in promoting access to care.[24]

B. Treatment funding is also less protective than comprehensive coverage.

25. The fund described above is limited to costs associated with COVID-19 testing. However, testing is a fairly inexpensive service when compared to *treatment* for a serious COVID-19 illness.

26. For example, one analysis of potential COVID-19 spending assumes that a COVID-19 test for an uninsured patient costs an average of $100, and the visit at which that test might be delivered costs an average of $112 (for a doctor's office) or $582 (for the emergency room). However, if a person is hospitalized for COVID-19, which the authors assume will happen in 2% of COVID-19 cases, hospital costs will average $17,000 if the patient does not require a ventilator and $58,000 if he or she does.[25]

27. In contrast to testing, Congress has not appropriated any funding specifically to reimburse for the COVID-19 treatment costs of the uninsured.

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[24] *See* Christen Linke Young et al., *Responding To COVID-19: Using The CARES Act's Hospital Fund To Help The Uninsured, Achieve Other Goals*, Health Affairs (Apr. 11, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200409.207680/full/ (discussing the ways in which fund-based reimbursement differs from insurance).

[25] Matthew Fiedler & Zirui Song, *Estimating Potential Spending on COVID-19 Care*, Brookings Inst. (May 7, 2020), https://www.brookings.edu/research/estimating-potential-spending-on-covid-19-care/ (tbl. 2 discussing unit prices of COVID-19 services).

28. However, Congress has provided a large "Provider Relief Fund,"[26] a fund administered by HHS to support health care providers as they incur COVID-19-related costs at the same time they experience major revenue shortages because of physical distancing measures that required postponing or canceling most non-urgent care.

29. HHS has determined that it will use a portion of this Provider Relief Fund to reimburse providers for COVID-19 treatment costs of the uninsured. Providers can submit claims for reimbursement through an online portal.[27] This arrangement suffers from many of the same limitations as the testing coverage fund, as well as some additional gaps due to the high cost of treatment and the structure of the support.

30. Most importantly, providers can only access the treatment funding if COVID-19 is the primary diagnosis associated with the health care claim.[28] Services (other than testing) delivered to patients who seek care because they think they may have COVID-19, but are not diagnosed as such will not be eligible for reimbursement. This would include all treatment services delivered to someone who tests negative for COVID-19, as well as services delivered that are not associated with COVID-19 even if the patient tests positive.[29]

31. COVID-19 patients often experience other illness, and therefore are especially likely to need comprehensive coverage for services beyond just COVID-19, but the fund will not

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[26] Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020); *see also* Paycheck Protection Program and Health Care Enhancement Act;*see also CARES Act Provider Relief Fund*, HHS, https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html (last visited May 27, 2020).

[27] *See COVID-19 Claims Reimbursement*.

[28] *See id.* (describing payment for "services with a primary COVID-19 diagnosis"). A narrow exception is available in the case of pregnancy; COVID-19 may be listed secondary to pregnancy.

[29] *See, e.g.*, *Frequently Asked Questions* (providing an example of cancer treatment for a COVID-19 patient that cannot be reimbursed).

reimburse any of those costs. Cost-related fears could lead some who do not know that they have COVID-19 to delay care, further slowing detection and accelerating the pandemic's spread.

32. The fund cannot be used to reimburse for any outpatient prescription drugs or hospice services, even if an individual has a COVID-19 diagnosis.[30]

33. In this environment, individuals in need of health care services will have no ability to predict if the costs they incur will be eligible for reimbursement from the fund. They do not know if they will test positive for COVID-19, or if the care they receive will be the type of service for which COVID-19 will be considered the primary diagnosis. They do not know if they will face significant outpatient drug costs.

34. Further, HHS has not specified the amount of funding that will be available to reimburse providers for COVID-19 treatment costs of the uninsured.[31] Given the high cost of COVID-19 treatment, the fund could be exhausted before a provider submits a request for reimbursement for the patient, leaving the patient responsible for the full bill. And because information about the size of the fund is unavailable, providers and uninsured individuals face significant uncertainty about whether a claim could ultimately be paid through the fund. This may be a particularly acute concern in cases where individuals are facing a long period of illness and hospitalization, because the provider will not be able to generate a claim for potential reimbursement until the individual is discharged from the hospital, several weeks in the future.

35. As above, even when services qualify and when funding is available, an individual patient has no direct recourse to the fund. It is at the discretion of the provider whether to seek fund reimbursement or bill the patient directly.

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[30] *See COVID-19 Claims Reimbursement*.

[31] *See Frequently Asked Questions* (under "General Questions" header; then click "How much money is available in the fund?") (declining to specify the amount of available funding).

36. For all of these reasons, concern about high costs could be a real barrier to accessing care and the existence of the treatment fund will not ameliorate those concerns in the way comprehensive health insurance would. The fund may alleviate some meaningful amount of financial burden on uninsured individuals and providers, but does not provide the assurance that comprehensive coverage can offer.

C. Short term insurance products have major gaps.

37. Short-term limited duration health insurance plans also have major gaps for patients who may need COVID-19 care, including their exclusion of pre-existing conditions and limitations on coverage.

38. These products often do not cover pre-existing conditions.[32] If any signs of illness appeared in the period before enrollment, or, often, in the days immediately following enrollment, the plan will not cover any claims, and the person will face costs as if they had been without any form of coverage. Further, if an individual becomes sick with COVID-19, the insurance company may engage in a lengthy examination of medical records to determine if the individual displayed any signs of illness prior to obtaining her insurance product. Press reports reflect that this process, known as post-claims underwriting, has been applied to patients seeking care related to concerns about COVID-19.[33]

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[32] *See* Christen Linke Young & Kathleen Hanick, *Misleading Marketing Of Short-Term Health Plans Amid COVID-19*, USC-Brookings Schaeffer Initiative for Health Pol'y (Mar. 24, 2020), https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2020/03/24/misleading-marketing-of-short-term-health-plans-amid-covid-19/.

[33] *See, e.g.*, Ben Conarck, *A Miami Man Who Flew to China Worried He Might Have Coronavirus. He May Owe Thousands*, Miami Herald (Feb. 24, 2020), https://www.miamiherald.com/news/health-care/article240476806.html; *see also Misleading Marketing Of Short-Term Health Plans Amid COVID-19*.

39. Aside from concerns about pre-existing condition exclusions, these plans have limited benefit designs that could leave consumers exposed to very large costs. A recent examination of 12 widely available short-term plans across three states (each of which uses the federal Exchange) finds that consumers needing hospital care for COVID-19 would be exposed to costs much higher than they would face if they had comprehensive health insurance. Patients requiring ventilation could face out-of-pocket costs greater than $30,000 in popular short-term plans, and even those with a lower cost hospitalization could be responsible for costs greater than $15,000.[34] In contrast, in a comprehensive ACA-regulated health insurance, out-of-pocket costs are capped at $8,150, and lower levels for lower-income households.[35]

40. As a result, short-term plans are likely far less effective in ameliorating cost-related barriers to care than comprehensive coverage. Consumers do not know if their illness will be considered a pre-existing condition and excluded from payment entirely, and even if not, they face significant costs if they are seriously ill.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 14, 2020

Washington, DC

Christen Linke Young

[34] *See* Emily Curran et al., *In the Age of COVID-19, Short-Term Plans Fall Short for Consumers*, The Commonwealth Fund (May 12, 2020), https://www.commonwealthfund.org/blog/2020/age-covid-19-short-term-plans-fall-short-consumers.

[35] *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020*, 84 Fed. Reg. 17,454, 17,541 (Apr. 25, 2019).

APPENDIX

CHRISTEN LINKE YOUNG

EXPERIENCE

Brookings Institution **Washington, DC**
Fellow, USC-Brookings Schaeffer Initiative for Health Policy 2018-Present
Conduct legal and policy research at preeminent public policy think-tank. Research portfolio focuses on implementation of the Affordable Care Act and forward-looking policies in health reform, including auto-enrollment, strategies for the regulation of non-compliant insurance products, and policies to improve subsidized coverage.

NC Department of Health and Human Services **Raleigh, NC**
Deputy Secretary 2017-2018
Served the State of North Carolina as the number two official in the Department of Health and Human Services, managing a $20 billion budget and 15,000 employees. Oversaw initial transformation of state Medicaid program from fee-for-service to managed care.

Center for Consumer Information and Insurance Oversight **Washington, DC**
Principal Deputy Director 2015-2017
Served as the second-highest ranking official in the federal agency responsible for implementing the insurance market reforms in the Affordable Care Act. Led the agency as the primary day-to-day decision-maker with responsibilities similar to a chief operating officer.

White House Domestic Policy Council **Washington, DC**
Senior Policy Advisor for Health Reform 2013-2015
Managed the policy portfolio related to the Affordable Care Act's insurance reforms, Medicaid expansion, and tax policy.

U.S. Department of Health and Human Services **Washington, DC**
Director of Coverage Policy, Office of Health Reform 2013
Supported the Secretary's Office in implementation of the Affordable Care Act's coverage expansion, including insurance reforms and Medicaid expansion.

U.S. Department of Health and Human Services **Washington, DC**
Policy Analyst & Presidential Management Fellow 2009-2011
Supported policy analysis in the Office of Health Reform and the Washington Office of the CDC.

EDUCATION

Yale Law School **New Haven, CT**
Juris Doctor 2009
Editor-in-Chief, *Yale Journal of Health Policy, Law, and Ethics*; Senior Editor & Admissions Committee, *Yale Law Journal*

Stanford University **Stanford, CA**
Bachelor of Science with Honors and with Distinction, Biological Sciences 2004

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Christen Linke Young, "Remanding *Texas v. U.S.* to the Lower Court Prolongs Harms to Consumers and the Health Care Industry," *Brookings Institution*, January 3, 2020.

Christen Linke Young, "The Supreme Court Will Hear a Health Care Case in December, but its Decision on Risk Corridors Won't Affect the ACA," *Brookings Institution*, November 4, 2019.

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Loren Adler, Steven M. Lieberman, Christen Linke Young, and Paul B. Ginsburg, "Considerations for Expanding International Reference Pricing beyond Medicare Part B," *Health Affairs Blog*, September 9, 2019.

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Christen Linke Young, Note, *Pay or Play and ERISA Section 514*, 10 YALE J. HEALTH POL'Y, L. & ETHICS 197 (2009).

Christen Linke Young, Note, *Childbearing, Childrearing, and Title VII*, 118 YALE L.J. 1182 (2009).

Christen Linke Young, *FDA Preemption Inputs in* Riegel v. Medtronic, 118 YALE L.J. POCKET PART 22 (2008).

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

DECLARATION OF DR. EMILY GEE

I, Dr. Emily Gee, declare under penalty of perjury as prescribed in 28 U.S.C. § 1746:

1. The facts contained in this declaration are known personally to me and, if called as a witness, I could and would testify competently thereto under oath. I submit this sworn declaration in support of the City of Chicago's motion for a preliminary injunction or, in the alternative, expedited summary judgment.

2. I am the Health Economist for the Health Policy team at the Center for American Progress in Washington, DC. The Center for American Progress (CAP) is an independent nonpartisan and multi-issue policy institute dedicated to improving the lives of all Americans. CAP staff regularly advise federal, state, and local government policy makers, and CAP analyses and policy proposals are frequently cited by the news media. I have worked at CAP since February 2017. I have written dozens of publications on health policy topics for CAP, including on health care reform, hospital finance, the Affordable Care Act (ACA), and the COVID-19

pandemic.[1] My research and analysis has received attention in such media outlets as Politico, NPR, Vox, *The Washington Post,* CNBC, and *The Hill.* I have also been interviewed for television as an expert on health policy issues by C-SPAN, Univision, and local networks.

3. Prior to my current job, I was a career employee for the federal government. I served as an Economist in the U.S. Department of Health and Human Services (HHS) in the Office of the Assistant Secretary for Planning and Evaluation. I led the office's team for Health Insurance Marketplace enrollment analytics, participated in interagency working groups on the implementation of the Affordable Care Act, and authored issue briefs on trends in health insurance coverage and eligibility for public insurance programs. I collaborated with colleagues across the Centers for Medicare and Medicaid Services (CMS) and other offices in HHS to support the department's outreach to uninsured individuals during the initial launch of the Exchanges and the first few ACA open enrollment periods. In fall 2016, I was detailed from HHS to the staff of the Council of Economic Advisers (CEA) at the White House. As an Economist at the CEA, my duties included tracking trends in health care coverage, access, and costs and reviewing regulations related to provider payments, prescription drugs, and private insurance.

4. I hold an A.B. in government from Harvard College. I earned an M.A. in Political Economy and a Ph.D. in Economics from Boston University, where I wrote my dissertation on consumer choice in health insurance markets. I also taught a course in health economics at Boston University, and I have given talks and guest lectures on health insurance coverage at

[1] *See Emily Gee*, Ctr. for Am. Progress, https://www.americanprogress.org/about/staff/gee-emily/bio/ (last visited May 28, 2020).

other academic institutions and conferences. My research on health insurance coverage has been published in peer-reviewed economics journals.

I. Summary of observations and opinions.

5. The COVID-19 pandemic is expected to cause tens of millions of Americans to lose their current health insurance coverage. This is a problem because, among other things, health care providers are often not reimbursed for care provided to uninsured individuals, and because uninsured individuals often delay seeking necessary care or forgo care altogether.

6. A national special enrollment period (SEP) would rapidly provide individuals who lacked coverage before the pandemic, as well as individuals who have lost coverage as a result, with the ability to obtain ACA-compliant coverage. Based on national enrollment figures and figures released by state Exchanges that have conducted their own special enrollment periods, I conservatively estimate that a national special enrollment period on the 38 federally-facilitated or hybrid Exchanges would have resulted in 422,000 to 667,000 Americans enrolling in such coverage from mid-March to mid-May 2020. A longer SEP would likely result in far more sign-ups.

II. Coverage losses during the pandemic and implications.

7. Prior to the COVID-19 pandemic, over half of all nonelderly Americans, or 153 million people, had health insurance coverage through an employer.[2] This includes both workers and their dependents.

8. Many Americans have lost insurance as a result of the pandemic. Specifically, over 38 million people filed unemployment claims from March through May 2020,[3] which also means that millions have lost their source of health insurance coverage.

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[2] *2019 Employer Health Benefits Survey: Summary of Findings*, Kaiser Fam. Found. (Sept. 25, 2019), https://www.kff.org/report-section/ehbs-2019-summary-of-findings/.

9. Two recent studies highlight the tremendous volume of potential coverage losses that the Exchanges may face this year. Based on unemployment claims filed as of early May, the Kaiser Family Foundation estimates 26.8 million people across the country would become uninsured due to loss of job-based health coverage if they don't sign up for other coverage. Of those, 12.7 million would be Medicaid eligible, 8.4 million would be eligible for tax credits through the Exchanges, and yet others would be eligible for unsubsidized Exchange coverage.[4]

10. The Urban Institute projects a shift in insurance coverage of a similar magnitude. It estimates that if the COVID-19 crisis generates a 20% increase in unemployment, 25 million people would lose their job-based coverage.[5] While 12 million could be expected to obtain coverage through Medicaid and 6 million through the Exchanges or other private coverage, about 7 million of those who lost employer-sponsored coverage would remain uninsured. The Urban report also notes that some people who lose job-based coverage may not realize they are eligible for Exchange coverage and that "creating a national special open enrollment period, regardless of whether a person had prior insurance coverage" could help minimize the number who end up uninsured.

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[3] *"Jaw-Dropping" Fraud Reported as Jobless Claims Reach 38.6 Million*, N.Y. Times, (May 21, 2020), https://www.nytimes.com/2020/05/21/us/coronavirus-news-tracker.html.

[4] Rachel Garfield et al., *Eligibility for ACA Health Coverage Following Job Loss*, Kaiser Fam. Found. (May 13, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/eligibility-for-aca-health-coverage-following-job-loss/.

[5] Bowen Garrett & Anuj Gangopadhyaya, *How the COVID-19 Recession Could Affect Health Insurance Coverage*, Urban Inst. 3 (May 2020), https://www.urban.org/sites/default/files/publication/102157/how-the-covid-19-recession-could-affect-health-insurance-coverage_0.pdf.

11. Surveys show that the uninsured are more than twice as likely to delay or forgo care due to cost compared to those with Medicaid.[6] Historically, people who are uninsured are less likely to have a usual source of care,[7] and are more likely to report that when they do seek out care, they rely on the emergency department.[8]

12. When uninsured and underinsured people seek care they cannot afford, hospitals and other providers, including clinics and emergency departments, sometimes provide uncompensated care. This can take the form of care provided free upfront as a form of charity or as written-off medical debt. In other cases, however, hospitals and other providers have historically resorted to aggressive measures to collect payment such as selling debt to collection, garnishing wages, or suing patients. Increasing comprehensive health insurance coverage, including through Exchange enrollment, would protect patients from medical debt and help ensure that health care providers are paid for services they provide. For example, studies show that uncompensated care declined as a share of hospitals' operating costs in the wake of the ACA's Medicaid expansion.[9]

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[6] *See, e.g.*, Jennifer Tolbert et al., *Key Facts About the Uninsured Population*, Kaiser Fam. Found. (Dec. 13, 2019), https://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/.

[7] Rachel Garfield et al., *The Uninsured and the ACA: A Primer—Key Facts about Health Insurance and the Uninsured Amidst Changes to the Affordable Care Act*, Kaiser Fam. Found. (Jan. 25, 2019), https://www.kff.org/report-section/the-uninsured-and-the-aca-a-primer-key-facts-about-health-insurance-and-the-uninsured-amidst-changes-to-the-affordable-care-act-how-does-lack-of-insurance-affect-access-to-care/.

[8] Rachel Garfield et al., *The Uninsured at the Starting Line: Findings from the 2013 Kaiser Survey of Low-Income Americans and the ACA*, Kaiser Fam. Found. (Feb. 6, 2014), https://www.kff.org/report-section/the-uninsured-at-the-starting-line-findings-from-the-2013-kaiser-survey-of-low-income-americans-and-the-aca-iii-gaining-coverage-getting-care/.

[9] *See, e.g.*, David Dranove et al., *Uncompensated Care Decreased at Hospitals in Medicaid Expansion States but Not at Hospitals in Nonexpansion States*, 35 Health Affairs 1471 (Aug. 1, 2016), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1344.

13. Without insurance, people run the risk of large and unexpected medical costs. Although the legislative packages passed by Congress during the pandemic have helped to make COVID-19 testing free and COVID-related care affordable, people in the United States remain vulnerable to high medical bills for care related to the diagnosis of and treatment related to COVID-19 symptoms. This includes patients who ultimately do not receive a COVID-19 test or are tested and treated for conditions other than COVID-19.[10] To stop the spread of the novel coronavirus, it is crucial that people with COVID-like illness be willing to step forward for testing and treatment, regardless of whether their illness is confirmed to be COVID-19.

III. The need for a broad, nationwide SEP.

14. In general, people who have lost job-based coverage qualify for a special enrollment period for individual market plans through the Affordable Care Act's Health Insurance Exchanges, allowing them to enroll outside the annual open enrollment period. As it is, the Exchanges will likely attract an unusually high number of enrollment applications during the pandemic, in addition to the typical SEP activity among people who qualify based on job changes, moving, marriage, and other qualifying events.

15. Opening a nationwide special enrollment period, without eligibility restrictions, in response to the pandemic would immediately provide an opportunity for many of the uninsured

[10] *See* Kao-Ping Chua & Rena Conti, *Congress Must Do More to Lower Out-Of-Pocket Costs for Coronavirus Detection*, Detroit Free Press (Apr. 26, 2020), https://www.freep.com/story/opinion/contributors/2020/04/25/coronavirus-testing-isnt-always-free-congress-should-fix-that/3016162001/; Phil Galewitz, *COVID-Like Cough Sent Him To ER—Where He Got A $3,278 Bill*, Kaiser Health News (May 25, 2020), https://khn.org/news/covid-like-cough-covid19-symptoms-emergency-room-billing-code-surprise-medical-bill/.

to obtain coverage. A dozen state-based exchanges, in states that operate their own enrollment platforms, have already offered SEPs to the uninsured due to the pandemic.[11]

16. However, CMS has not declared a similar SEP for the 38 states using the federally-facilitated Exchange (FFE) platform, including the state-based Exchanges that use the federal HealthCare.gov website as an enrollment portal. These states account for the vast majority of Exchange enrollment: during the open enrollment period for 2020 coverage, 11.4 million people enrolled in Exchange coverage nationwide; of these, 8.3 million people were enrolled in FFE states.[12]

17. Without a nationwide SEP with broad eligibility, newly jobless Americans face hurdles to obtaining Exchange coverage. If a person qualifies for an SEP based on the loss of job-based coverage, they generally need to file documents proving their eligibility and receive verification prior to enrollment. This process may be overly burdensome at a time when millions of Americans who have lost their jobs are simultaneously experiencing other disruptions to their lives, such as complying with stay-at-home orders and being unable to access websites for filing for unemployment.

18. Reportedly, CMS has waived the requirements to file documentation to qualify for an SEP for loss of job-related coverage during the pandemic, allowing an attestation instead.[13] Yet as of May 27, the federal HealthCare.gov enrollment portal still tells consumers

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[11] *State Data and Policy Actions to Address Coronavirus*, Kaiser Fam. Found. (June 11, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/state-data-and-policy-actions-to-address-coronavirus/.

[12] *Marketplace Enrollment, 2014–2020*, Kaiser Fam. Found. (2020), https://www.kff.org/health-reform/state-indicator/marketplace-enrollment/.

[13] Amy Lotven, *CMS Won't Do SEP Outreach, But Will Grant Flexibility*, InsideHealthPolicy, Apr. 20, 2020, https://insidehealthpolicy.com/daily-news/cms-wont-do-sep-outreach-will-grant-flexibility.

who say they have lost coverage that "you may be required to submit documents showing the coverage you lost and the date it ended" and that they can "select a plan now and submit the documents later," along with a link to "acceptable documents."[14] The appearance of these requirements may discourage some people from seeking coverage or completing applications.

19. In addition, no SEP is available for uninsured people who have lost their job or are working reduced hours but did not lose job-based coverage, or for people who were uninsured or underinsured to begin with. As of 2018, approximately 28 million Americans were uninsured, according to the U.S. Census Bureau.[15] A categorical special enrollment period without eligibility restrictions would allow these individuals to enroll as well.

IV. Estimates for how many would seek to enroll.

20. National enrollment figures and figures from the state exchanges that offered their own special enrollment period are the best measure for estimating how many Americans might seek to enroll through a national SEP. For example, Covered California, the Exchange for the state of California, was among those that opened enrollment to "any eligible uninsured individuals" due to the pandemic. It made enrollment eligibility criteria "similar to those in place during the annual open-enrollment period." Covered California reported that 123,810 people had signed up via an SEP between March 20 and May 16, "nearly 2.5 times higher than the level

[14] *It Looks Like You May Qualify for A 2020 Special Enrollment Period*, HealthCare.gov, https://www.healthcare.gov/screener/loss-of-coverage.html (last visited May 27, 2020).

[15] Edward R. Berchick et al., *Health Insurance Coverage in the United States: 2018*, No. P60-267 (RV), U.S. Census Bureau (Nov. 8, 2019), https://www.census.gov/library/publications/2019/demo/p60-267.html.

Covered California saw during the same time period in 2019."[16] Covered California's SEP is scheduled to close on June 30.[17]

21. Based on those figures, and as explained more fully below, I conservatively estimate that about 422,000 to 667,000 people would have enrolled in coverage if CMS had allowed a similar SEP during that roughly 60-day March–May period. More would enroll if the SEP were to last beyond that.

22. The 422,000 figure uses historical SEP enrollment as a starting point. CMS had reported that "[f]or states using the Federal platform for plan year 2017, 1.1 million individuals applied for coverage after OEP [the Open Enrollment Period] and made a plan selection through a SEP, while approximately 9.2 million individuals had an active plan selection at the close of the 2017 OEP."[18] In other words, SEP activity in a typical year is about 12% of total open enrollment plan selections. If 2020 SEP enrollment were similar to that in 2017, in the absence of the pandemic and its associated economic disruption, one would expect total SEP enrollment for 2020 to be 12% of total open enrollment, or 1.0 million enrollments. This would mean approximately 169,000 expected enrollments over a given 60-day period if SEP enrollment were spread out evenly over the 12 months of the year. If CMS had declared an SEP open to all eligible uninsured Americans and the FFE states had SEP enrollment also roughly 2.5 times the typical level (akin to Covered California), we would have expected 422,000 people to have

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[16] Press Release, *Covered California Sees More Than 123,000 Consumers Sign Up for Coverage During the COVID-19 Pandemic*, Covered Cal. (May 20, 2020), https://www.coveredca.com/uploads/05-20-20-coveredca-sep-data.pdf.

[17] Press Release, *California Responds to COVID-19 Emergency by Providing Path to Coverage for Millions of Californians*, Covered Cal. (Mar. 20, 2020), https://www.coveredca.com/newsroom/news-releases/2020/03/20/california-responds-to-covid-19-emergency-by-providing-path-to-coverage-for-millions-of-californians/.

[18] *The Exchanges Trend Report*, CMS (July 2, 2018), https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf.

enrolled in Exchange coverage in the FFM states, which is 253,000 more people compared to expected normal levels.

23. For the second, 667,000 estimate, note that Covered California's total SEP enrollment during the 60-day COVID SEP was equal to about 8% of that state's 1.5 million sign-ups during the open enrollment period for plan year 2020 coverage and the state says that SEP activity was 2.5 times higher than typical than last year over the same 60-day period. If CMS had designated a similar SEP and enrollment was equivalent to 8% of the 8.3 million open enrollment period sign-ups, then the 38 FFE states would have enrolled a total of 667,000 people via that SEP. If, like in California, that FFE SEP enrollment had been 2.5 times greater than typical, then that total FFE SEP sign-ups would have been 396,000 greater than would be expected in the absence of the pandemic over the period.

24. Again, I believe these estimates of SEP enrollment are conservative. If an SEP for the FFE commenced sometime after today, enrollment for a given 60-day period might be even greater. Given that the pandemic and the economic hardship it has caused are expected to last months, an SEP of a longer duration would likely result in even more enrollment in the Exchanges. Moreover, Covered California's SEP began relatively early in the pandemic, and the mounting job losses and the crisis's financial strain on families may have heightened the salience of health insurance coverage among potential enrollees.

25. In comparison, an analysis by health care analyst Charles Gaba estimates that, based on recent jobless claims numbers, as many as 1.8 million to 2.4 million people would enroll in Exchange coverage if there were an SEP for the pandemic in all states.[19] In addition, the

[19] Charles Gaba, *UPDATE: 1.8 - 2.4 Million more Americans would likely #GetCovered if HealthCare.Gov launched #COVID19 SEP*, ACASignups.net (Apr. 14, 2020),

projections by the Kaiser Family Foundation and the Urban Institute also suggest that the economic effects of the pandemic will make millions newly eligible for subsidized and unsubsidized coverage. The extent to which those people enroll in coverage—and avoid becoming uninsured—will depend on awareness of the Exchanges and the ease of enrollment.

26. A national SEP with broad eligibility could reduce uninsurance beyond the Exchanges. An SEP is likely to have spillover effects that boost enrollment in other public programs, including among those eligible for Medicaid and the Children's Health Insurance Program (CHIP). The "welcome mat" effect of the ACA's coverage expansion is well-documented: the expansion of Medicaid in some states and the opening of the Exchanges led to increases in the rate of insurance coverage among people who were already eligible for Medicaid/CHIP.[20] Amid the ongoing financial strain of the economic crisis on American families, Medicaid/CHIP coverage is also more important for protecting them from additional, unexpected costs from health care.

27. Some may argue that introducing an SEP during a pandemic increases the risk of adverse selection in the Exchanges, making it more likely that people who are or expect to be sicker than average enroll in coverage, which could raise insurers' costs and increase premiums in the future. Concern about adverse selection is why health insurance enrollment is typically only available during certain annual periods. In my opinion, the value of expanding coverage amid the novel threat posed by the pandemic outweighs the risk of some adverse selection in

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http://acasignups.net/20/04/16/update-18-24-million-more-americans-would-likely-getcovered-if-healthcaregov-launched.

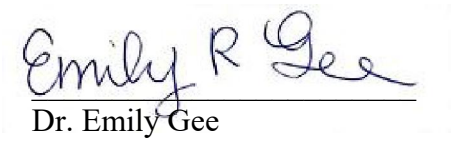
[20] Molly Frean et al., *Understanding ACA's Coverage Gains: Welcome Mat Effect & State Marketplaces Keys to Success*, Geo. Univ. Health Pol'y Inst.: Say Ahhh! Blog, (May 18, 2016), https://ccf.georgetown.edu/2016/05/18/understanding-acas-coverage-gains-welcome-mat-effect-state-marketplaces-keys-successful-expansion/.

enrollment under a broad SEP. In fact, enrollees at the margin may be younger and healthier than average. An SEP for the uninsured could attract enrollees among the so-called young invincibles who previously believed that their good health made insurance not worth the cost. Some of the states that have created a COVID-19 SEP for their own Exchanges have seen just such an increase in younger customers. Maryland and Rhode Island report that more than half of those enrolling through the COVID-19 SEP are below the age of 35.[21] By contrast, just 35% of enrollees in the FFE during open enrollment were under age 35.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 12, 2020

Washington, DC



Dr. Emily Gee

[21] Rachel Schwab et al., *During the COVID-19 Crisis, State Health Insurance Marketplaces Are Working to Enroll the Uninsured*, The Commonwealth Fund: To The Point, (May 19, 2020), https://www.commonwealthfund.org/blog/2020/during-covid-19-crisis-state-health-insurance-marketplaces-are-working-enroll-uninsured.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

DECLARATION OF GILBERT ORBEA

I, Gilbert Orbea, declare under penalty of perjury as prescribed in 28 U.S.C. § 1746:

1. The facts contained in this declaration are based on my personal knowledge, and I can testify competently to them if called upon to do so.

2. I am a Legal Assistant at Democracy Forward Foundation, which serves as counsel to the City of Chicago in the above-captioned matter. I submit this sworn declaration in support of the City's motion for a preliminary injunction or, in the alternative, expedited summary judgment.

3. Attached as Exhibit B-1 is a true and correct copy of Mohana Ravindranath, *Trump Officials Weigh Reopening Obamacare Enrollment Over Coronavirus*, Politico (Mar. 21, 2020), available at https://www.politico.com/news/2020/03/21/trump-administration-obamacare-coronavirus-140806.

4. Attached as Exhibit B-2 is a true and correct copy of Adam Cancryn et al., *How Trump Surprised His Own Team by Ruling Out Obamacare*, Politico (Apr. 3, 2020), available at https://www.politico.com/news/2020/04/03/trump-obamacare-coronavirus-164285.

5. Attached as Exhibit B-3 is a true and correct copy of Margot Sanger-Katz & Reed Abelson, *Obamacare Markets Will Not Reopen, Trump Decides*, N.Y. Times (Apr. 1, 2020), available at https://www.nytimes.com/2020/04/01/upshot/obamacare-markets-coronavirus-trump.html.

6. Attached as Exhibit B-4 is a true and correct copy of Scott Bixby et al., *Biden Tells Trump: Stop the 'Pettiness' and Reopen Obamacare*, Daily Beast (Apr. 3, 2020), available at https://www.thedailybeast.com/biden-tells-trump-stop-the-pettiness-and-reopen-obamacare.

7. Attached as Exhibit B-5 is a true and correct copy of Susannah Luthi, *Trump Rejects Obamacare Special Enrollment Period Amid Pandemic*, Politico (Mar. 31, 2020), available at https://www.politico.com/news/2020/03/31/trump-obamacare-coronavirus-157788.

8. Attached as Exhibit B-6 is a true and correct copy of excerpts of *Transcript: ABC News Anchor David Muir Interviews President Trump*, ABC News (Jan. 25, 2017), available at http://abcnews.go.com/Politics/transcript-abc-news-anchor-david-muir-interviews-president/story?id=45047602.

9. Attached as Exhibit B-7 is a true and correct copy of Alan Rappeport, *Trump Says He Got Rid of Obamacare. The I.R.S. Doesn't Agree*, N.Y. Times (May 6, 2018), available at https://www.nytimes.com/2018/05/06/business/trump-obamacare-irs.html.

10. Attached as Exhibit B-8 is a true and correct copy of Laura Litvan (@LauraLitvan), Twitter (June 23, 2018, 4:04 PM), available at https://twitter.com/LauraLitvan/status/1010614472946352128.

11. Attached as Exhibit B-9 is a true and correct copy of excerpts of *President Trump Calls the Show!*, Rush Limbaugh Show (Aug. 1, 2018), available at https://www.rushlimbaugh.com/daily/2018/08/01/president-trump-calls-the-show/amp/.

12. Attached as Exhibit B-10 is a true and correct copy of excerpts of *Speech: Donald Trump Holds a Political Rally in Southaven, MS – October 2, 2018*, Factbase, available at https://factba.se/transcript/donald-trump-speech-maga-rally-southaven-ms-october-2-2018.

13. Attached as Exhibit B-11 is a true and correct copy of excerpts of *Speech: Donald Trump Holds a Political Rally in Huntington, West Virginia – November 2, 2018*, Factbase, available at https://factba.se/transcript/donald-trump-speech-maga-rally-huntington-wv-november-2-2018.

14. Attached as Exhibit B-12 is a true and correct copy of Jim Acosta (@Acosta), Twitter (Nov. 2, 2018, 8:19 PM), available at https://twitter.com/acosta/status/1058514065595777024?s=21.

15. Attached as Exhibit B-13 is a true and correct copy of Nikki Carvajal, *Trump Says Administration Will Continue Legal Fight to Eliminate Obamacare*, CNN (May 6, 2020), available at https://www.cnn.com/2020/05/06/politics/trump-obamacare/index.html.

16. Attached as Exhibit B-14 is a true and correct copy of Greg Johnson, *Former Blackjewel Workers Get Special Exemption from Health Marketplace*, Gillette News Record (Sept. 5, 2019), available at https://www.gillettenewsrecord.com/news/local/article_df4c2e6b-6e6f-5f74-875a-7a2417a944ed.html.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 15, 2020

Washington, DC

/s/ Gilbert Orbea
Gilbert Orbea

Exhibit B-1

POLITICO

CORONAVIRUS

Trump officials weigh reopening Obamacare enrollment over coronavirus

A number of Democratic-leaning states that run their own health insurance marketplaces have recently reopened enrollment.

Centers for Medicare and Medicaid Services Administrator Seema Verma. | Carolyn Kaster/AP Photo

By **MOHANA RAVINDRANATH**
03/21/2020 07:06 PM EDT

The Trump administration is considering whether to create a special enrollment period for Obamacare coverage because of the coronavirus emergency, a CMS spokesperson confirmed.

A number of Democratic-leaning states that run their own health insurance marketplaces have recently reopened enrollment, encouraging uninsured residents to get covered amid the pandemic. Most states, however, use the federal marketplace overseen by the Trump administration, HealthCare.gov.

Major health insurance lobbies on Friday said they would support reopening enrollment in Obamacare markets if the government covered anticipated losses, despite some initial reluctance. Some insurers feared getting saddled with huge costs if many coronavirus patients signed up for coverage.

The insurer lobbies, America's Health Insurance Plans and the Blue Cross Blue Shield Association, called on Congress this week to include funding in the upcoming coronavirus stimulus package to offset potential losses from covering more people.

The Wall Street Journal first reported the administration was weighing a special enrollment period.

A spokesperson for CMS, which oversees the insurance marketplaces, said people should also check HealthCare.gov to see if they already qualify for a

special enrollment period because they lost their job or other circumstances.

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Trump's reopening troubles play out in his White House

3

Exhibit B-2

POLITICO

CORONAVIRUS

How Trump surprised his own team by ruling out Obamacare

Insurers were prepared to extend coverage, HHS officials were largely on board, but the White House refused to reopen enrollment.

President Donald Trump at a daily White House coronavirus briefing. | Win McNamee/Getty Images

By **ADAM CANCRYN**, **NANCY COOK** and **SUSANNAH LUTHI**
04/03/2020 10:30 PM EDT

As the coronavirus ran rampant and record jobless numbers piled up, the

nation's health insurers last week readied for a major announcement: The Trump administration was reopening Obamacare enrollment to millions of newly uninsured Americans.

It was an announcement that never came.

The White House instead rejected the prospect of allowing new sign-ups across the 38 Affordable Care Act marketplaces it controls — a decision that shocked the health care industry, triggered widespread criticism and prompted a scramble within the administration to find a new way to care for the growing population left exposed to the pandemic.

It's also one that allowed Trump to sidestep an awkward reckoning with the Affordable Care Act, which he's long vowed to kill, and the health care program bearing the name of his Democratic predecessor. The president opposed reopening the Obamacare marketplaces when presented with the option, one person familiar with the decision said — prompting the creation of an initiative that federal officials are now rushing to construct.

"You have a perfectly good answer in front of you, and instead you're going to make another one up," said one Republican close to the administration. "It's purely ideological."

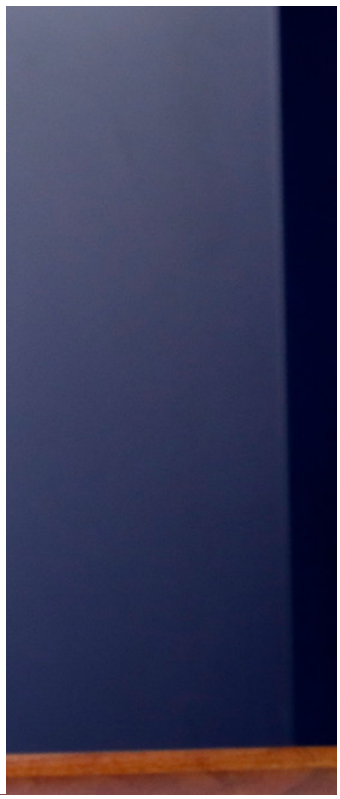
On Friday, Trump touted his administration's plan to cover uninsured patients' coronavirus treatments by paying hospitals for their costs, on the condition

that providers also not stick those people with separate charges.

“This should alleviate any concern uninsured Americans may have about seeking the coronavirus treatment,” Trump said during a news briefing. “So that, I think, answers the question pretty well and very much in favor of our great people.”

The rollout of the new hospital payment program capped a frenetic several days within the administration, prompted by a White House official’s confirmation Tuesday that there would be no reopening of the Obamacare markets.

That declaration surprised even some officials in the Health and Human Services Department, who believed the concept was still under consideration. And amid a crush of criticism from Democrats led by 2020 presidential frontrunner Joe Biden, it worried officials who viewed the verdict as an unforced error in the middle of a historic pandemic.



“It’s a bad decision opticswise,” one administration official said in the immediate aftermath. “It politicizes people’s access to health services during a

serious national health emergency."

Over the prior weeks, health officials charged with overseeing Obamacare had debated offering special access to those caught without insurance as the novel coronavirus spread, officials told POLITICO.

Several states with control over their own health exchanges had already flung their doors open in the past month, in an acknowledgment of the deepening crisis that's already killed thousands and threatens to persist well into the summer.

"We are in a unique situation," Michele Eberle, executive director in charge of Maryland's Obamacare market, said Wednesday, as the state led by GOP Gov. Larry Hogan announced it would enroll people through June 15. "The decision to extend the enrollment deadline was made to ensure as many people as possible get the coverage they need."

Health insurers that would be on the hook for covering the new population, including the Blue Cross Blue Shield Association, had also thrown their vocal support behind the idea.

"A Special Enrollment Period would offer much needed coverage to millions of Americans and mitigate the potential impact on providers and hospitals which will be forced to rely on emergency funding," the Alliance of Community

Health Plans wrote in a March letter to Centers for Medicare and Medicaid Services Administrator Seema Verma.

The move made sense to many in both the industry and Trump's own administration, because Americans who lose their health insurance as a result of losing their job are already eligible to sign up for Obamacare outside the traditional monthlong enrollment period. With the coronavirus pandemic straining hospitals and the administration's projections growing increasingly dire, health officials began signaling to insurers that it was preparing to give the broader pool of uninsured Americans a fresh shot at getting coverage, three people with knowledge of the discussions said.

And by late March, administration officials sent word to insurers that the call would soon be official: They were reopening Obamacare, an unprecedented move that would have recognized the depth of the public health emergency.

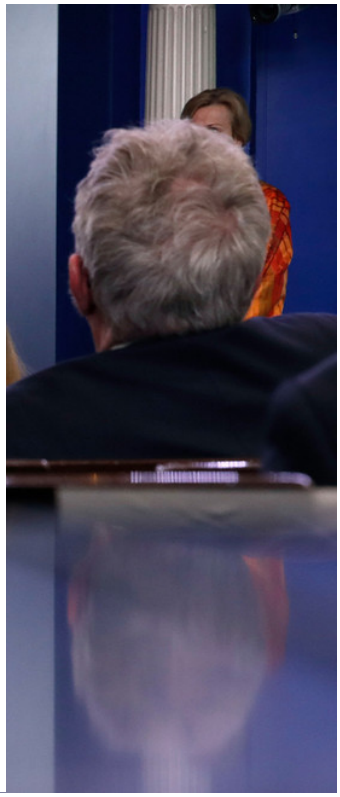
Major health insurance groups prepped news releases in anticipation of an announcement as soon as March 28, two people with knowledge of the arrangements said.

But that Saturday passed quietly, as inside the White House, senior aides to Trump balked at giving the proposal a final sign-off. Among the concerns: The insurers calling loudly for reopening the markets would return weeks later seeking a bailout, as their new enrollees racked up medical expenses, a former senior administration official familiar with the decision said.

White House aides largely agreed it was far better to instead spend that money on hospitals, said two senior administration officials, even after officials at HHS and CMS had signaled plans to reopen the exchanges.

The aides also worried that Obamacare coverage would remain unaffordable for many Americans even if the administration reopened the markets — introducing a host of new political risks, another former senior administration official added.

By Tuesday, HealthCare.gov's grand reopening was off, with a White House official telling POLITICO that the administration was exploring alternative options.



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HHS spokespeople declined to address a series of questions about the decision-making process.

“We do not comment on internal deliberations," an HHS spokesperson said. "This has been publicly addressed during White House press briefings and we would point you to those comments.”

The White House declined comment.

Health and Human Services Secretary Alex Azar on Friday insisted that paying providers directly for coronavirus treatment represented a faster and more targeted solution.

The uninsured will be able to seek treatment immediately, without worrying about first purchasing insurance coverage, Azar said. And hospitals will be reimbursed swiftly for their expenses, on the additional condition that they not stick their patients with surprise bills.

“In many respects, it’s better for those uninsured individuals,” Azar said. “What President Trump is doing here with this money is an unprecedented disease-specific support of care for individuals to make sure that people get treatment.”

Yet the announcement comes with fresh questions about how smoothly the administration can run the payment process in the middle of an all-consuming crisis, how much of the $100 billion fund already earmarked for hospitals it will consume and how expansive the coverage for the uninsured will be.

If Trump had chosen instead to reopen the HealthCare.gov website — as 11 largely blue states that control their own markets have already done — people without insurance could buy more comprehensive policies that not only would

cover coronavirus treatments but any follow-up treatment, mental-health care, and future check-ups.

Trump, however, has long opposed Obamacare, pledging on the campaign trail to eliminate it and making the law's repeal and replacement a top priority of his presidency. That aspiration ended in failure in 2017, though the administration has successfully rolled back a central requirement that all Americans purchase health insurance.

The White House has since sought to limit Obamacare's reach, while backing a lawsuit by GOP-led states to wipe out the law altogether — a position it's continued to hold as coronavirus cases mount.

The decision not to reopen Obamacare enrollment prompted an immediate rebuke from Democrats and insurers.

"This callous decision will cost lives. Period," Biden tweeted on Wednesday.

The White House decision also caught the hospital industry off guard, frustrating executives who spent the past week awaiting guidance for how strained front-line facilities could access the new funding.

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"We're going to provide care to everyone, and we particularly want the uninsured to feel secure that the financing's not going to get in the way of their care. At the same time, though, the purpose of the $100 billion fund was to keep the doors of hospitals open," said Chip Kahn, CEO of the Federation of American Hospitals, which represents for-profit hospital systems. "I was a little disappointed that the first thing we hear about the fund is that it's going to be used for some other purpose."

Hospital groups are still scrambling for clarity on how much money would be taken from the fund and what the process would look like — warning that creating a whole new system for covering the uninsured might further delay payouts.

"You know what that's called? That's called single payer," one Republican lobbyist said of the plan to directly cover expenses for the uninsured.

Trump administration health officials are still trying to answer those key questions, too — a sign of how hastily the proposal was assembled, with the

White House only granting final approval hours before it was announced on Friday.

Still, administration officials maintain that the program represents a better solution than asking people to get their own coverage under Obamacare.

“People who lose their jobs and insurance can buy ACA insurance if they want, but we’re covering Covid testing for free and banning balance billing," said one senior administration official. "What is better than that? People want care, not coverage."

And hospitals could end up warming to the program, depending on whether the government reimburses according to a provision in Congress’ rescue package that mandates higher-than-normal pay rates for treating coronavirus patients.

“Medicare is a mediocre payer,” one lobbyist said, "but they’re a fast mediocre payer.”

Yet it’s not likely to quell criticism from consumer advocates and Democrats, who contend that it will force millions of Americans to remain uninsured — with little assurance so far that the government will similarly cover follow-up doctor visits or treatments for other medical conditions like pneumonia that are linked to coronavirus.

For Democrats in particular, the episode has energized a party that’s struggled in recent weeks to balance attacking Trump over a response they view as catastrophic with wariness over appearing overly political in the midst of a pandemic.

With attention shifting back to Obamacare — which has grown increasingly popular since the GOP’s failed 2017 bid to repeal the law — Democrats have appeared to find stable footing, pillorying the administration over its policy making.

“We have a health crisis, and it looks like we’re going to have a health insurance crisis,” Sen. Elizabeth Warren (D-Mass.) said in a lengthy Twitter

video attacking the White House's stance. "It's time for the federal government to just step up and say, 'We're going to cover everyone who doesn't have health insurance.'"

CORRECTION: An earlier version of this story misstated the name of a group representing nonprofit health insurers. It is the Alliance of Community Health Plans, not the Association of Community Health Plans.

FILED UNDER: DONALD TRUMP, DONALD TRUMP 2020, HEALTH CARE, CORONAVIRUS

Exhibit B-3

The Coronavirus Outbreak ›

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UPSHOT

Obamacare Markets Will Not Reopen, Trump Decides

The move would have made it easier for people who have recently lost jobs to obtain health insurance.


By **Margot Sanger-Katz** and **Reed Abelson**

April 1, 2020

President Trump late last week on his way to Naval Station Norfolk in Virginia. Sarah Silbiger/Getty Images

The Trump administration has decided against reopening the Affordable Care Act's Healthcare.gov marketplaces to new customers, despite broad layoffs and growing fears that people will be uninsured during the coronavirus outbreak.

The option to reopen markets, in what is known as a special enrollment period, would have made it easier for people who have recently lost jobs or who had already been uninsured to obtain health insurance. The administration has established such special enrollment periods in the past, typically in the wake of natural disasters.

The administration had been considering the action for several weeks, and President Trump mentioned such conversations in a recent news briefing. But according to a White House official, those discussions are now over. The news of the decision was previously reported by Politico.

The decision will not prevent Americans who recently lost their jobs from obtaining health insurance if they want it. Under current law, people who lose job-based insurance already qualify to enroll for health insurance on the marketplaces, but are required to provide proof that they lost their coverage. A special enrollment period would have made it easier for such people to enroll, because it would not require that paperwork. It also would have provided a new option for people who chose not to buy health insurance this year but want it now.

Though the administration continues to run the Affordable Care Act marketplaces, it has taken numerous steps to weaken them, and President Trump continues to call for the health law's elimination and replacement. The administration has joined a lawsuit with a group of Republican states that calls for the entire law to be overturned, which the Supreme Court will consider in its next term. Mr. Trump recently told reporters that he continues to support the suit, and would like to replace the law, though he has not specified a preferred policy alternative.

"What we want to do is get rid of the bad health care and put in a great health care," he said, in response to a question on March 22 about the lawsuit.

So far, the administration has declined to publicize the existing options for Americans who have recently lost health benefits through job reductions.

Eleven states and the District of Columbia have established special

enrollment periods to allow people to obtain new insurance coverage. The states are California, Colorado, Connecticut, Maryland, Massachusetts, Minnesota, Nevada, New York, Rhode Island, Vermont and Washington, and they control their marketplaces. But federal action would have been required to allow customers to re-enter the markets in the 38 states with markets run by Healthcare.gov. or that use the federal platform. (Idaho, which also runs its own marketplace, has decided against a special enrollment period.)

Insurers, which had been arguing in favor of the enrollment period, had been hopeful just a few days ago that the White House might announce such a step. But the situation suddenly became “fluid,” in the description of one executive. Another described the administration as divided about whether to proceed, especially given the president’s support for the lawsuit that would overturn the law.

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Numerous other health care provider and consumer groups, including the American Diabetes Association, Families USA and the New Hampshire Nurses Association, wrote a joint letter to the administration last month asking it to establish a special enrollment period. The groups argued that forcing people to verify eligibility "would not only delay care receipt, it would deter enrollment by healthy customers, endangering the individual-market risk pool," the grouping of customers that determines what the insurers charge for a policy.

Governors of several states also asked the administration to grant a special enrollment period, including Republican governors in Arizona and New Hampshire, and Democratic ones in Oregon, Michigan and New Jersey.

Many Democratic politicians criticized the decision Wednesday as insensitive to the needs of the public in a crisis, including Joe Biden, who leads the race for the Democratic presidential nomination. The Democratic Congressional Campaign Committee also released a statement, suggesting it may become a campaign issue. Democrats made health care a centerpiece of many House races in the 2018 midterm elections.

"In the midst of a global pandemic, Washington Republicans continue their crusade against the health and safety of the American public," said Fabiola Rodriguez, a spokeswoman for the group, in the statement. "By blocking uninsured Covid-19 patients from getting health care, Trump and his allies have decided to bankrupt American families. The American people deserve to know if House Republicans will stand up for the millions of Americans who face the challenge of being jobless and uninsured during the Covid-19 pandemic."

The Coronavirus Outbreak

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Updated May 28, 2020

“What is the risk of catching coronavirus from a surface?

Touching contaminated objects and then infecting ourselves with the germs is not typically how the virus spreads. But it can happen. A number of studies of flu, rhinovirus, coronavirus and other microbes have shown that respiratory illnesses, including the new coronavirus, can spread by touching contaminated surfaces, particularly in places like day care centers, offices and hospitals. But a long chain of events has to happen for the disease to spread that way. The best way to protect yourself from coronavirus —

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Both Democratic and Republican members of Congress had also urged the administration to consider a special enrollment period. But Congress declined to require such an enrollment period in its last round of coronavirus legislation, instead leaving the decision to federal officials.

In a statement Wednesday, Senator Cory Booker of New Jersey recommended that Congress include a special enrollment provision in its next round of coronavirus legislation. He had also proposed such language be included in the last bill. “At a time when our health care system is already under enormous strain, it makes no sense to willingly allow even more individuals to go without coverage,” he said.

Even though the White House official described the matter as decided, officials have the capability to establish a special enrollment period at any time.

Noah Weiland contributed reporting.

Comments 695
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Exhibit B-4

Biden Tells Trump: Stop the 'Pettiness' and Reopen Obamacare

URGENT CARE

"Trump must also withdraw his support for a partisan lawsuit that would undo the Affordable Care Act and take health coverage away from almost 20 million Americans," Biden said.

Scott Bixby, Sam Brodey, Hunter Woodall, Asawin Suebsaeng

Updated Apr. 03, 2020 8:03PM ET
Published Apr. 03, 2020 3:41PM ET

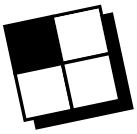
Once Lockdown Ends
ALAINA DEMOPOULOS

It's Official: Laura Ingraham Wants Your Grandmother to Die
MOLLY JONG-FAST

Vladimir Putin Is in Deep Trouble
ANNA NEMTSOVA

Former vice president and presumptive Democratic presidential nominee Joe Biden demanded that the Trump administration reopen enrollment in the Affordable Care Act health insurance exchanges, as millions of Americans—many of them newly unemployed—face the prospect of enduring the coronavirus pandemic without access to healthcare.

"During this outbreak, when health care coverage is more important than ever, Donald Trump is refusing to give those who have been uninsured access to the best resource we have: the Affordable Care Act's marketplaces," Biden said in an exclusive statement to The Daily Beast, in which he



for a special enrollment period.

"This is no time to put pettiness and ideology above helping those who are in the greatest need," Biden said, calling the spread of the novel coronavirus "the worst public health crisis in generations"—one for which the president failed to prepare the nation, "despite warning after warning."

Biden's statement reflects the fervent desire among many Democrats to make health insurance expansion a policy priority as the coronavirus continues to spread across the country and dislodges millions of people from their workplaces. Trump has faced mounting pressure to allow for a special enrollment period so that individuals who don't have insurance can purchase it.

...Virus Be Damned

| PLAYING THE HITS |

Sam Brodey

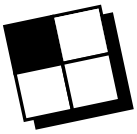
Last week, Trump told reporters that reopening the exchanges in light of the unique and dire circumstances was "something we're talking to a lot of people about." By this week, however, the administration had rejected the idea, dumbfounding health officials, insurers, and various others who'd hoped they would, or expected them to do so.

In meetings at the White House in the time between his stated consideration and his announced rejection of the idea, Trump on multiple occasions had referred to Obamacare as "a failure," and questioned why the administration should bother

And during a press briefing on Thursday, Trump reaffirmed that he was against leaning on Obamacare exchanges to help the uninsured get coverage in light of a growing pandemic. The president told reporters that he had a supposedly "better" idea.

"We are going to get a cash payment to the people and we are working out the mechanics of that with the legislature," he said. "So we are going to try and get them a cash payment because just opening it up doesn't help as much, so we're going to work it out... for that certain group of people a cash payment."

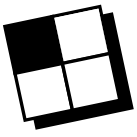
But the term "cash payment" confused even some of the president's own White House officials—two of whom messaged The Daily Beast while the press briefing was



not, in fact, heard about any proposals floated internally to airdrop “bags of cash” to people who’d just lost their jobs and health insurance.

When The Daily Beast asked the president Thursday night what he meant by delivering “cash payment” to offset loss of coverage, Trump stared blankly before quickly kicking it over to Vice President Mike Pence to try to explain the confusing new announcement. Pence’s answer, however, related to funding hospital treatment of coronavirus victims, not to any direct cash payments to workers seeking healthcare.

Asked during Friday's briefing about how federal stimulus money will help the uninsured, and whether it would be easier to re-open the markets, Health and Human Services Sec. Alex Azar said people who



Earlier in the briefing, Azar emphasized that funding will be used to cover costs of "delivering COVID-19 care for the uninsured."

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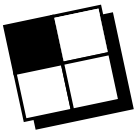
"Then what we're doing is taking from that $100 billion to providers, taking money and saying if you're a provider, and you care for anybody who's uninsured, we are going to compensate you for doing that and we're going to compensate you at the medicare reimbursement rates,

individuals.

“They're going to get first dollar coverage,” he said. “They're going to get care in the United States and the providers going to be made whole from this program.”

Though Congress has passed three different coronavirus relief bills, lawmakers have not yet approved any legislation to reopen Obamacare’s exchanges. The crisis, however, has grown only more dire. Individuals who lose employer-based health insurance are allowed to shop for new plans on the Obamacare exchanges, and a handful of states do still have active open enrollment periods.

But of the nearly 10 million Americans who have applied for unemployment benefits in the past two weeks, only 3.5 million are estimated to have lost their insurance along

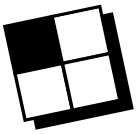


insurance marketplace during a pandemic. Some of those individuals may qualify for Medicaid, but experts say not everyone will be able to.

Democratic congressional leaders say they will fight to include such provisions to address lack of access to insurance in a widely-anticipated fourth round of coronavirus-related legislation, which could come as soon as this month.

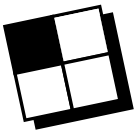
“We should open it,” said Sen. Chuck Schumer (D-N.Y.), the Senate Democratic leader, when asked about the exchanges by The Daily Beast on a Friday conference call. “This is a crisis; any way we can help people try to get health care, we should do it.”

Schumer also referenced Trump and Pence’s comments about “cash payments,” saying that the “administration is twisting



The Daily Beast reached out to a dozen GOP congressional offices to ask if they support opening the exchanges, but none responded. Key GOP lawmakers, however, have done more in recent years to shore up Obamacare than to dismantle it, and the party could warm to special enrollment as a way to ward off more aggressive Democratic health care measures, like Medicaid expansion, that are being proposed as a response to the coronavirus.

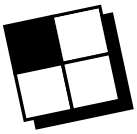
The lack of federal help so far has led some states, like Washington, to take their own action. In a statement to The Daily Beast, Washington Gov. Jay Inslee, a former 2020 Democratic presidential candidate, called on leaders to make sure people “get the medical care they need—especially as



state's Exchange just made the decision to extend our special enrollment period for anyone without insurance to get covered through May 8," Inslee said. "As states grapple with a rapidly evolving public health emergency, the federal government should do the same."

A similar sentiment was echoed by Michigan Gov. Gretchen Whitmer. Both her state and Inslee's have become focal points of the coronavirus pandemic, and both have been criticized by Trump in the midst of the health crisis. Last week, Trump bragged about telling Pence, the leader of the coronavirus task force, to skip calling the leaders of those two hard-hit areas.

"If they don't treat you right, I don't call," Trump said at the time.

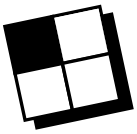


level, along with the private sector, to boost healthcare access. But she was "disappointed that the Administration is refusing to allow for a special enrollment period under the Affordable Care Act."

Thirteen GOP governors' offices were also asked by The Daily Beast about the Trump administration's decision, but only one responded with a comment.

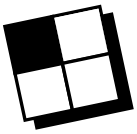
"Ohio is aware of this issue," a spokesperson for Gov. Mike DeWine said in an email. "Our Ohio Department of Insurance is monitoring the situation closely."

Advocates for healthcare reform have accused Trump of opposing reopening the exchanges because he is hostile to the Affordable Care Act itself, evidenced by his administration's continued attempts in federal court to



card is dangerously undermining our health care system with baseless attacks of Medicaid, sabotage of ACA exchanges, and toxic proposed budget cuts to Medicare," said Kyle Morse, a spokesperson for the liberal PAC American Bridge. "With 3.5 million people losing employer-sponsored health coverage in the middle of a pandemic, Donald Trump's decision to keep the exchanges closed for business will lead to higher death tolls and medical bills. Uninsured Americans are already being denied care and dying from Coronavirus, Trump's decision all but ensured that more will follow."

Biden told The Daily Beast that the president's continued pursuit of that case would eliminate health coverage for tens of millions of people.



Affordable Care Act and take health coverage away from almost 20 million Americans," Biden said.

Loading...

Exhibit B-5

POLITICO

CORONAVIRUS

Trump rejects Obamacare special enrollment period amid pandemic

President Donald Trump and administration officials recently said they were considering relaunching HealthCare.gov.

Win McNamee/Getty Images

By **SUSANNAH LUTHI**
03/31/2020 05:19 PM EDT
Updated: 03/31/2020 06:11 PM EDT

The Trump administration has decided against reopening Obamacare enrollment to uninsured Americans during the coronavirus pandemic, defying calls from health insurers and Democrats to create a special sign-up window amid the health crisis.

President Donald Trump and administration officials recently said they were considering relaunching HealthCare.gov, the federal enrollment site, and insurers said they privately received assurances from health officials overseeing the law's marketplace. However, a White House official on Tuesday evening told POLITICO the administration will not reopen the site for a special enrollment period, and that the administration is "exploring other options."

The annual enrollment period for HealthCare.gov closed months ago, and a special enrollment period for the coronavirus could have extended the opportunity for millions of uninsured Americans to newly seek out coverage. Still, the law already allows a special enrollment for people who have lost their workplace health plans, so the health care law may still serve as a safety net after a record surge in unemployment stemming from the pandemic.

Numerous Democratic-leaning states that run their own insurance markets have already reopened enrollment in recent weeks as the coronavirus threat grew. The Trump administration oversees enrollment for about two-thirds of states.

Insurers said they had expected Trump to announce a special enrollment period last Friday based on conversations they had with officials at the Centers for Medicare and Medicaid Services, which runs HealthCare.gov enrollment. It wasn't immediately clear why the Trump administration decided against the special enrollment period. CMS deferred comment to the White House.

Trump confirmed last week he was seriously considering a special enrollment period, but he also doubled down on his support of a lawsuit by Republican states that could destroy the entire Affordable Care Act, along with coverage for the 20 million people insured through the law.

People losing their workplace coverage have some insurance options outside of the law's marketplaces. They can extend their employer plan for up to 18 months through COBRA, but that's an especially pricey option. Medicaid is also an option for low-income adults in about two-thirds of states that have adopted Obamacare's expansion of the program.

Short-term health insurance alternatives promoted by Trump, which allow enrollment year-round, is also an option for many who entered the crisis without coverage. Those plans offer skimpier coverage and typically exclude insurance protections for preexisting conditions, and some blue states like California and have banned them or severely restricted them. The quality of the plans vary significantly and, depending on the contract, insurers can change coverage terms on the fly and leave patients with exorbitant medical bills.

- The White House is **struggling to keep its staffers safe** while pushing for reopening.
- **Jerome Powell** offers a grim unemployment forecast.
- Obama said leaders weren't "even pretending to be in charge." Trump **dismissed him** as "grossly incompetent."

Read all coronavirus coverage »

Major insurers selling Obamacare plans were initially reluctant to reopen the law's marketplaces, fearing they would be crushed by a wave of costs from Covid-19, the disease caused by the novel coronavirus. But the main insurance lobby, America's Health Insurance Plans, endorsed the special enrollment period roughly two weeks ago while also urging lawmakers to expand premium subsidies to make coverage more affordable for middle-income people.

Congress in last week's $2 trillion stimulus passed on that request, as well as insurers' petition for an open-ended government fund to help stem financial losses from an unexpected wave in coronavirus hospitalizations.

Democrats pushing for the special enrollment period are also grappling with the high costs facing many people with insurance despite new pledges from plans to waive cost-sharing. Obamacare plans and a growing number of those offered by employers impose hefty cost-sharing and high deductibles that could still burden infected Americans with thousands of dollar in medical bills.

House Energy and Commerce Chairman Frank Pallone (D-N.J.) on a press call Monday contended that "we also need to have free treatment" after Congress eliminated out-of-pocket costs for coronavirus tests.

"We did the testing, which is now free, and everybody, regardless of their insurance, gets it," Pallone said. "But that has to be for the treatment as well."

FILED UNDER: DONALD TRUMP, DONALD TRUMP 2020, OBAMACARE, CORONAVIRUS

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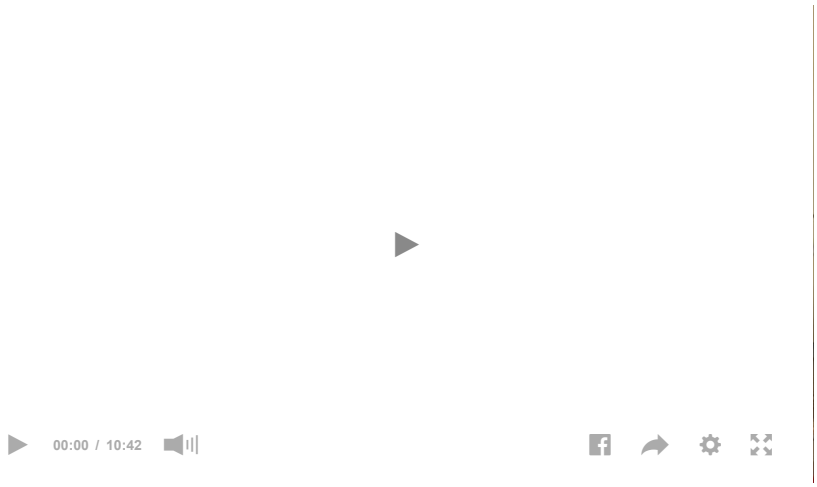
3

Exhibit B-6

TRANSCRIPT: ABC News anchor David Muir interviews President Trump

David Muir's interview with President Trump on Jan. 25, 2017.

By **ABC NEWS**
January 25, 2017, 10:25 PM • 45 min read



Trump: 'I Can Be the Most Presidential Person Ever' Other Than Lincoln

Five days in, has the weight of the office changed President Trump? "I want to make this a great success for the American people and for the people who put me in this position."

— -- On Wednesday, Jan. 25, 2017, ABC News "World News Tonight" anchor David Muir interviewed President Donald Trump in the White House. The following is a transcript of the interview:

DAVID MUIR: Mr. President, it's an honor to be here at the White House.

PRESIDENT TRUMP: Thank you very much, David.

DAVID MUIR: Let me ask you, has the magnitude of this job hit you yet?

PRESIDENT TRUMP: It has periodically hit me. And it is a tremendous magnitude. And where you really see it is when you're talking to the generals about problems in the world. And we do have problems in the world. Big problems. The business also hits because the -- the size of it. The size.

I was with the Ford yesterday. And with General Motors yesterday. The top representatives, great people. And they're gonna do some tremendous work in the United States. They're gonna build plants back in the United States. But when you see the size, even as a businessman, the size of the investment that these big companies are gonna make, it hits you even in

Top Stories

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Jan 25, 10:25 PM

ABC News Live Stream
Jan 03, 1:34 PM

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Man slashes married couple with machete, says he was angry over coronavirus lockdown
May 18, 7:25 AM

70 cases of COVID-19 at French schools days after re-opening
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unleash something that's gonna be terrific. And remember this, before Obamacare you had a lot of people that were very, very happy with their health care.

And now those people in many cases don't even have health care. They don't even have anything that's acceptable to them. Remember this, keep your doctor, keep your plan, 100 percent. Remember the $5 billion website? Remember the website fiasco. I mean, you do admit that I think, right? The website fiasco.

Obamacare is a disaster. We are going to come up with a new plan ideally not an amended plan because right now if you look at the pages they're this high. We're gonna come up with a new plan that's going to be better health care for more people at a lesser cost.

DAVID MUIR: Last question because I know you're gonna show me around the White House. Last question on this. You've seen the estimate that 18 million Americans could lose their health insurance if Obamacare is repealed and there is no replacement. Can you assure those Americans watching this right now that they will not lose their health insurance or end up with anything less?

PRESIDENT TRUMP: So nobody ever deducts all the people that have already lost their health insurance that liked it. You had millions of people that liked their health insurance and their health care and their doctor and where they went. You had millions of people that now aren't insured anymore.

DAVID MUIR: I'm just asking about the people ...

PRESIDENT TRUMP: No, no.

DAVID MUIR: ... who are nervous and watching ...

PRESIDENT TRUMP: We ...

DAVID MUIR: ... you for reassurance.

PRESIDENT TRUMP: ... here's what I can assure you, we are going to have a better plan, much better health care, much better service treatment, a plan where you can have access to the doctor that you want and the plan that you want. We're gonna have a much better health care plan at much less money.

And remember Obamacare is ready to explode. And you interviewed me a couple of years ago. I said '17 -- right now, this year, "'17 is going to be a disaster." I'm very good at this stuff. "'17 is going to be a disaster cost-wise for Obamacare. It's going to explode in '17."

And why not? Obama's a smart guy. So let it all come do because that's what's happening. It's all coming do in '17. We're gonna have an explosion. And to do it right, sit back, let it explode and let the Democrats come begging us to help them because it's on them. But I don't wanna do that. I wanna give great health care at a much lower cost.

Exhibit B-7

The New York Times https://nyti.ms/2FQb4Zo

Trump Says He Got Rid of Obamacare. The I.R.S. Doesn't Agree.

By Alan Rappeport

May 6, 2018

WASHINGTON — At a rally in Michigan a little over a week ago, President Trump assured his supporters that he had kept his promise to abolish the Affordable Care Act — even though Congress had failed to repeal the Obama-era health law.

"Essentially, we are getting rid of Obamacare," Mr. Trump said, reminding a cheering crowd that the individual mandate that required most people to have health insurance or pay a penalty was scrapped as part of the Republican tax bill he signed into law last year. "Some people would say, essentially, we have gotten rid of it."

But despite Mr. Trump's longstanding desire to unwind the signature legislative achievement of his predecessor, many parts of the Affordable Care Act remain in place. And the Trump administration is even enforcing some of its provisions more aggressively than President Barack Obama did — a reality that has enraged business groups and Republicans in Congress who still want the law officially repealed.

While the individual mandate may be dead, the employer mandate — the requirement that many companies offer health insurance to their workers or pay a penalty — is very much alive. Under Mr. Trump, the Internal Revenue Service has been pursuing companies that fail to comply with the mandate and, according to the agency, was sending penalty notices to more than 30,000 businesses around the country.

Business groups are pushing for the I.R.S. to stop enforcing the mandate and House Republicans, who voted to repeal much of the Affordable Care Act a year ago, have proposed legislation to eliminate it. But most Democrats oppose major changes to the law and the Republican leaders in the Senate have shown no interest in tackling health care after last year's stinging defeat.

The employer mandate requires companies with more than 50 full-time employees to provide health benefits to eligible employees or face fines of more than $2,000 per worker. The Congressional Budget Office predicted that these fines would total $12 billion in 2018.

The I.R.S. is working on settlements with some of the businesses that have had technical issues or paperwork glitches, according to David Kautter, the Treasury Department's assistant secretary for tax policy and the acting I.R.S. commissioner.

But other companies that have failed to provide insurance will face stiff fines.

"I think it is horribly unfair and unjust," Representative Jody Hice, a Republican from Georgia who has been a leading voice in the opposition to the employer mandate, said at a hearing where Mr. Kautter testified in April. "What I am asking at this point is for the I.R.S. to continue not to enforce it, as is what took place under the Obama administration," he said, referring to a reprieve that was granted while businesses and the government sorted out compliance details.

Some lawyers contend that the I.R.S. is on shaky ground in trying to enforce the employer mandate penalties, arguing that the government has not followed proper procedures, like notifying employers that they were in violation of the law.

"The Affordable Care Act and federal regulations clearly state that a health insurance exchange must notify an employer that one or more employees qualified for premium tax credits before the I.R.S. can impose penalties," said Christopher E. Condeluci, an employee benefits lawyer. "Most of the employers subject to penalties for 2015 never received the notices required under the law."

A worker answered questions about Affordable Care Act enrollment last year in Georgia. Under Mr. Trump, the Internal Revenue Service has been pursuing companies that fail to comply with the employer mandate and is sending penalty notices to more than 30,000 businesses around the country. Audra Melton for The New York Times

E. Neil Trautwein, a vice president of the National Retail Federation, said some penalties resulted from an employer's failure to check a particular box on a government form indicating that it had offered coverage to eligible employees.

In one case, Mr. Trautwein said, a $20 million penalty was imposed on a restaurant chain because one of its vendors had failed to check the proper box. "The penalty was negotiated down to zero," Mr. Trautwein said. "It was an inadvertent mistake in filling out a complicated new form."

John D. Arendshorst, an employee benefits attorney at Varnum, said he has been busy fielding questions from companies that have received proposed assessments from the I.R.S. and said the government has shown a willingness to reduce penalties when appropriate. In one case, a business with about 500 employees received an assessment for $1.9 million. That was ultimately reduced to $20,000 because the penalty was caused by a computer error.

"They were shocked for sure," Mr. Arendshorst said of the initial penalty letter. "They felt it was a big mistake and it turned out to be."

Under the Affordable Care Act, the employer mandate was to take effect in 2014. The Obama administration delayed enforcement for an additional year after employers said they needed more time to comply with rules requiring them to report on the coverage they provided to employees. And the Treasury Department needed more time to clarify the requirements. It was not until late last year that the I.R.S. had the capacity to determine which businesses were in violation of the mandate, and the agency is just now sending penalty letters related to the 2015 tax year. Penalty letters for the 2016 and 2017 tax years are expected to follow soon.

Republicans criticized the decision to begin enforcing the mandate as a parting shot by the former I.R.S. commissioner John Koskinen, whom they had previously assailed over the agency's scrutiny of conservative nonprofit organizations. While Mr. Trump had issued an executive order that called for easing the Affordable Care Act's regulations, the Treasury Department, which oversees the I.R.S., said it was required to abide by the law and enforce the employer mandate.

Mr. Koskinen pushed back against the idea that he was attempting to punish conservatives by jump-starting enforcement of the employer mandate, and he said that companies had been given plenty of notice that they needed to provide insurance to their employees.

"The I.R.S. does not have the authority not to collect the money," Mr. Koskinen said in an interview, adding that there was no reason to hold off on penalizing companies. "Delaying wouldn't accomplish anything except delay."

Business groups have been lobbying Congress to repeal the employer mandate or to get the I.R.S. to stop enforcing it. They argue that companies did not receive sufficient notice that they needed to comply with a provision of the health law that had not been enforced for seven years.

"The employer mandate always existed to support the individual mandate," said Jim Klein, president of the American Benefits Council. "There's no logic or fairness in having an employer mandate in the absence of having an individual mandate."

Mr. Klein said he would like to see a legislative fix to address the situation.

Mr. Trump himself has added to the confusion over the mandate by repeatedly asserting that the Affordable Care Act had been essentially eliminated because Republicans did away with the individual mandate.

"It's yet another reason why the employer mandate needs to go," Representative Kevin Brady of Texas, the Republican chairman of the House Ways and Means Committee, said of the penalties.

Exhibit B-8

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Laura Litvan
@LauraLitvan

Trump mocks John McCain's ``thumbs down'' on the Obamacare repeal, tells Nevada Republican convention that ``it doesn't matter. We gutted it anyway.''

4:04 PM · Jun 23, 2018 · Twitter Web Client

6.9K Retweets **6.5K** Likes

mclem8649 @mclem8649 · Jun 23, 2018
Replying to @LauraLitvan
You DO understand that his base is ecstatic about "gutting" Obamacare.
10 3 35

Lynn-just Lynn @Polyesther123 · Jun 23, 2018
Replying to @LauraLitvan and @ShawnaGrafton
It's sickening. His depravity knows no bounds. People are going to die. People are losing children. And if they get their way, Medicare and Medicaid will be gutted as well. The only thing that matters is that the rich get more, because they never can have enough.
1 9 20

Phil USA @phil200269 · Jun 24, 2018
Replying to @LauraLitvan and @JoyAnnReid
RINO John McCain Campaigned
On Repealing Obamacare.

Traitor McCain Took The Fake DNC Financed Steele Dossier To The FBI Which Began The Russian Collusion Hoax Investigation.

The Government Is Infested and We Elected Trump To Be The Exterminator.

#MAGA
#AmericaFirst

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Corbly, Jon @Corb_The_Lesser · Jun 23, 2018
Replying to @LauraLitvan
Who doubts Trump takes personal pleasure in knowing his "gutting" of Obamacare causes actual pain and suffering in actual people?

31 130 718

la blonde atomique @lacothren · Jun 23, 2018
Enjoying the suffering of others-the hallmark of sadism-can be part of the picture in “the dark triad” in personality : narcissism, psychopathy and Machiavellianism. People high in the dark triad traits callously use people to their own advantage.

4 146 513

John Lewis
@johntaltonlewis

Exhibit B-9

• • • MENU

President Trump Calls the Show!

by Rush Limbaugh - Aug 1,2018

RUSH 24/7 LISTEN

RUSH: So I have this note on the call screener computer: “On the hotline…” We don’t have a hotline. “On the hotline, you’re receiving a phone call in recognition of your anniversary broadcast. You’ll want to take this immediately.” Okay. So we’re going to the phones and we have a special guest. Who is it?

haven't given anybody reason to doubt you. You haven't betrayed anybody or made them think that you're going to. An example: Here you are suggesting that you'd be willing to maybe — you'd talk about — shutting down the government if that's what it took to get this wall built.

THE PRESIDENT: Yeah.

RUSH: Now the traditional Republican says, "Oh, no! No! Don't say that!" There you are saying, "Oh, yeah. I'll be glad to do it if that's what it takes."

THE PRESIDENT: Yeah, I actually think it would be positive.

RUSH: People don't understand your voters rally to you for that.

THE PRESIDENT: We had Obamacare repealed and replaced, and a man — I won't mention his name. But a man at 2 o'clock in the morning went thumbs down, and he campaigned for years on repeal and replace. We had the chance. Nobody even spoke to him about it, because it was something that was unthinkable what he did, and because of that… But still, I have just about ended Obamacare. We have great health care. We have a lot of great things happening right now. New programs are coming out.

We got rid of the individual mandate. But that was very disappointing to me that night — and he did it because of me, probably. But that was very disappointing. That was a horrible thing he did to our country. And, frankly, it cost $1 trillion because we would have saved $1 trillion, on top of which we would have had good health care. But we're doing it a different way. We have to go a different route. But he cost us a trillion dollars. And the other thing is the wall. We've started it. It's like pulling teeth, though, getting these guys to get it done is. You have no idea how tough I've been.

I say, "Hey, if you have a shutdown, you have a shutdown."

Now, the shutdown could also take place after the election. I happen to think it's a great political thing, because people want border security. It's not just the wall, Rush, as you know. It's border security. It's getting rid of catch and release, where you catch somebody, he can be a criminal of

Exhibit B-10

Speech: Donald Trump Holds a Political Rally in Southaven, Mississippi - October 2, 2018

people president America United States Supreme Court Mississippi country Supreme Court justice fake news

Negative

Donald Trump

1

Hello, Mississippi, hello. Beautiful. [Audience Chants USA] Well, I have to start by saying that 2020 is looking really easy, isn't it? I think the fake news media back there is starting to get it, folks. I think they're starting. They're starting to understand what's going on. And I'm thrilled to be back in this great state, with thousands of proud, loyal, hard-working American patriots.

American patriots Mississippi AI Audience Chants USA proofread transcript hard-working American patriots

Negative

Donald Trump

2

Thank you. In less than two years, we've achieved the biggest comeback in American history. That's what's happened. The economy is booming. Wages are rising. And more Americans are working today than ever before. Today -- ever before. Think of it. Now, just think of that. Today, we have more Americans working than we've ever had in the history of our country, right now, today.

American Patriots Mississippi hardworking American Patriots fake news media biggest comeback

Positive

Donald Trump

81

We'll take it from China. We'll take it from the European Union, who has taken advantage of us for years. We'll take it from Japan. We'll take it from our new, beautiful transaction, which is a fair transaction, and good for them, too, Mexico, Canada. We're going to have plenty of money coming in, folks, when we fix up these horrible trade deals.

European Union | China | Japan | sanctuary cities | Day. Sanctuary cities | horrible trade deals

Positive

Donald Trump

82

So we're going to take care of pre-existing conditions. People that have a problem are going to be helped by the Republican Party from -- from the time I got elected, really. You look at what we've done with Obamacare. It's a disaster. We had it beaten. But I'll say it a different way than I have been saying it. We didn't get one Democrat vote.

Border Patrol | Republican Party | ICE | pre-existing conditions | job | Democrat vote

Negative

Donald Trump

83

We had it repealed and replaced. A little shocked took place early in the morning. But the fact is, we didn't get one Democrat vote. We would have saved a trillion dollars -- think of it -- our country would have saved $1 trillion had we gotten that extra vote. We didn't get one vote from one Democrat. But we've pretty much dismantled it. And here's a nice story.

San Diego | California | Democrat vote | extra vote

Negative

Donald Trump

Exhibit B-11

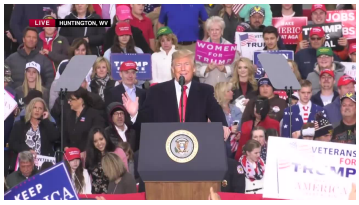
Speech: Donald Trump Holds a Political Rally in Huntington, West Virginia - November 2, 2018

people West Virginia Democrats America United States United States Senate health care vote country

Positive

Donald Trump

1



Wow, thank you so much. Hello, West Virginia. What a place. You know, we only won West Virginia by 42 points last time. 42 points. You know what that is? That's like -- did anyone ever hear of 42 points -- and we're going to better this time, OK? But I'm thrilled to be back in this great state. I love this state with thousands of hard working American patriots.

West Virginia AI proofread transcript working American patriots

Negative

Donald Trump

2

And what job numbers we had today. Did you hear? Did you hear? We're going to that. They all say speak about the economy. Speak about the economy. Well, we have the greatest economy in the history of our country... but sometimes it's not as exciting to talk about the economy, right? Because we have a lot of other things to talk about.

West Virginia hardworking American patriots economy

Negative

Donald Trump

3

69

Few thousand? We had over 100,000 people that wanted to come. We had 22,000 people in the arena. We had thousands and thousands of people outside of the arena. Donald Trump spoke today in front of a crowd of a few thousand people. Can you believe it? It's called the fake news, folks. But I head President Obama speak today.

Democrats | Donald Trump | President Obama | illegal aliens

Negative

Donald Trump

70

I had to listen -- I was in the plane; I had nothing else to do. I heard him talk about telling the truth. He was talking about you have to tell the truth. And yet 28 times he said you can keep your doctor if you like your doctor. You can keep your plan if you like your plan. They were all lies. Over and over again you heard that.

West Virginia | $100 billion | illegal immigration costs | entire state budget | truth

Negative

Donald Trump

71

Just used it to pass a terrible healthcare plan that we are decimating strike by strike. You saw what happened to the individual mandate, the most unpopular part. And we actually had Obamacare killed except for one Republican vote and any Democrat -- one Democrat and we would have had it obliterated and you would have had great healthcare.

fentanyl | terrible healthcare plan | ultra lethal fentanyl | youth drug Fentanyl

Negative

Donald Trump

Exhibit B-12

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Jim Acosta @Acosta · Nov 2, 2018
Trump in Indiana: "we've decimated Obamacare."
1.5K 3.3K 3.9K

Replies

Dafnie @catjjjjjjjjjj · Nov 2, 2018
Replying to @Acosta
And these people are still cheering him? Are they all high?
69 39 655

Loud & Proud @proudfeminist47 · Nov 2, 2018
Replying to @Acosta and @nutmom123
Cover this Jim!
10 58 133

Jules @IAmJulesWard · Nov 2, 2018
Replying to @Acosta
The lengths that Trump and the Republicans will go to in order to deny healthcare to Americans is staggering.

#VoteBlueThisTuesday
15 67 270

View more replies

More Tweets

Robert Reich @RBReich · May 16
Call me old-fashioned, but it's nice to see a president speak in coherent sentences.
2.3K 15K 138K

Scott Dworkin @funder · May 17
BREAKING: TV ratings for Obama's event last night were higher than almost any show on broadcast tv all last week.
1.8K 19.2K 124.6K

Dan Rather @DanRather · May 17
President Trump does so much projecting, he might as well open up a movie theater.
2.2K 14.2K 97.5K

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Relevant people

Jim Acosta
@Acosta
Follow
CNN Chief White House Correspondent. Author of NYT Bestseller, "The Enemy of the People." Winner of NY Press Club "Truth to Power" award. I believe in #realnews

What's happening

COVID-19 · LIVE
COVID-19: China commits $2 billion to fight the pandemic

COVID-19 · LIVE
COVID-19 updates for the US

Trending in United States
#timmylovespocs

Politics · Trending
Saudi Arabia
80.5K Tweets

Entertainment · Trending
Pauly D
7,053 Tweets

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and his recovery efforts are making that clearer than ever.

11.8K 19.6K 93.2K

Eugene Gu, MD @eugenegu · May 17

No matter what Eric Trump does, and I'm sure he'll have many gaffes, always remember that he stole charity money from kids with cancer.

634 21K 88.7K

Adam Schiff @RepAdamSchiff · May 17

As President Obama said last night,

"Doing what feels good, what's convenient, what's easy, that's how little kids think."

Not how leaders act.

Being a leader means doing what's right, even when it's hard. Especially when it's hard.

To bring people together, and save lives.

7.2K 17.9K 82.1K

Kamala Harris @KamalaHarris · 21h

They're trying to dismantle the United States Postal Service and privatize it. We must fight with every breath we have to make sure USPS workers are protected and everyone has access to reliable, affordable mail service. Congress must take immediate action to protect the USPS.

1.5K 18.3K 73.1K

Josh Campbell @joshscampbell · May 17

I've grieved in silence since March because the last thing you needed was more sad news, but here's a tribute to my pup, taken too soon by illness.

If you're raising a glass tonight, please raise one for Wilshire—an amazing friend who brightened the day of everyone he ever met.

6.7K 2.2K 64K

Chuck Schumer @SenSchumer · May 17

It's May 17th, and President Trump still doesn't have an adequate national testing strategy.

5K 12K 60.3K

andy lassner @andylassner · May 17

Our kids are not Don Jr. and Eric, so today is already a win for all of us.

Happy Sunday.

Search Twitter

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Scott Dworkin @funder · May 17
Obama dominated Trump last night.
1.1K 5.4K 52K

Rick Wilson @TheRickWilson · 18h
I'm blocked by Eric The Slow. My pain is constant and sharp.
2.3K 3.8K 51.4K

Joe Biden @JoeBiden · 19h
In times of crisis, Americans stand as one. It's who we are. And it's how we're going to get through this — together.
3.5K 8.3K 49.8K

Exhibit B-13

politics

LIVE TV

Trump says administration will continue legal fight to eliminate Obamacare

By Nikki Carvajal
Updated 3:24 PM ET, Wed May 6, 2020

Washington (CNN) — President Donald Trump said Wednesday his administration will continue to push the Supreme Court to invalidate the Affordable Care Act, defying a last-minute request from Attorney General William Barr to modify the administration's position.

"We're not doing anything. In other words, we're staying with the group, with Texas and the group," Trump told reporters in the Oval Office.

As it stands now, the Trump administration position fully backs the lawsuit filed by a group of Republican states seeking to invalidate the entire Affordable Care Act.

"Obamacare is a disaster, but we've run it very well, and we've made it barely acceptable," Trump said. "It was a disaster under President Obama, and it's very bad health care. What we want to do is terminate it and give health care. We'll have great health care, including preexisting conditions."

Trump said the administration had "already pretty much killed it because we got rid of the individual mandate."

"We want to terminate health care for -- under Obamacare because it's bad, and we're replacing it with a great health care at far less money and it includes preexisting conditions," he said. The White House has yet to offer an alternative to the 2010 law.

On Tuesday, CNN first reported on Barr's push to persuade the administration to modify its position in the Obamacare dispute that will be heard at the Supreme Court this fall,

With a Wednesday deadline to make any alterations to its argument looming, Barr made his case in a room with Vice President Mike Pence, White House counsel Pat Cipollone, members of the Domestic Policy Council, press secretary Kayleigh McEnany and several other officials. The meeting ended without a decision and it was not immediately clear if any shift in the Trump administration's position will emerge.

Related Article: Supreme Court hears Obamacare contraceptive mandate challenge via telephone

Barr and other top advisers have argued against the hard-line position for some time, warning it could have major political implications if the comprehensive health care law appears in jeopardy as voters head to the polls in November.

Asked about Barr's push, Trump said he "didn't know about that suggestion."

"I think I've spoken a lot about this to Bill Barr, and we're totally in lock step with all of the many states that want to see much better health care." Trump said.

House Democrats cite coronavirus in defense of law

Lawyers for the House of Representatives launched a broad defense of the Affordable Care Act, telling the Supreme Court that access to affordable health care is a "life-or-death matter for millions of Americans."

In briefs filed Wednesday, the lawyers linked the law to Covid-19 and said it had become an "indispensable precondition to the social intercourse on which our security, welfare and liberty ultimately depend."

In addition, 20 states, led by California, filed legal papers with the Supreme Court defending the law, arguing that it has allowed tens of millions of Americans to obtain health care coverage, slowed the growth of health care costs and conferred substantial savings on the states.

UPDATE: This story has been updated with responses from the House and California.

CNN's Ariane de Vogue contributed to this report.

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Exhibit B-14

BREAKING

Former Blackjewel workers get special exemption from health marketplace

By GREG JOHNSON NEWS RECORD MANAGING EDITOR gjohnson@gillettenewsrecord.net
Sep 25, 2019 0

PDF document

DOI Blackjewel alert
Sep 25, 2019 0

Former Wyoming Blackjewel LLC coal miners who have been out of work since July 1 and without health insurance since their group health plan was canceled Aug. 31 can sign up for the federal health insurance marketplace retroactively to Sept. 1.

The Wyoming Department of Insurance has successfully lobbied the Centers for Medicare and Medicaid Services (CMS) to make an "exceptional circumstances" special enrollment period through Oct. 30, said Denise Burke, an attorney with the state Department of Insurance.

The exception allows former Blackjewel coal

How to apply

Retroactive track

- **What:** Marketplace health insurance

coverage retroactive to Sept. 1, 2019.

- **Deadline:** Oct. 30
- **Who to contact:** You must call the state Department of Insurance at 307-777-7401 or 800-438-5768. Ask for Ruth Case.
- **What then?:** Identify yourself as someone whose coverage through Blackjewel/Revelation was terminated Aug. 31 and you want to enroll in a marketplace plan with a Sept. 1 start date. Department of Insurance staff will help you secure a marketplace ID number and begin the application process. The state DOI will give the information to the Centers for Medicare and Medicaid Services, which will evaluate the application (this may take several days).
- **Finish it up:** CMS will mail an eligibility notice and, if you qualify, give instructions on how to finalize enrollment through healthcare.gov.
- **Need help?:** Call Ruth Case at 307-777-7401 or 800-438-5768.

Regular track

- **What:** Marketplace health insurance coverage beginning at a date of your choosing.
- **Deadline:** Oct. 30
- **Who to contact:** Visit

miners an option to buy health insurance off the marketplace and made it retroactively effective to Sept. 1, which means workers and family members with ongoing health issues can continue treatment as if they never lost insurance.

That CMS made the allowance for Blackjewel workers in Wyoming “is pretty extraordinary,” Burke said, adding that the Department of Insurance “had to advocate pretty hard for the miners.”

Since nearly 600 Blackjewel employees at the Eagle Butte and Belle Ayr mines in Campbell County were abruptly locked out of their jobs July 1, the workers have been in a legal limbo.

At first, they were unable to access their 401(k) retirement accounts to tide them over while waiting for a potential call back to work because the company contended they weren’t laid off, only furloughed, and were still considered employees. As the bankruptcy process progressed, the company’s group health insurance was canceled as of Aug. 31.

Because the plan was canceled and Blackjewel is insolvent and in bankruptcy, employees did not have the option to extend their health coverage through COBRA, which would’ve allowed workers to extend their health coverage for up to 18 months after losing their jobs.

When their health coverage ended Aug. 31, a 60-

direct online at healthcare.gov or call 800-318-2596.

- **What then?:** Complete an application and indicate that you lost health coverage within the last 60 days. After the marketplace determines you're eligible for a special enrollment period, select a plan (you may be required to submit documents to confirm you lost coverage, like a termination notice from the health care provider or employer visit healthcare.gov/help/prove-coverage-loss for more information about this step). Pay your premium when confirmed. You'll get a notice when to do this.
- **Need help?:** Visit localhelp.healthcare.gov or call Wyoming 211.

day grace period began for former coal miners to buy private health care coverage or enroll through the federal marketplace.

While that grace period remains, in this case it's Oct. 30, the "exceptional circumstances" waiver by CMS will allow people to enroll any time before that date with an option to make coverage retroactive to Sept. 1, Burke said.

While that also means paying for September under whatever plan is chosen, it will help some workers and their families dealing with ongoing serious medical issues that can't be treated without continuous coverage, she said. With this, it would be like their coverage hadn't been interrupted.

"This gives them some options they didn't have before," she said.

The exception basically means any former Wyoming Blackjewel employee signing up for marketplace health care coverage will have two tracks to choose from. One is to make it retroactive and the other allows a choice of when coverage will begin.

Collection

Blackjewel bankruptcy

Thirty-two Blackjewel coal operations in Wyoming, Kentucky, Virginia and West Virginia are in limbo after the company

filed for Chapter 11 ban…

Greg Johnson

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

REQUEST FOR JUDICIAL NOTICE

In support of its motion for a preliminary injunction or, in the alternative, expedited summary judgment, the City of Chicago hereby requests that the Court take notice of certain relevant documents and facts. These materials consist of publicly available government records and other publications the accuracy of which cannot reasonably be disputed. They may be considered in assessing the merits of the agency's action as well as other non-merits issues, like standing and remedy. Thus, Chicago's request should be granted.

Under Rule 201 of the Federal Rules of Evidence, a district court may take judicial notice of any document or fact "not subject to reasonable dispute because it … can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). It is well-established that "judicial notice may be taken of public records and government documents available from reliable sources." *Johnson v. Comm'n on Presidential Debates*, 202 F. Supp. 3d 159, 167 (D.D.C. 2016), *aff'd*, 869 F.3d 976 (D.C. Cir. 2017); *accord Democracy Forward Found. v. White House Office of Am. Innovation*, 356 F. Supp. 3d 61, 62 n.2 (D.D.C. 2019); *Connecticut v. U.S. Dep't of Interior*, 344 F. Supp. 3d 279, 306 n.23 (D.D.C.

2018); *Abdus-Sabur v. Hope Vill., Inc.*, 221 F. Supp. 3d 3, 10 n.3 (D.D.C. 2016). In particular, courts have taken judicial notice of government publications regarding the scope and the effects of the novel coronavirus. *See Geller v. De Blasio*, 2020 WL 2520711, at *2 & n.1 (S.D.N.Y. 2020) (taking notice of "public health statistics reported by [New York] City").

These documents, as well as those attached to the Declaration of Gilbert Orbea, are relevant to multiple issues presented by this lawsuit. Although courts typically review agency action on the basis of the administrative record, they may consider evidence outside the record "where the administrative record itself is so deficient as to preclude effective review." *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013) (per curiam), or where there has been a "strong showing of bad faith or improper behavior," *Theodore Roosevelt Conservation P'ship v. Salazar*, 616 F.3d 497, 514 (D.C. Cir. 2010). As the Supreme Court recently reiterated, courts must assess whether the agency's stated rationale "is incongruent with what the record reveals about the agency's priorities and decisionmaking process." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019). As explained in Chicago's motion, there is substantial reason to think that Defendants' decision rested on an impermissible basis for action other than the agency's stated rationale. *See* MSJ § I.C.1.

Moreover, extra-record evidence is admissible for purposes other than the merits of the agency's action. Specifically, extra-record evidence may be used to establish that the agency took or did not take a specific action, *Grace v. Whitaker*, 344 F. Supp. 3d 96, 113 (D.D.C. 2018)—*i.e.*, that Defendants refused to provide a special enrollment period. Such evidence is also admissible for purposes of standing and justiciability, *Chesapeake Climate Action Network v. Export-Import Bank of the U.S.*, 78 F. Supp. 3d 208, 217 (D.D.C. 2015), as well as relief, *Eco Tour Adventures, Inc. v. Zinke*, 249 F. Supp. 3d 360, 369 n.7 (D.D.C. 2017).

Chicago therefore requests that the Court take notice of the following documents:

1. Attached as Exhibit A-1 is a true and correct copy of *State-Based Exchanges*, Ctr. for Consumer Info. & Insurance Oversight, available at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/state-marketplaces (last updated November 1, 2019).

2. Attached as Exhibit A-2 is a true and correct copy of *When Is Open Enrollment for 2020?*, Health Markets (Apr. 15, 2020), available at https://www.healthmarkets.com/resources/health-insurance/open-enrollment/.

3. Attached as Exhibit A-3 is a true and correct copy of excerpts of *Federally-Faciliated Marketplace (FFM) and Federally-Facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual*, CMS (July 19, 2016), available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/ENR_FFMSHOP_Manual_080916.pdf.

4. Attached as Exhibit A-4 is a true and correct copy of *Special Enrollment Periods for Complex Issues*, HealthCare.gov, available at https://www.healthcare.gov/sep-list/ (last visited June 14, 2020).

5. Attached as Exhibit A-5 is a true and correct copy of Memorandum from Randy Pate, Dir., Ctr. for Consumer Info. and Insurance Oversight to All Federally-Facilitated Exchange, Qualified Health Plan, and Stand-Alone Dental Plan Issuers (Aug. 9, 2018), available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/8-9-natural-disaster-SEP.pdf.

6. Attached as Exhibit A-6 is a true and correct copy of Memorandum from Randy Pate, Dir., Ctr. for Consumer Info. and Insurance Oversight to All Federally-Facilitated

Exchange, Qualified Health Plan, and Stand-Alone Dental Plan Issuers (Sept. 28, 2017), available at https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-Hurricane-Disasters-Guidance.pdf.

7. Attached as Exhibit A-7 is a true and correct copy of *CMS Announces Additional Special Enrollment Periods to Help Individuals Impacted by Hurricanes in Puerto Rico and the U.S. Virgin Islands*, CMS (Jan. 17, 2018), available at https://www.cms.gov/newsroom/press-releases/cms-announces-additional-special-enrollment-periods-help-individuals-impacted-hurricanes-puerto-rico.

8. Attached as Exhibit A-8 is a true and correct copy of *Special Enrollment Period (SEP) and Hardship Exemptions for AmeriCorps Members*, CMS (May 6, 2014), available at https://marketplace.cms.gov/technical-assistance-resources/5-6-14-americorp-sepfinal.pdf.

9. Attached as Exhibit A-9 is a true and correct copy of *Cases in the US*, CDC, available at https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last visited June 14, 2020).

10. Attached as Exhibit A-10 is a true and correct copy of *What Law Enforcement Personnel Need to Know About Coronavirus Disease 2019 (COVID-19)*, CDC, available at https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-law-enforcement.html (last updated Mar. 14, 2020).

11. Attached as Exhibit A-11 is a true and correct copy of *What You Should Know About COVID-19 to Protect Yourself and Others*, CDC (June 1, 2020), available at https://www.cdc.gov/coronavirus/2019-ncov/downloads/2019-ncov-factsheet.pdf.

12. Attached as Exhibit A-12 is a true and correct copy of *Determination that A Public Health Emergency Exists*, Pub. Health Emergency (Jan. 31, 2020), available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

13. Attached as Exhibit A-13 is a true and correct copy of *30 Days to Slow the Spread*, White House (Mar. 16, 2020), available at https://www.whitehouse.gov/wp-content/uploads/2020/03/03.16.20_coronavirus-guidance_8.5x11_315PM.pdf.

14. Attached as Exhibit A-14 is a true and correct copy of *An In-Depth Look at COVID-19's Early Effects on Consumer Spending and GDP*, Council of Econ. Advisers (Apr. 29, 2020), available at https://www.whitehouse.gov/articles/depth-look-covid-19s-early-effects-consumer-spending-gdp/.

15. Attached as Exhibit A-15 is a true and correct copy of *April's Job Losses Show Many Workers Are Still Connected to Their Employers*, Council of Econ. Advisers (May 8, 2020), available at https://www.whitehouse.gov/articles/aprils-job-losses-show-many-workers-still-connected-employers/.

16. Attached as Exhibit A-16 is a true and correct copy of excerpts of *CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again*, CDC (May 2020), available at https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.

17. Attached as Exhibit A-17 is a true and correct copy of *What to Do If You Are Sick*, CDC, available at https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html (last updated May 8, 2020).

18. Attached as Exhibit A-18 is a true and correct copy of *Silver State Health Insurance Announces Exceptional Circumstance Enrollment Period*, News 4 (Mar. 17, 2020),

available at https://mynews4.com/news/local/silver-state-health-insurance-announces-exceptional-circumstance-enrollment-period.

19. Attached as Exhibit A-19 is a true and correct copy of *State Health Exchange Offers Special Enrollment Period Due to Virus*, KOMO News (Mar. 11, 2020), available at https://komonews.com/news/coronavirus/state-health-exchange-offers-special-enrollment-period-due-to-virus.

20. Attached as Exhibit A-20 is a true and correct copy of Office of the Governor, *Governor Lamont Provides Update on Connecticut's Coronavirus Response Efforts*, New Fairfield's HamletHub (Apr. 5, 2020), available at https://news.hamlethub.com/newfairfield/events/todays-events/47538-governor-lamont-provides-update-on-connecticut-s-coronavirus-response-efforts.

21. Attached as Exhibit A-21 is a true and correct copy of Jessica A. Botelho, *Coronavirus Cases in RI Reach 20; Health Benefits Available for Uninsured*, NBC 10 News (Mar. 14, 2020), available at https://turnto10.com/news/coronavirus/raimondo-to-hold-coronavirus-briefing.

22. Attached as Exhibit A-22 is a true and correct copy of *Uninsured Coloradans Can Enroll During a Special Enrollment Period in Response to COVID-19 Outbreak*, Connect for Health Colo. (Mar. 19, 2020), available at https://connectforhealthco.com/uninsured-coloradans-can-enroll-during-a-special-enrollment-period-in-response-to-covid-19-outbreak/.

23. Attached as Exhibit A-23 is a true and correct copy of *NY State of Health and New York State Department of Financial Services Announce Special Enrollment Period for Uninsured New Yorkers, as Novel Coronavirus Cases Climb*, N.Y. State Dep't of Health (Mar.

16, 2020), available at https://www.health.ny.gov/press/releases/2020/2020-03-16_nysoh_special_enrollment_period.htm.

24. Attached as Exhibit A-24 is a true and correct copy of *News and Events*, Vermont Health Connect, available at https://info.healthconnect.vermont.gov/news (last visited June 14, 2020).

25. Attached as Exhibit A-25 is a true and correct copy of *Massachusetts Health Connector Offers Extended Enrollment for Uninsured Individuals to Ease Coronavirus Fears*, Mass. Health Connector (Mar. 11, 2020), available at https://www.mahealthconnector.org/massachusetts-health-connector-offers-extended-enrollment-for-uninsured-individuals-to-ease-coronavirus-fears.

26. Attached as Exhibit A-26 is a true and correct copy of *California Responds to COVID-19 Emergency by Providing Path to Coverage for Millions of Californians*, Covered Cali. (Mar. 20, 2020), available at https://www.coveredca.com/newsroom/news-releases/2020/03/20/california-responds-to-covid-19-emergency-by-providing-path-to-coverage-for-millions-of-californians/.

27. Attached as Exhibit A-27 is a true and correct copy of *DC Health Link Expands Opportunities to Get Covered During Public Health Emergency*, DC Health Link (Apr. 6, 2020), available at https://www.dchealthlink.com/node/3425.

28. Attached as Exhibit A-28 is a true and correct copy of *Coronavirus Emergency Extends Special Enrollment Period Until June 15*, Md. Health Connection, available at https://www.marylandhealthconnection.gov/coronavirus-sep/ (last visited June 14, 2020).

29. Attached as Exhibit A-29 is a true and correct copy of *Coronavirus (COVID-19) Emergency Special Enrollment Period*, MNSure, available at https://www.mnsure.org/new-customers/enrollment-deadlines/special-enrollment/covid19-sep.jsp (last visited June 14, 2020).

30. Attached as Exhibit A-30 is a true and correct copy of Donald J. Trump (@realDonaldTrump), Twitter (July 28, 2017, 2:25 AM), available at https://twitter.com/realDonaldTrump/status/890820505330212864.

31. Attached as Exhibit A-31 is a true and correct copy of *Remarks by President Trump at the 2017 Values Voter Summit*, White House (Oct. 13, 2017), available at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-2017-values-voter-summit/.

32. Attached as Exhibit A-32 is a true and correct copy of *Remarks by President Trump at S.204, "Right to Try" Bill Signing*, White House (May 30, 2018), available at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-s-204-right-try-bill-signing/.

33. Attached as Exhibit A-33 is a true and correct copy of excerpts of *Remarks by President Trump at a Fox News Town Hall, Scranton, PA*, White House (Mar. 6, 2020), available at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-fox-news-town-hall-scranton-pa/.

34. Attached as Exhibit A-34 is a true and correct copy of excerpts of *Remarks by President Trump on Protecting Seniors with Diabetes*, White House (May 26, 2020), available at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-protecting-seniors-diabetes/.

35. Attached as Exhibit A-35 is a true and correct copy of *QuickFacts United States; Chicago City, Illinois*, U.S. Census Bureau, available at https://www.census.gov/quickfacts/fact/table/US,chicagocityillinois/PST045219 (last visited June 14, 2020).

36. Attached as Exhibit A-36 is a true and correct copy of *Economy at a Glance, Chicago-Joliet-Naperville, IL*, U.S. Bureau of Labor Stats., available at https://www.bls.gov/eag/eag.il_chicago_md.htm (last visited June 14, 2020).

37. Attached as Exhibit A-37 is a true and correct copy of *Insurance Expansion, Hospital Uncompensated Care, and the Affordable Care Act*, HHS (Mar. 23, 2015), available at https://aspe.hhs.gov/system/files/pdf/139226/ib_UncompensatedCare.pdf.

38. Attached as Exhibit A-38 is a true and correct copy of Thomas DeLeire et al., *Impact of Insurance Expansion on Hospital Uncompensated Care Costs in 2014*, HHS (Sept. 1, 2014), available at https://aspe.hhs.gov/system/files/pdf/77061/ib_UncompensatedCare.pdf.

39. Attached as Exhibit A-39 is a true and correct copy of *Emergency Declaration Press Call Remarks by CMS Administrator Seema Verma*, CMS (Mar. 13, 2020), available at https://www.cms.gov/newsroom/press-releases/emergency-declaration-press-call-remarks-cms-administrator-seema-verma.

40. Attached as Exhibit A-40 is a true and correct copy of Memorandum from Jerry Mulcahy, Dir., to All Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans (May 5, 2020), available at https://www.cms.gov/files/document/special-enrollment-period-sep-individuals-affected-fema-declared-weather-related-or-other-major.pdf.

41. Attached as Exhibit A-41 is a true and correct copy of *Enrollment Issues for COVID-19 Pandemic-Related National Emergency Questions and Answers for Medicare*

Beneficiaries, CMS, available at https://www.cms.gov/files/document/enrollment-issues-covid-ab-faqs.pdf (last visited June 14, 2020).

42. Attached as Exhibit A-42 is a true and correct copy of *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, CMS (June 5, 2020), available at https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

43. Attached as Exhibit A-43 is a true and correct copy of *Coronavirus Waivers & Flexibilities*, CMS, available at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers (last updated June 10, 2020).

44. Attached as Exhibit A-44 is a true and correct copy of *Emergency Use Authorization*, FDA, available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov (last updated June 13, 2020).

45. Attached as Exhibit A-45 is a true and correct copy of Letter from Christopher S. Murphy, Senator, et al. to Alex M. Azar II, HHS Sec'y (Apr. 7, 2020), available at https://www.manchin.senate.gov/imo/media/doc/SEP%20Letter%20to%20Azar%204.7.20%20Final.pdf?cb.

46. Attached as Exhibit A-46 is a true and correct copy of Letter from Matthew Eyles, President & CEO, Am.'s Health Insurance Plans & Scott Serota, President & CEO, Blue Cross Blue Shield Ass'n to Nancy Pelosi, Speaker of the House et al. (Mar. 19, 2020), available at https://www.ahip.org/wp-content/uploads/AHIP-and-BCBSA-Legislative-Recommendations-03.19.2020.pdf.

47. Attached as Exhibit A-47 is a true and correct copy of Letter from Insurers and Others to Nancy Pelosi, Speaker of the House (Apr. 28, 2020), available at

https://www.aha.org/system/files/media/file/2020/04/Letter%20COVID%20Coverage%20Coalition.pdf.

48. Attached as Exhibit A-48 is a true and correct copy of Letter from Organizations to Alex M. Azar II, HHS Sec'y et al. (Mar. 20, 2020), available at https://younginvincibles.org/wp-content/uploads/2020/03/Request_Emergency-Special-Enrollment-Period-to-Combat-COVID-19.pdf.

49. Attached as Exhibit A-49 is a true and correct copy of Memorandum from Samara Lorenz, Dir., Oversight Grp., Ctr. for Consumer Info. & Insurance Oversight (May 14, 2020), available at https://www.cms.gov/files/document/Temporary-Relaxed-Enforcement-Of-Group-Market-Timeframes.pdf.

Dated: June 15, 2020

Respectfully submitted,

/s/ John T. Lewis
John T. Lewis (D.C. Bar No. 1033826)
Robin F. Thurston (D.C. Bar No. 1531399)
Benjamin Seel (D.C. Bar No. 1035286)
Sean A. Lev (D.C. Bar No. 449936)
Democracy Forward Foundation
1333 H Street NW
Washington, DC 20005
(202) 448-9090
jlewis@democracyforward.org
rthurston@democracyforward.org
bseel@democracyforward.org
slev@democracyforward.org

Mark A. Flessner
Stephen J. Kane
Rebecca Hirsch
Affirmative Litigation Division
City of Chicago Department of Law
121 N. LaSalle St., Room 600
Chicago, IL 60602
mark.flessner@cityofchicago.org
stephen.kane@cityofchicago.org
rebecca.hirsch2@cityofchicago.org

Counsel for Plaintiff

Exhibit A-1

CCIIO

The Center for Consumer Information & Insurance Oversight

State-based Exchanges

Since January 1, 2014, consumers and small businesses in every state (including the District of Columbia) have had access to obtain health and/or dental insurance coverage through Individual or Small Business Health Options Program (SHOP) Health Insurance Exchanges, operated by States through State-based Exchanges (SBEs), or operated by the Federal government through the Federally-facilitated Exchange (FFE).

States who wish to establish a SBE are required to convey their intent in doing so by submitting a declaration letter to the Department of Health and Human Services (HHS), Center for Medicare and Medicaid Services (CMS). States were also eligible, through November 2014, to apply for Federal grants to support the establishment of their SBE. Since 2014, CMS's Center for Consumer Information and Insurance Oversight (CCIIO) has been providing conditional approval for states requesting to establish a SBE. Historic declaration letters and other correspondence from States related to Exchange establishment can be found here. Since 2014, a few States who were conditionally approved to operate a SBE have transitioned to a different Exchange model. As of November 1, 2019, there are 13 SBEs, and 6 State-based Exchanges on the Federal platform (SBE-FPs). SBE-FPs are SBEs who rely on HHS services for performing certain Exchange functions, particularly eligibility and enrollment, while still retaining responsibility for performing certain Exchange functions such as Qualified Health Plan (QHP) certification and consumer outreach and assistance functions. Three of the SBE-FPs also utilize the Federal platform for their SHOP eligibility functions. The

Updates

March 5, 2020

Information Related to COVID–19 Individual and Small Group Market Insurance Coverage

March 12, 2020

FAQs on Essential Health Benefits Coverage and the Coronavirus (COVID-19)

March 18, 2020

FAQs on Catastrophic Plan Coverage and the Coronavirus Disease 2019 (COVID-19)

three SBE-FPs that perform SHOP eligibility functions are noted below by an asterisk next to the SBE-FP's name.

Below is a list of the SBEs and SBE-FPs, and where available, a state's declaration letter, HHS/CMS' conditional approval letter, and a State's Exchange website link. For further information, please contact the State directly.

Note: People using assistive technology may not be able to fully access information in these files. For assistance, please e-mail AltFormatRequest@cms.hhs.gov.

Updated: November 1, 2019

State-based Exchanges for Plan Year 2020:

California

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Covered California Website

Colorado

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Connect for Health Colorado Website

Connecticut

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Access Health CT Website

District of Columbia

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- DC Health Link Website

Idaho

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Your Health Idaho Website

Maryland

March 24, 2020

FAQs on Availability and Usage of Telehealth Services through Private Health Insurance Coverage in Response to Coronavirus Disease 2019 (COVID-19)

March 24, 2020

Payment and Grace Period Flexibilities Associated with the COVID-19 National Emergency

March 24, 2020

FAQs on Prescription Drugs and the Coronavirus Disease 2019 (COVID-19) for Issuers Offering Health Insurance Coverage

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Maryland Health Connection Website

Massachusetts

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Massachusetts Health Connector Website

Minnesota

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- MNsure Website

Nevada

- Declaration Letter (PDF)
- Conditional Letter (PDF)
- Nevada Health Link Website

New York

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- New York State of Health Website

Rhode Island

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- HealthSource RI Website

Vermont

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Vermont Health Connect Website

Washington

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Washington Health Plan Finder Website

State-based Exchanges on the Federal Platform for Plan Year 2020:

in the Individual and Small Group Markets

April 11, 2020

FAQs about Families First Coronavirus Response Act and the Coronavirus Aid, Relief, and Economic Security Act Implementation

*This document was updated on April 15, 2020, to correct an error in footnote 10 regarding the current end date of the public health emergency related to COVID 19.

April 13, 2020

Postponement of 2019 Benefit Year HHS-operated

***Arkansas**

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- My Arkansas Health Insurance Marketplace Website

Kentucky

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Kentucky Health Benefit Exchange Website

New Jersey

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- New Jersey Health Insurance marketplace Website

New Mexico

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- BeWellNM Website

***Oregon**

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Oregon Health Insurance Marketplace Website

Pennsylvania

- Declaration Letter (PDF)
- Conditional Approval (PDF)
- Pennsylvania Health Insurance Marketplace Website

Risk Adjustment Data Validation (HHS-RADV)

MD 21244

Receive Email Updates

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Connect with CMS

Exhibit A-2

When Is Open Enrollment for 2020?

Health Insurance Topics: Affordable Care Act
Print April 15, 2020 Enrollment Period

Editor's Note for the Coronavirus (COVID-19): Find updates about health insurance options, including short-term health insurance plans and Special Enrollment Periods (SEPs) related to the spread of the coronavirus, at the bottom of the page.

The 2020 Open Enrollment Period began November 1, 2019, and ended December 18, 2019, for most states.

Some states chose to extend their specific Open Enrollment 2020 periods. (You will find more information on these states' extended deadlines in the chart at the very bottom of the page.)

Find your state below to figure out your dates for Open Enrollment 2020.

States	Open Enrollment Dates for 2020
Alabama	November 1, 2019 – December 18, 2019
Alaska	November 1, 2019 – December 18, 2019
Arizona	November 1, 2019 – December 18, 2019
Arkansas	November 1, 2019 – December 18, 2019
California	See chart below.
Colorado	See chart below.
Connecticut	See chart below.
Delaware	November 1, 2019 – December 18, 2019
Florida	November 1, 2019 – December 18, 2019
Georgia	November 1, 2019 – December 18, 2019
Hawaii	November 1, 2019 – December 18, 2019
Idaho	November 1, 2019 – December 16, 2019
Illinois	November 1, 2019 – December 18, 2019
Indiana	November 1, 2019 – December 18, 2019

Top Stories

Healthcare Reform News Updates

The Pros and Cons of the Affordable Care Act

The Top 5 Things You Need to Know About Obamacare

Resources

Health Insurance

Small Business

Other Products

Iowa	November 1, 2019 – December 18, 2019
Kansas	November 1, 2019 – December 18, 2019
Kentucky	November 1, 2019 – December 18, 2019
Louisiana	November 1, 2019 – December 18, 2019
Maine	November 1, 2019 – December 18, 2019
Maryland	See chart below.
Massachusetts	See chart below.
Michigan	November 1, 2019 – December 18, 2019
Minnesota	See chart below.
Mississippi	November 1, 2019 – December 18, 2019
Missouri	November 1, 2019 – December 18, 2019
Montana	November 1, 2019 – December 18, 2019
Nebraska	November 1, 2019 – December 18, 2019
Nevada	See chart below.
New Hampshire	November 1, 2019 – December 18, 2019
New Jersey	November 1, 2019 – December 18, 2019
New Mexico	November 1, 2019 – December 18, 2019
New York	See chart below.
North Carolina	November 1, 2019 – December 18, 2019
North Dakota	November 1, 2019 – December 18, 2019
Ohio	November 1, 2019 – December 18, 2019
Oklahoma	November 1, 2019 – December 18, 2019
Oregon	November 1, 2019 – December 18, 2019
Pennsylvania	November 1, 2019 – December 18, 2019
Rhode Island	See chart below.
South Carolina	November 1, 2019 – December 18, 2019
South Dakota	November 1, 2019 – December 18, 2019
Tennessee	November 1, 2019 – December 18, 2019
Texas	November 1, 2019 – December 18, 2019
Utah	November 1, 2019 – December 18, 2019
Vermont	See chart below.
Virginia	November 1, 2019 – December 18, 2019
Washington	See chart below.

Life Insurance
Medicare
Short Term
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Videos
Countdown to the 2020 Medica…
All About Accident Insurance
HealthMarkets is “Your Insuran…
Get Free Help This Medicare E…

Glossary Terms
Open Enrollment Period
Premium
Special Enrollment Period (SEP)

Washington DC	See chart below.
West Virginia	November 1, 2019 – December 18, 2019
Wisconsin	November 1, 2019 – December 18, 2019
Wyoming	November 1, 2019 – December 18, 2019

The first day coverage begins is often called the effective date. Most states' Open Enrollment 2020 deadline (December 18) matched up with an effective date of January 1, 2020. This means that, as long as you enrolled by the December 18 deadline, your 2020 coverage began on January 1, 2020, the first day of the year.

I'm Concerned About the Coronavirus. Can I Still Buy Health Insurance for 2020?

Several state-run exchanges have enacted Special Enrollment Periods (SEPs) in response to the coronavirus (COVID-19) outbreak. These SEPs allow state residents to purchase individual health insurance plans if they weren't previously insured for 2020 or lost coverage.

The dates below are for states with SEPs related to the spread of coronavirus.

State	April 1 Effective Date Deadline	May 1 Effective Date Deadline	June 1 Effective Date Deadline	July 1 Effective Date Deadline
California	March 31, 2020	April 30, 2020	May 31, 2020	June 30, 2020
Colorado	April 3, 2020	April 30, 2020	–	–
Connecticut	April 2, 2020	April 17, 2020	–	–
Maryland	April 15, 2020	May 15, 2020	June 15, 2020	–
Massachusetts	March 23, 2020	April 23, 2020	May 23, 2020	May 25, 2020
Minnesota	April 21, 2020	–	–	–
Nevada	April 1, 2020	April 30, 2020	May 15, 2020	–
New York	–	April 15, 2020	–	–
Rhode Island	March 31, 2020	April 15, 2020	–	–
Washington	April 8, 2020	May 8, 2020	–	–
Washington DC	March 31, 2020	April 30, 2020	May 31, 2020	June 15, 2020
Vermont*	April 17, 2020	April 17, 2020	–	–

*Vermont residents may choose either April 1, 2020, or May 1, 2020, for their coverage start date.

My State Doesn't Have an SEP for the Coronavirus. Can I Still Get Coverage?

Yes. You have options if you missed the 2020 Open Enrollment Period and you *do not* qualify for a Special Enrollment Period (SEP). You can enroll in a short-term health insurance plan, which is a good fit for temporary coverage. Short-term insurance coverage can range from 30 days to three months. Short-term health insurance plans offer:

- Affordable premiums,
- Quick approval, and
- Flexible terms.

Short-term health insurance plans might be a good fit for healthy people, as they will not cover preexisting conditions like Affordable Care Act (ACA) plans.

If you *do* not qualify for an SEP and decide not to enroll in a short-term health plan, if you missed the 2020 Open Enrollment Period and you *do not* qualify for a SEP, you will have to wait until Open Enrollment begins for 2021. You can qualify for an SEP if you have experienced a qualifying life event that prevented you from meeting the enrollment deadline. Qualifying life events can include:

- The loss of health insurance through a job or Medicare eligibility.
- Household changes such as marriage, divorce, a death in the family, or having a baby.
- A change in your home address.

You can see a full list of qualifying life events here. You have 60 days to enroll in a plan, if you qualify for an SEP. But, if you miss that 60-day window, you will have to wait until OEP begins for 2021 to get an individual health insurance policy.

HMIAMKT0027 4-2020

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Sources:
Kaiser Family Foundation (2013). Average Single Premium per Enrolled Employee For Employer-Based Health Insurance.

Exhibit A-3

Federally-facilitated Marketplace (FFM) and Federally-facilitated Small Business Health Options Program (FF-SHOP) Enrollment Manual

This manual is effective as of July 19, 2016. All enrollments made on or after July 19, 2016, should be processed in accordance with the operational requirements set forth in this document. CMS intends to update this Manual regularly, and publish clarifying bulletins between updates. All previous versions of bulletins that have been incorporated into this version of the manual should be considered superseded by this manual. If you have questions related to content posted within this manual, please email: EnrollmentGuidance@cms.hhs.gov.

changes may result in an updated eligibility determination and may qualify the consumer for an SEP to make coverage changes.

2.2 OPEN ENROLLMENT AND COVERAGE EFFECTIVE DATES

During the OEP, a QI may enroll in a QHP. The QI can make multiple elections during the OEP. However, the last election made by the end of the OEP that is effectuated will be the coverage in which the QI is enrolled through the FFM. If the QI enrolled in a QHP and paid for the first month's premium payment (i.e., binder payment), as required by 45 CFR §155.400(e), but then selected another QHP during the OEP and that enrollment is effectuated for the same coverage effective date, the issuer of the QHP in which coverage was previously effectuated will need to cancel the coverage and refund premiums. The issuer of that QHP will receive notification of the plan selection change from the Marketplace. Outstanding enrollments will also be identified during enrollment reconciliation.

Coverage effective dates are based on a QI's QHP selection date and begin as early as January 1 of the applicable plan year. QIs who qualify for an SEP during the OEP may receive a coverage effective date as indicated in Section 5, Special Enrollment Periods. Under 45 CFR §155.310(c), the FFM must accept an application and make an eligibility determination at any point in time during the year, which will enable consumers to learn whether they are eligible for an SEP for FFM coverage, or for Medicaid or CHIP, for which there are generally no restrictions on when a consumer can enroll.

Exhibit 4 illustrates coverage effective dates for the 2017 OEP.

Exhibit 4 – Coverage Effective Dates for the 2017 FFM OEP

Plan Selection Date	Coverage Effective Date
November 1, 2016, through December 15, 2016	January 1, 2017
December 16, 2016, through December 31, 2016	February 1, 2017
January 1, 2017, through January 15, 2017	February 1, 2017
January 16, 2017, through January 31, 2017	March 1, 2017

2.3 ENROLLMENT TRANSACTIONS

Federal regulation (45 CFR §155.270) requires each Marketplace to use standards, implementation specifications, operating rules, and code sets adopted by HHS under HIPAA and the ACA when conducting certain electronic transactions with a covered entity, such as a QHP issuer. Additionally, HHS oversees and monitors FFM issuers and non-Exchange entities to verify compliance with security and privacy standards, as required by 45 CFR §155.280.

The Marketplace, QHP, and QDP issuers transmit enrollment transactions in files using the Accredited Standards Committee (ASC) X12 834 Benefit Enrollment and Maintenance Version 5010 (834 enrollment transaction), adopted by the Secretary on January 23, 2009.

5. SPECIAL ENROLLMENT PERIODS (APPLICABLE TO INDIVIDUAL MARKET FFM, QHP/QDP)

Pursuant to 45 CFR §155.420, Special Enrollment Periods (SEPs) constitute periods outside of the Open Enrollment Period (OEP) and the FFM and FF-SHOP initial enrollment period when a QI may enroll in a QHP/QDP and/or an enrollee may elect to change a current QHP/QDP selection. This section provides an overview of events that trigger SEPs and details about administering them. It includes material that applies to the individual market FFM and to the FF-SHOP (references to "FFM" include the individual FFM and the FF-SHOP); information on SEPs that applies only to the FF-SHOP is available in Section 3.4.

5.1 AVAILABILITY AND LENGTH OF SEPS

The FFM determines whether a QI and/or enrollee is eligible for an SEP based on a qualifying event described in 45 CFR §155.420(d). Pursuant to 45 CFR §155.420(c), unless otherwise stated, SEPs in the FFMs last 60 days from the date of the triggering event. Exceptions include:

- Certain SEPs for which the FFM has the flexibility to define the length of the SEP based on the circumstances, such as SEPs related to enrollment errors, exceptional circumstances, and misrepresentation.[25] The SEPs for these situations may last less than 60 days, depending on the specific situation, but will not last for longer than 60 days.

In addition, it is important to note that the FFM offers advanced availability of the SEP for loss of MEC, so QIs have up to 60 days before or up to 60 days after the loss of coverage to qualify for an SEP and enroll in a QHP.

5.2 SEP TRIGGERING EVENTS AND COVERAGE EFFECTIVE DATES

Consumers may qualify for an SEP under 45 CFR §155.420(d) based on certain "triggering events." Certain SEPs are available to all QIs who experience a triggering event, while others are only available to current enrollees, or consumers who previously had MEC.

Coverage effective dates for consumers who enroll through an SEP are established in 45 CFR §155.420(b). As described in 45 CFR §155.420(b)(1), **regular coverage effective dates** for enrollment during an SEP are:

[25] See 45 CFR §155.420(c)(3). In the case of QIs/enrollees eligible for an SEP based on criteria in 45 CFR §155.420(d)(4), (d)(5), or (d)(9), the Marketplace may define the length of the SEP "as appropriate based on the circumstances of the SEP, but in no event shall the length of the SEP exceed 60 days."

- The first day of the month following QHP selection if selection took place between the first and 15th day of any month; or
- The first day of the second month following QHP selection if selection took place between the 16th and the last day of any month.

Other Coverage Effective Dates

Pursuant to 45 CFR §155.420(b)(2)(iii), a Marketplace may provide for a coverage effective date that is appropriate based on the circumstances of the SEP. Certain SEPs offer "**accelerated coverage effective dates**," which provide a coverage effective date of the first day of the month following plan selection, regardless of whether plan selection takes place in the first or second half of the month. For example, consumers who qualify for an SEP due to a loss of MEC may be eligible to enroll in coverage with an accelerated coverage effective date.

Some SEPs offer coverage **retroactive** to a specific date. For example, when consumers have experienced a Marketplace error, they will be given the option for a retroactive coverage effective date back to their initially intended coverage effective date, absent the error. Retroactive effective dates also accommodate consumers who gain or become a dependent through birth, adoption, placement in foster case, or a child support or other court order.

Exhibit 25 summarizes SEP triggering events from 45 CFR §155.420(d) as well as coverage effective dates for each SEP. It also includes information on whether consumers can access the SEP through the Marketplace application or through the Marketplace Call Center, and provides SEP enrollment codes.

SEP Category	Regulatory Authority under 45 CFR §155.420	SEP Description from Regulation	Enrollment Code	Accessed Through
6. Other qualifying changes	(d)(9) – Experience an exceptional circumstance	A QI's, enrollee's, or his or her dependent's, enrollment or non-enrollment in a QHP is the result of an exceptional circumstance, as determined by the Secretary of HHS, including being incapacitated or experiencing a natural disaster. The enrollment or non-enrollment of a QI, enrollee, or his or her dependent in a QHP is the result of an unforeseen event or reflects a first-time requirement for Marketplace enrollees (such as the Tax Season SEP for consumers impacted by the individual shared responsibility payment). The enrollment or non-enrollment of a QI, enrollee, or his or her dependent, enrollment or non-enrollment in a QHP is the result of a significant life event resulting in lack of access to his or her application or account and the individual, enrollee, or dependent has experienced a change in situation or status that now requires that he or she obtain minimum essential coverage. This includes victims of domestic abuse or spousal abandonment. This also includes AmeriCorps servicemen and women who are starting or ending their service. **Coverage Effective Dates**: Vary based on circumstances.	EX	CMS Caseworker, Marketplace Call Center (in some cases, Application)

Exhibit A-4

HealthCare.gov

Special Enrollment Periods for complex issues

IMPORTANT: Recently impacted by a hurricane or other natural disaster?

If you were qualified to enroll in Marketplace coverage during Open Enrollment or a Special Enrollment Period but were unable to enroll due to a hurricane or other natural disaster, you may be eligible for another Special Enrollment Period. To qualify, you must live (or have lived during the event) in a county that is eligible to apply for "individual assistance" or "public assistance" by the Federal Emergency Management Agency (FEMA) (https://www.fema.gov/disasters). If you are eligible, you have 60 days from the end of the FEMA-designated incident period to complete your enrollment in Marketplace coverage and request a retroactive start date based on when you would have picked a plan if not for the disaster. See the following link for FEMA designation information: https://www.fema.gov/disasters (https://www.fema.gov/disasters). For help enrolling through this Special Enrollment Period, contact the Marketplace Call Center (/contact-us/).

Outside the Open Enrollment Period, you can enroll in a private health plan through the Marketplace **only** if you qualify for a Special Enrollment Period.

You can qualify for a Special Enrollment Period if either of the following applies to you:

- You have a qualifying life event (/glossary/qualifying-life-event) like having a baby, getting married, or losing minimal essential coverage (/glossary/minimum-essential-coverage). Learn more about Special Enrollment Periods and other coverage options outside Open Enrollment (/coverage-outside-open-enrollment/).
- You have other complicated situations, as described on this page.

Other complicated cases that may qualify you for a Special Enrollment Period

Below are cases and examples that may also qualify you for a Special Enrollment Period:

- You experience an exceptional circumstance (/sep-list/#exceptional)
- You experience a Marketplace enrollment or plan information display error (/sep-list/#error)
- You live or previously lived in a state that hasn't expanded Medicaid and you become newly eligible for help paying for a Marketplace insurance plan (/sep-list/#state)
- You are determined ineligible for Medicaid or CHIP (/sep-list/#ineligible)
- You gain or become a dependent due to a child support or other court order (/sep-list/#dependent)
- You experience domestic abuse/violence or spousal abandonment (/sep-list/#domestic)
- You get an appeal decision that's in your favor (/sep-list/#appeal)

Exceptional circumstance

You faced a serious medical condition or natural disaster that kept you from enrolling. For example:

- An unexpected hospitalization or temporary cognitive disability, or were otherwise incapacitated
- A natural disaster, such as an earthquake, massive flooding, or hurricane

Enrollment or plan information display errors

- Misinformation, misrepresentation, misconduct, or inaction of someone working in an official capacity to help you enroll (like an insurance company, navigator, certified application counselor, or agent or broker) kept you from:
    - Enrolling in a plan
    - Enrolling in the right plan
    - Getting the premium tax credit or cost-sharing reduction you were eligible for
- A technical error occurred when you applied on HealthCare.gov -- you probably saw an error message when completing your application – that prevented:
    - You from enrolling in a plan, **or**

- Your health insurance company from receiving your enrollment information

- The wrong plan data was displayed on HealthCare.gov at the time that you selected your health plan, such as benefit or cost-sharing information.

Becoming newly eligible for help paying for a Marketplace insurance plan during or after living in a state that hasn't expanded Medicaid

You previously lived in a state that hasn't expanded Medicaid and weren't eligible for Medicaid or advance payments of the premium tax credit (APTC) because your income was too low. But in the last 60 days, you had an increase in household income or moved, making you newly eligible for premium tax credits (/glossary/premium-tax-credit).

Being determined ineligible for Medicaid or CHIP

You applied for Medicaid or CHIP during the Marketplace Open Enrollment Period and your state Medicaid or CHIP agency determined that you weren't eligible for Medicaid or CHIP after Open Enrollment ended. You may qualify for a Special Enrollment Period regardless of whether you applied through:

- The Marketplace and your information was sent to your state Medicaid or CHIP agency, **or**
- Your state Medicaid or CHIP agency directly

Gaining or becoming a dependent due to a child support or other court order

You gained a new dependent or became a dependent of someone else due to a court order. Your coverage would start the effective date of the court order – even if you enroll in the plan up to 60 days afterward.

Having experienced domestic abuse/violence or spousal abandonment

You're a survivor of domestic abuse/violence or spousal abandonment and want to enroll in your own health plan separate from your abuser or abandoner. You can enroll by contacting the Marketplace Call Center (/contact-us/). Your dependents may be eligible too.

If you're married to your abuser/abandoner, you can answer on your Marketplace application that you're unmarried, without fear of penalty for mis-stating your marital status. You then become eligible for a premium tax credit and other savings on a Marketplace plan, if you qualify based on your income.

If you qualify for this SEP, you'll have 60 days to enroll in a Marketplace plan.

Prevailing on an appeal

You believe you received an incorrect eligibility determination or an incorrect coverage effective date and file an appeal with the Marketplace. If the ruling goes in your favor, you'll be given the option to enroll in or change plans either retroactively or prospectively.

If you think you qualify for a Special Enrollment Period

If you think you qualify for a Special Enrollment Period for one of the situations listed on this page, contact the Marketplace Call Center at 1-800-318-2596 (TTY: 1-855-889-4325)

The representative will ask for information about your situation to determine if your circumstances qualify you for a Special Enrollment Period. The representative will help you apply and enroll in coverage.

If you're already enrolled in a plan and you get a Special Enrollment Period, you can stay in your current plan in most cases, or you can switch plans. In some limited cases, you may qualify for an earlier effective date of coverage. Remember, you must make the first premium payment before your coverage becomes effective.

Filing an appeal

If your request for a Special Enrollment Period is denied, you can file an appeal. If the denial is found incorrect, you can get coverage back to the date your Special Enrollment Period was denied.

How to file an appeal:

- Select your state's appeal form (/marketplace-appeals/appeal-forms/), download it, and fill it out
- Mail your appeal to:

  Health Insurance Marketplace
  Attn: Appeals
  465 Industrial Blvd.
  London, KY 40750-0061

When possible, include a copy of any eligibility determination notice or other official notice you received. This isn't required, but will help us process your appeal.

When mailing the appeal request to the Health Insurance Marketplace, be sure to include the last 4 digits of the London, KY ZIP code (40750-0061). This will help your appeal arrive faster.

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A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore, MD 21244

Exhibit A-5

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C4-21-26
Baltimore, Maryland 21244-1850

CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

DATE: August 9, 2018

TO: All Federally-facilitated Exchange (FFE) Qualified Health Plan (QHP) and Stand-alone Dental Plan Issuers

FROM: Randy Pate
Director, Center for Consumer Information and Insurance Oversight

SUBJECT: Emergency and Major Disaster Declarations by the Federal Emergency Management Agency (FEMA) – Special Enrollment Periods (SEPs), Termination of Coverage, and Payment Deadline Flexibilities, Effective August 9, 2018

Special Enrollment Periods. The FFEs offer SEPs outside of the annual Open Enrollment Period (OEP) to individuals who experience qualifying events. Typically, individuals have 60 days from the date of the qualifying event to enroll in a Qualified Health Plan (QHP). However, if an individual or his or her dependents are affected by an emergency or major disaster that is recognized with a formal declaration from the Federal Emergency Management Agency (FEMA) and that emergency or major disaster prevents the individual or his or her dependents from enrolling within 60 days of the qualifying event, the individual and his or her dependents will be eligible for an Exceptional Circumstances SEP under 45 CFR §155.420(d)(9) that allows them to complete their Exchange enrollment.

Additionally, an individual or his or her dependents who are affected by an emergency or major disaster that is recognized with a formal declaration from FEMA and that emergency or major disaster prevents the qualified individual or his or her dependents from enrolling during the OEP will also be eligible for an Exceptional Circumstances SEP under 45 CFR §155.420(d)(9).

Individuals will be considered "affected by a FEMA-declared emergency or major disaster" (hereinafter referred to as FEMA-emergency affected) and eligible for an Exceptional Circumstances SEP under 45 CFR §155.420(d)(9) if they were unable to enroll in an enrollment period for which they were eligible (i.e., either the OEP or a SEP) due to a FEMA-declared emergency or major disaster. To demonstrate this, individuals will be required to attest that they meet the following eligibility requirements: 1) they resided in any of the counties that are eligible to apply for "individual assistance" or "public assistance" by FEMA either during the FEMA-designated incident period of the emergency or major disaster, or at the time of application for enrollment; and 2) they were affected by the emergency or disaster, and that it prevented them from completing enrollment. See https://www.fema.gov/disasters for all FEMA declarations of emergency and major disasters.

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Length of SEP and Coverage Effective Dates. FEMA-emergency affected individuals will have up to 60 days from the end of the FEMA-designated incident period to select a new QHP through the FFE or make changes to their existing QHP enrollment. FEMA-emergency affected individuals can choose to have coverage start in the future, pursuant to regular effective date rules outlined in 155.420(b)(1), or can request an effective date that would have applied if they had selected a plan during their original enrollment opportunity on or after the FEMA-designated incident start date. Coverage effective date rules vary based on the date of plan selection and the qualifying event for the enrollment opportunity. For more information regarding coverage effective date rules, see Special Enrollment Period Overview at https://marketplace.cms.gov/technical-assistance-resources/special-enrollment-periods-.html.

For example, Mary Smith's employer-sponsored health insurance coverage ended on June 1. Because Mary lost minimum essential coverage (MEC), she qualifies for an SEP under 45 CFR §155.420(d)(1)(i) and has 60 days from the loss of MEC, through July 31st, to select a QHP. However, Mary was unable to complete her FFE application and QHP selection by July 31st because a severe tropical storm flooded the ground floor of her home in Mobile County, Alabama (AL). She stayed with relatives in nearby Clark County for several days until the flood waters receded, and then spent the next several weeks cleaning up the damage.

On July 7th, FEMA announced a Major Disaster Declaration related to the storm and flooding, with an incident period of June 20th-22nd. FEMA designated several AL counties, including Mobile, as eligible to apply for public assistance. As such, even though her SEP for loss of MEC has expired, Mary is now eligible for an Exceptional Circumstances SEP under 45 CFR §155.420(d)(9) and may apply for and select FFE coverage through August 21st (60 days from June 22nd). If Mary selects a QHP between August 1st and August 15th, she will be eligible to start coverage in the future (on September 1st, per regular effective date rules) or in the past (on July 1st or August 1st – effective dates that would have been available if she had chosen a plan during the loss of MEC SEP window, but after June 20th, the FEMA incident start date). Additionally, if Mary selects a plan under this Exceptional Circumstances SEP between August 16th and August 21st, she will be eligible to start retroactive coverage on July 1st or August 1st (effective dates that would have been available if she had chosen a plan during the loss of MEC SEP window, but after June 20th, the FEMA incident start date), or choose to start coverage in the future, on October 1st, per regular effective date rules.

Table 1 provides additional samples of qualifying events and coverage dates for FEMA-emergency affected individuals.

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Table 1. Sample SEP Coverage Effective Dates for FEMA-Emergency Affected Individuals

Qualifying Event	Date of Qualifying Event	Qualifying Enrollment Period End Date	FEMA Incident Start Date	FEMA Incident End Date	Exceptional Circumstance SEP End Date	Plan Selection Date Example	Available Coverage Effective Date(s)
Birth or Adoption*	6/1	7/31	6/20	6/22	8/21	8/3	6/1,7/1, 8/1, or 9/1
Birth or Adoption*	6/1	7/31	7/5	7/23	9/22	9/21	6/1, 8/1, 9/1, or 11/1
Loss of Coverage	6/1	7/31	6/20	6/22	8/21	8/5	7/1, 8/1,or 9/1
Loss of Coverage	6/23	8/22	6/20	7/22	9/21	9/3	7/1, 8/1, 9/1 or 10/1
Annual OEP	n/a	12/15	11/2	11/15	1/14	12/19	1/1 or 2/1
Annual OEP	n/a	12/15	11/30	12/10	2/9	2/3	1/1 or 3/1

*Per 45 CFR §155.420(b)(2)(i), the Exchange is required to ensure that coverage is effective for a qualified individual on the date of birth, adoption, placement for adoption, placement in foster care, or effective date of the child support order or other court order. However, qualified individuals may also call the Marketplace Call Center to alternatively elect a coverage effective date for the first of the month following plan selection or following regular coverage effective rules.

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How to Enroll in Coverage. To request an Exceptional Circumstances SEP, FEMA-emergency affected individuals must contact the Marketplace Call Center at 1-800-318-2596 or TTY at 1-855-889-4325 and indicate they were eligible for another enrollment window, but were unable to complete their enrollment due to a FEMA-designated emergency or disaster. To expedite the SEP process, in advance of calling the Marketplace Call Center, FEMA-emergency affected individuals can complete an application on HealthCare.gov directly or with the assistance of a Navigator, Agent/Broker, Certified Application Counselor, or Direct Enrollment Partner. The initial eligibility results may show the individual is not eligible to enroll because the OEP or SEP has ended. Each SEP request must be individually re-evaluated by a caseworker, which may take several days. Caseworkers will review an individual's eligibility for the SEP using available information from Marketplace consumer records and public information on FEMA declarations. Individuals will be notified of the SEP eligibility determination by mail. Once an individual receives notice he or she is eligible for the SEP, he or she may visit HealthCare.gov (or call the Marketplace Call Center) to select a plan.

Additional Special Enrollment Period Information. Individuals impacted by natural disasters that do not receive FEMA designations may be considered for eligibility individually for an Exceptional Circumstances SEP under 45 CFR §155.420(d)(9). For example, if an individual was a victim of a house fire and was displaced during OEP, he or she may be eligible for an Exceptional Circumstances SEP. Individuals impacted by any natural disaster such that they are unable to enroll during an enrollment opportunity for which they qualify may contact the Marketplace Call Center at 1-800-318-2596 or TTY at 1-855-889-4325 to request enrollment.

Additionally, individuals may experience qualifying events due to a natural disaster that make them eligible for other SEPs allowing them to access a new QHP. For example, an individual who temporarily relocated due to a hurricane and is now residing outside of his or her current QHP's service area may be eligible for an SEP due to this move. See https://marketplace.cms.gov/outreach-and-education/special-enrollment-periods-available-to-consumers.pdf for more information on what circumstances and situations allow for an SEP. Consumers eligible for one of the other SEPs listed at that link can apply for coverage directly through https://www.healthcare.gov/.

Termination of Enrollment or Coverage. The FFEs permit an individual to choose to terminate his or her coverage through the FFE for any reason. Enrollees who terminate their coverage due to hardship from a FEMA-designated or other natural disaster may be exempted from associated tax penalties. Further, the Tax Cuts and Jobs Act of 2017 will eliminate the individual mandate penalty owed by consumers who do not maintain minimum essential coverage (MEC) or obtain an exemption, effective beginning in tax year 2019. For more information regarding hardship exemptions, see: https://marketplace.cms.gov/technical-assistance-resources/exemption-general-hardship.pdf

Consumer Payments and Grace Period Extensions. If issuers comply with a state regulatory authority's request, in reaction to a natural disaster or other emergency disruption within a state,

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to extend premium payment deadlines and delay cancellations for non-payment of premium, CMS may exercise enforcement discretion with regard to regulatory requirements such as the deadline for payment to effectuate coverage and the deadline for payment of premiums under grace periods, including for individuals receiving APTCs.

Relief from Compliance Standards (e.g., enrollment processing). CMS will consider refraining from taking compliance actions in instances where a QHP issuer's failure to comply was the direct result of the conditions created by a FEMA-designated natural disaster, and the issuer could not have taken reasonable steps in advance to prevent the compliance failure.

Please direct any questions to your CMS Account Manager.

Exhibit A-6

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CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT

DATE: September 28, 2017

TO: All Federally-facilitated Exchange (FFE) Qualified Health Plan (QHP) and Stand-alone Dental Plan Issuers

FROM: Randy Pate
Director, Center for Consumer Information and Insurance Oversight

SUBJECT: 2017 Hurricane Disasters – Special Enrollment Periods (SEPs), Termination of Coverage, and Grace Period Flexibilities

Special Enrollment Periods. The FFE offers SEPs outside of the annual Open Enrollment Period to individuals who experience qualifying events. Typically, such individuals have 60 days from the date of the qualifying event to enroll in a QHP. However, all individuals who experience(d) an SEP-qualifying event between 60-days prior to the start date of the incident period designated by Federal Emergency Management Agency (FEMA) and December 31, 2017, but were unable to complete the application and plan selection process because they were affected by a hurricane-related weather event in 2017, will be eligible for an additional 60-day Exceptional Circumstances SEP under 45 CFR §155.420(d)(9) that will allow them to complete their Exchange enrollment.

Individuals will be considered "affected" and eligible for this SEP if they experienced an SEP-qualifying event and attest that they reside, or resided at the time of the hurricane, in any of the counties declared as meeting the level of "individual assistance" or "public assistance" by FEMA.

This SEP will allow these affected individuals to select a new 2017 QHP through the FFE or make changes to their existing 2017 QHP enrollment through the FFE at any time through December 31, 2017. Affected individuals will be able to request a retroactive effective date based on the date of when they would have selected a plan under their original SEP but no earlier than the date that would have applied if the individual had selected a plan on the FEMA-designated incident start date of the service area in which they resided. We will continue to examine the circumstances in the areas affected by hurricanes and will consider taking action that reaches beyond December 31, 2017, if needed. Affected individuals may contact the Marketplace Call Center at 1-800-318-2596 or TTY at 1-855-889-4325 to request enrollment using this SEP.

Additionally, individuals may experience qualifying events due to a hurricane that makes them eligible for other SEPs allowing them to access a new 2017 QHP. For example, an individual who temporarily relocated due to a hurricane and is now residing outside of their current QHP's service area may be eligible for an SEP due to this move. See https://marketplace.cms.gov/outreach-and-education/special-enrollment-periods-available-to-consumers.pdf for more information on what circumstances and situations allow for an SEP. Consumers eligible for one of the other SEPs listed at that link can apply for coverage directly through HealthCare.gov.

The FFE typically requires pre-enrollment verification for new QHP enrollees who are attempting to enroll via certain SEP types. If eligibility for one of these SEPs is not otherwise verified, applicants are directed to send to the FFE documentation proving eligibility for the SEP before the FFE can make a final SEP eligibility determination and send the enrollment to the issuer. The FFE will waive this verification requirement, including by permitting attestation for applicants with pended enrollments who attest to residing in areas affected by hurricanes and who created an application between 60-days prior to the start date of the incident period designated by FEMA and December 31, 2017.

In addition to the above-mentioned SEPs for the 2017 plan year, individuals attesting to residing in or moving from areas affected by a hurricane-related weather event in 2017 will be eligible for an Exceptional Circumstances SEP under 45 CFR §155.420(d)(9) that extends the 2018 Annual Open Enrollment Period through December 31, 2017. Such individuals may contact the Marketplace Call Center at 1-800-318-2596 or TTY at 1-855-889-4325 to request enrollment using this SEP after December 15, 2017. We will continue to examine the circumstances in the areas affected by hurricanes and will consider taking action that reaches beyond December 31, 2017, if needed.

Termination of Enrollment or Coverage. The FFE permits an individual to choose to terminate his or her coverage through the FFE for any reason. Enrollees who terminate their coverage due to hardship from a hurricane may be exempted from associated tax penalties. For more information, see: https://marketplace.cms.gov/technical-assistance-resources/exemption-general-hardship.pdf

Consumer Payments and Grace Period Extensions. The FFE has established regulatory parameters at 45 CFR §§155.400(e) and 156.270(g) regarding consumer payment deadlines to effectuate coverage and timelines for payment of premiums under grace periods for consumers receiving advance premium tax credits (APTCs). In response to requests or direction from the applicable state authorities, issuers may consider setting more generous deadlines for payments to effectuate prospective coverage, such as allowing affected enrollees to make a binder payment (1) more than 30 days after the coverage effective date for coverage effectuated under regular coverage effective date rules pursuant to 45 CFR 155.400(e)(1)(i), or, (2) for prospective coverage to be effectuated under special effective date rules pursuant to 45 CFR

155.400(e)(1)(ii), on a date occurring after the later of the date the issuer receives the enrollment transaction or the effective date for such coverage.

CMS will allow QHP issuers to comply with state health insurance authorities' direction or requests to provide extensions for enrollments occurring up to one week before an incident period designated by FEMA through the end of such incident period, but in the absence of specific state guidance relating to the length of such extensions, QHP issuers may allow affected enrollees an extension of no more than 60 days from the original binder payment deadline.

When acting in response to a request or direction from the state health insurance authorities, issuers also may provide a more generous grace period for consumers receiving APTC. Where an affected individual's (as defined above) three-month grace period expires or will expire on or after the date one week prior to the start date of an incident period designated by FEMA, CMS will not take enforcement action against a QHP issuer that does not immediately terminate the affected individual's coverage at the end of the three-month grace period The qualified health plan issuer may grant such an affected individual an additional 60 days, or an extension period whose length is determined by the request or order of the applicable state authorities, to satisfy past due premium payments.

QHP issuers may implement these grace period extensions from the date one week before the start of an incident period designated by FEMA through the end of such incident period. Issuers must, however, provide to enrollees adequate notice that the enrollees' coverage will not be terminated in accordance with 156.270(g) and how such grace period extensions might affect Guaranteed Availability for the enrollees – especially when an issuer has adopted and correctly implemented the new policy on guaranteed availability in the Market Stabilization Rule which, under certain circumstances, allows QHP issuers to require satisfaction of delinquent payments before issuing or renewing coverage. See 82 Fed. Reg. 18346, 18349 – 53 (Apr. 18, 2017), https://www.gpo.gov/fdsys/pkg/FR-2017-04-18/pdf/2017-07712.pdf. Although the length of the grace period may be extended, the basic operations of the grace period for enrollees receiving the benefit of APTC's would remain unchanged. Issuers must pay all appropriate claims for services rendered to the enrollee during the first month of the grace period and may pend claims for services rendered to the enrollee in subsequent months of the grace period; notify HHS of such non-payment of premiums; notify providers of the possibility for denied claims when an enrollee is beyond the first month of the grace period; and return APTC for the subsequent months if the enrollee exhausts the grace period.

Relief from Compliance Standards (e.g. enrollment processing). CMS will consider refraining from taking compliance actions in instances where a QHP issuer's failure to comply was the direct result of the conditions created by recent storms, and the issuer could not have taken reasonable steps in advance to prevent the compliance failure.

Please direct any questions to your CMS Account Manager.

Exhibit A-7

CMS Announces Additional Special Enrollment Periods to help Individuals Impacted by Hurricanes in Puerto Rico and the U.S. Virgin Islands

Jan 17, 2018 Coverage, Medicare Part C

Share

Agency provides extended special enrollment periods for 2018 Medicare and Exchange coverage

The Centers for Medicare & Medicaid Services (CMS) announced additional opportunities for individuals affected by the 2017 hurricanes in Puerto Rico and the U.S. Virgin Islands to enroll in Medicare health and drug plans and health coverage through the Federal Health Insurance Exchange. CMS is providing these special enrollment periods so that certain individuals and families who were impacted can access health coverage on the Exchange and have additional time to join, drop, or switch Medicare health and prescription drug plans. CMS announced initial special enrollment period opportunities in September, this extends these opportunities through March 31, 2018.

“CMS is committed to making it as easy as possible for individuals and families whose lives have been disrupted by these hurricanes to access the healthcare coverage they need during this difficult time,” said CMS Administrator Seema Verma. “The impacts of a hurricane can last for months. These special enrollment periods provide the necessary flexibility for our beneficiaries to obtain and maintain coverage while dealing with the lingering aftermath of the storms. We will continue to monitor the circumstances in Puerto Rico and the U.S. Virgin Islands and will take additional action as necessary.”

CMS established the following special enrollment periods to support individuals impacted by the 2017 hurricanes in Puerto Rico and the U.S. Virgin Islands:

- **Federal Health Insurance Exchange special enrollment period:** Individuals affected by the 2017 hurricanes in Puerto Rico and the U.S. Virgin Islands who relocated to a state that uses the Federal Health Insurance Exchange, but were unable to enroll during the 2018 Annual Open Enrollment Period or any other special enrollment period, are eligible for an exceptional circumstance special enrollment period to enroll in 2018 Exchange coverage. Individuals in this situation may request this special enrollment period through March 31, 2018. These individuals should contact the Exchange Call Center at 1-800-318-2596 to request enrollment using this special enrollment period.

- **Medicare special enrollment period extension:** This special enrollment period will allow individuals affected by the 2017 hurricanes in Puerto Rico and the U.S. Virgin Islands to enroll, dis-enroll or switch Medicare health or prescription drug plans through March 31, 2018. This special enrollment period can be used even if the beneficiary made a choice during Medicare's fall open enrollment period. The special enrollment period can also be used for those who left Puerto Rico and would like to enroll in a local Medicare Advantage or Medicare prescription drug plan that would better meet their healthcare needs. Beneficiaries who change their permanent residence, rather than temporarily relocate, and no longer reside in their plan service area, are eligible to join a Medicare Advantage or prescription drug plan offered in the new area in which they reside through the existing residence change special enrollment period. Individuals who were displaced and return to Puerto Rico or the U.S. Virgin Islands are also eligible for the residence change special enrollment period. Individuals in these situations may contact 1-800-MEDICARE to request enrollment using this special enrollment opportunity.

For more information on special enrollment periods for the Federal Health Insurance Exchange, visit: https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Territories-SEP-Guidance.pdf

For more information on special enrollment period extension for Medicare, visit: https://www.cms.gov/About-CMS/Agency-

Information/Emergency/Downloads/Extension-SE-Period-PR-VI-CA-Wildfire.pdf

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Exhibit A-8

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information and Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

Date: May 2, 2014

Subject: Special Enrollment Periods and Hardship Exemptions for Persons Meeting Certain Criteria

This guidance provides information related to three types of special enrollment periods (SEPs) for persons seeking to enroll in qualified health plans (QHPs) through the Federally-facilitated Marketplace (FFM). State-based Marketplaces (SBMs) are encouraged to adopt similar special enrollment periods. The document also contains information about two hardship exemptions available for eligible consumers in FFM and SBM states.

A. Background

45 CFR 155.420(d)(9) specifies that an Exchange must provide a special enrollment period when "[t]he qualified individual or enrollee, or his or her dependent, demonstrates to the Exchange, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Exchange may provide."

Section 5000A of the Internal Revenue Code provides that, beginning in January 2014, nonexempt individuals who do not have minimum essential coverage (MEC) or who are not otherwise exempt will make a shared responsibility payment with their federal income tax returns. Pursuant to section 5000A(e)(5), the Secretary of HHS may determine that individuals who have suffered a hardship with respect to the ability to enroll in minimum essential coverage are exempt from the individual shared responsibility provision. *See* 45 CFR 155.605(g).

B. Specific Special Enrollment Periods and Hardship Exemptions

1. Hardship Exemption for Persons who Obtained Coverage that was Effective as of May 1, 2014

On October 28, 2013, HHS issued guidance indicating that individuals who enroll in QHPs through the Marketplace prior to the close of the initial open enrollment period would be eligible for a hardship exemption from the shared responsibility payment for the months prior to the effective date of the individual's coverage.[1] Further, on March 26, 2014, HHS noted that, consistent with previous guidance, consumers who receive a special enrollment period for being "in line" by March 31 and select new coverage in the FFM, will be eligible for a hardship exemption from the shared responsibility payment for the months prior to the effective date of their coverage, because they were treated as if they had enrolled in coverage by March 31.[2]

[1] http://www.cms.gov/CCIIO/resources/fact-sheets-and-FAQs/downloads/enrollment-period-faq-10-28-2013.pdf
[2] http://www.cms.gov/cciio/Resources/Regulations-and-Guidance/Downloads/in-line-SEP-3-26-2014.pdf

HHS is concerned that some consumers may not have realized that the relief provided by the guidance above was limited solely to those individuals purchasing QHPs through the Marketplace. HHS recognizes that individuals who obtained other forms of MEC effective as of May 1, 2014 outside of the Marketplace (including individual or group plans) are, to a large extent, similarly situated to those who purchased QHPs through the Marketplace with a May 1, 2014 effective date. Accordingly, HHS will extend a comparable hardship exemption for all months prior to the effective date of coverage for those individuals who obtained MEC effective on or before May 1, 2014 outside of the Marketplace.[3] This hardship exemption is available to consumers in states with a Federally-facilitated Marketplace or a State-based Marketplace. Individuals are not required to submit an exemption application to the Marketplace.

2. Special Enrollment Periods for Individuals Eligible for or Enrolled in COBRA

The Consolidated Omnibus Budget Reconciliation Act (COBRA) gives group health plan participants and beneficiaries the right to choose to continue their group health plan benefits for limited periods of time under certain circumstances such as voluntary or involuntary job loss, reduction in the hours worked, transition between jobs, death, divorce, and other life events. *See* ERISA sections 601-608.

Section 155.420(d)(1) of title 45 of the CFR provides special enrollment periods for QHPs in the Marketplace to persons eligible for COBRA when: (1) such persons initially are eligible for COBRA due to a loss of other minimum essential coverage; and (2) when such persons' COBRA coverage is exhausted. In addition, COBRA beneficiaries are able to choose QHPs in the Marketplace during the annual open enrollment period and if they are determined eligible for any other special enrollment periods outside of the open enrollment period.

HHS is concerned that former Model COBRA Continuation Coverage Election Notices (Model Election Notices) (and substantially similar documents provided by employers) did not address, or did not sufficiently address, Marketplace options for persons eligible for COBRA and COBRA beneficiaries. Thus, persons eligible for COBRA and COBRA beneficiaries may have had insufficient information to understand they only can enroll in QHPs in the Marketplace during the open enrollment period and special enrollment periods as described above.[4] As a result, in accordance with 45 CFR 155.420(d)(9), HHS is providing an additional special enrollment period based on exceptional circumstances so that persons eligible for COBRA and COBRA beneficiaries are able to select QHPs in the FFM.

Affected individuals have 60 days from the date of this bulletin, that is, through July 1, 2014, to select QHPs in the FFM. These individuals should contact the Marketplace call center at 1-800-

[3] The IRS and Treasury Department intend to publish guidance allowing an individual to claim a hardship exemption from the individual shared responsibility provision for the months in 2014 prior to the effective date of the individual's coverage if the individual enrollment in minimum essential coverage becomes effective on or before May 1, 2014.

[4] Contemporaneous with the release of this bulletin, DOL is releasing updated versions of the Model Election Notice and the Model COBRA Continuation Coverage General Notice. These new model notices reflect that the Marketplace is now open and better describes individuals' coverage options.

318-2596 to activate the special enrollment period. They should inform the Marketplace call center that they are calling about their COBRA benefits and the Marketplace. Once determined eligible for the special enrollment period, consumers can then view all plans available to them and continue the enrollment process over the phone or online through creating an account on healthcare.gov or logging into their existing account.

3. Special Enrollment Periods for Individuals Whose Individual Market Plans are Renewing Outside of Open Enrollment

45 CFR 147.104(b)(2) provides that a health insurance issuer in the individual market must provide a limited open enrollment period beginning on the date that is 30 calendar days prior to the date the policy year ends in 2014. In the Proposed Rule on Exchange and Insurance Market Standards for 2015 and Beyond, HHS proposed amending 45 CFR 155.420(d)(1) to adopt a special enrollment period for the FFM that is aligned with the limited special enrollment period in 45 CFR 147.104(b)(2). HHS is currently reviewing comments submitted for the Proposed Rule on Exchange and Insurance Market Standards for 2015 and Beyond.

In light of 45 CFR 147.104(b)(2), consumers may have reasonably expected to have an option not to renew non-calendar year individual market policies and to receive a special enrollment period in the FFM outside of the open enrollment period. Therefore, at this time, in accordance with 45 CFR 155.420(d)(9), HHS will provide special enrollment periods consistent with 45 CFR 147.104(b)(2).

Affected individual market consumers will be able to report to the FFM that they will not renew their plan up to 60 days before the renewal date, and can get coverage in the FFM effective the first of the month following the renewal date. Consumers will also have 60 days from the renewal date to select QHPs in the FFM. If a QHP is selected after the renewal date, coverage will be prospective based on the date of plan selection. These individuals should indicate "loss of other coverage" on their Marketplace application, if they would like to apply for and enroll in a QHP offered by the Marketplace plan, if otherwise eligible.

4. Special Enrollment Periods and Hardship Exemption for AmeriCorps/VISTA/National Civilian Community Corps Members

The Corporation for National and Community Service (CNCS), a Federal agency, manages and provides grants for the AmeriCorps State and National, VISTA, and National Civilian Community Corps (NCCC) programs. These programs provide funding and other support for individuals engaged in national service. CNCS is required to ensure that the members in these programs have health coverage. *See* 42 USC § 12571 (AmeriCorps); 42 USC § 4955(b)(1) (VISTA); and 42 USC § 12618(d) (NCCC).

CNCS and its AmeriCorps programs do not provide group health plan coverage to members because members do not have an employment relationship with either CNCS or its grantees. Some AmeriCorps State and National grantees currently provide coverage to members through short-term limited-duration coverage, as defined in 45 CFR 144.103. With respect to the VISTA

and NCCC members, CNCS contracts with an entity to administer a self-funded health plan. Neither the short-term limited-duration coverage nor the self-funded coverage is MEC. CNCS currently encourages its AmeriCorps grantees to consider meeting their obligation to ensure coverage by providing reimbursement to members for the purchase of Marketplace QHPs. VISTA and NCCC members are also encouraged to seek coverage through the FFM or SBMs. However, many members begin and end their terms of service outside of the open enrollment period. Further, members who have been receiving short-term limited-duration coverage or self-funded coverage will not be able to access QHP coverage in the Marketplace outside of an open enrollment period upon completion of their service, given that this coverage is not MEC and therefore currently does not qualify members for the loss of MEC special enrollment period.

In accordance with 45 CFR 155.420(d)(9), and in light of the statutory obligation for health coverage to be provided to the participants in the AmeriCorps State and National, VISTA, and NCCC programs, HHS has determined that the following individuals and their dependents,[5] as described in 45 CFR 155.420(a)(2), have experienced "exceptional circumstances" and are eligible for a special enrollment period in the FFM:

- Individuals who are beginning service in the AmeriCorps State and National, VISTA, or NCCC programs.
- Individuals who are concluding their service in the AmeriCorps State and National, VISTA, or NCCC programs and are losing access to short-term limited duration coverage or self-funded coverage.

Affected AmeriCorps State and National, VISTA, and NCCC members have 60 days from their triggering event, defined as either the date they begin service, or the date they lose access to short-term limited duration coverage or self-funded coverage from these programs, to select QHPs through the FFM. Coverage will be prospective based on the date of plan selection. These individuals should contact the Marketplace call center at 1-800-318-2596 to activate the special enrollment period. They should inform the Marketplace call center that they are beginning or concluding service with AmeriCorps State and National, VISTA, or NCCC. Once determined eligible for the special enrollment period, consumers can then view all plans available to them and continue the enrollment process over the phone or online through creating an account on healthcare.gov or logging into their existing account.

In addition, in recognition of the need for a transition period, HHS is exercising its authority to establish an additional hardship exemption for calendar year 2014 for certain individuals engaged in service in AmeriCorps State and National, VISTA, or NCCC programs. Specifically, an individual is eligible to receive a hardship exemption certification for all months in calendar year 2014 that include a day on which the individual is engaged in service in AmeriCorps State and National, VISTA, or NCCC programs and is covered either by short-term limited duration coverage or self-funded coverage provided by these programs during their term of service. This hardship exemption is available to consumers in states with a Federally-facilitated Marketplace or a State-based Marketplace. Consumers in all states except Connecticut will need to request

[5] This SEP applies to dependents even though coverage is not provided to dependents of members during their AmeriCorps/VISTA/NCC service, to ensure that the entire family has an option to elect coverage.

the hardship exemption certification using the hardship exemption form available at HealthCare.gov/exemptions, selecting reason #14, and filling in “AmeriCorps”, VISTA” or “NCCC” as the reason. Such individuals in the state of Connecticut should contact Access Health CT to apply for this exemption.

Exhibit A-9

Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

Cases in the U.S.

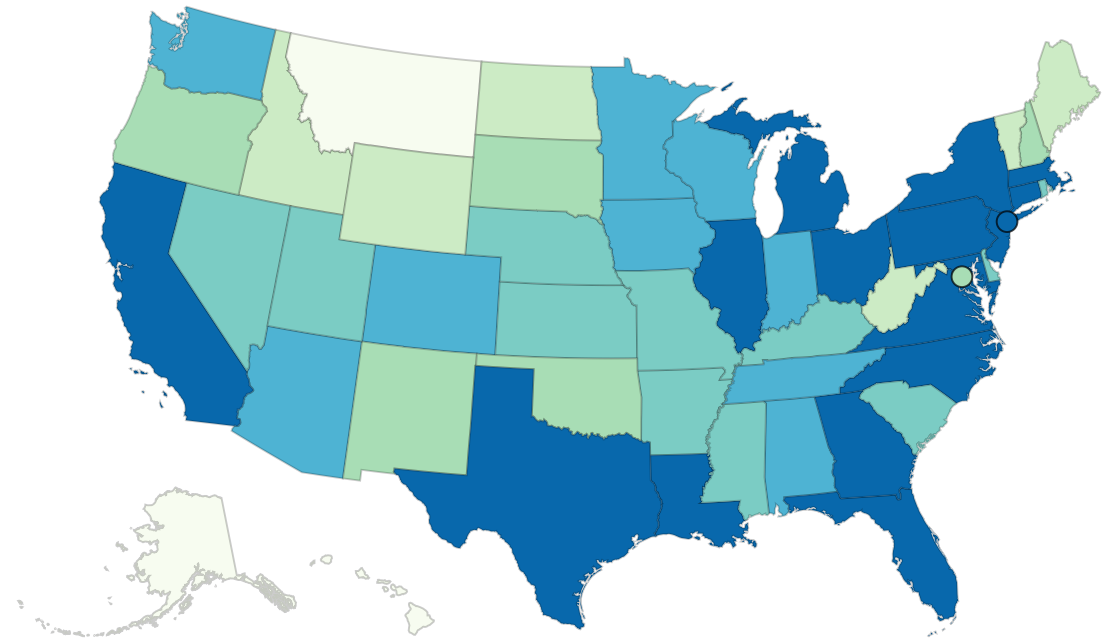
Last updated on June 14, 2020

TOTAL CASES	TOTAL DEATHS
2,063,812	115,271
25,468 New Cases*	646 New Deaths*

Cases & Deaths by Jurisdiction

37 jurisdictions report more than 10,000 cases of COVID-19.

This map shows COVID-19 cases and deaths reported by U.S. states, the District of Columbia, New York City, and other U.S.-affiliated jurisdictions. Hover over the map to see the number of cases and deaths reported in each jurisdiction. To go to a jurisdiction's health department website, click on the jurisdiction on the map.



Jurisdictions +

Add U.S. Map to Your Website

Cases & Deaths by County

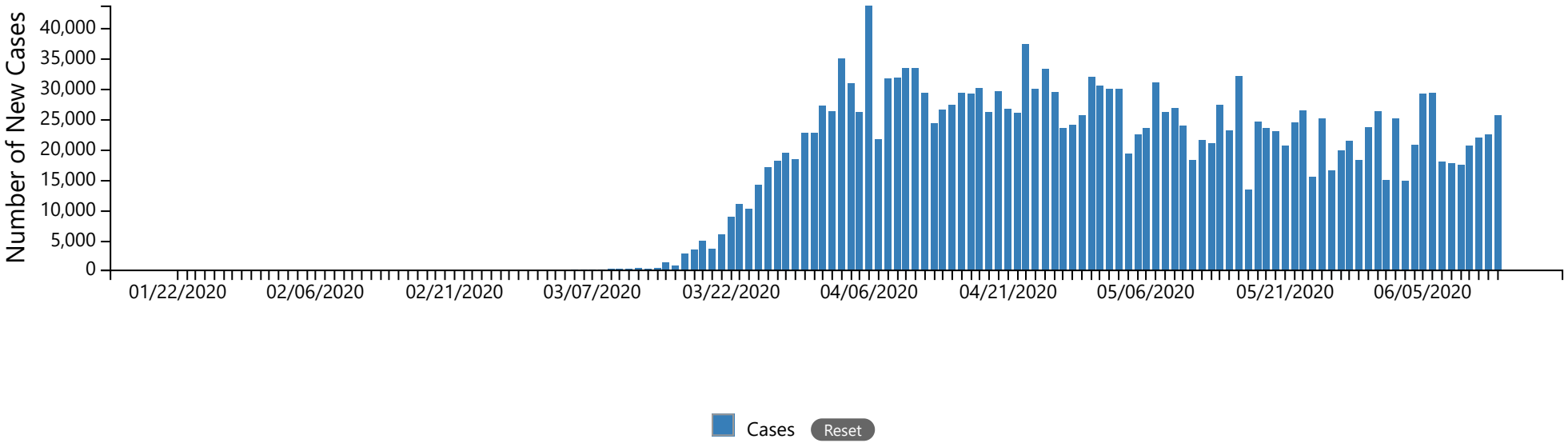
Select a state to view the number of cases and deaths by county. This data is courtesy of USAFacts.org

Select a State

View County Data

New Cases by Day

The following chart shows the number of new COVID-19 cases reported each day in the U.S. since the beginning of the outbreak. Hover over the bars to see the number of new cases by day.

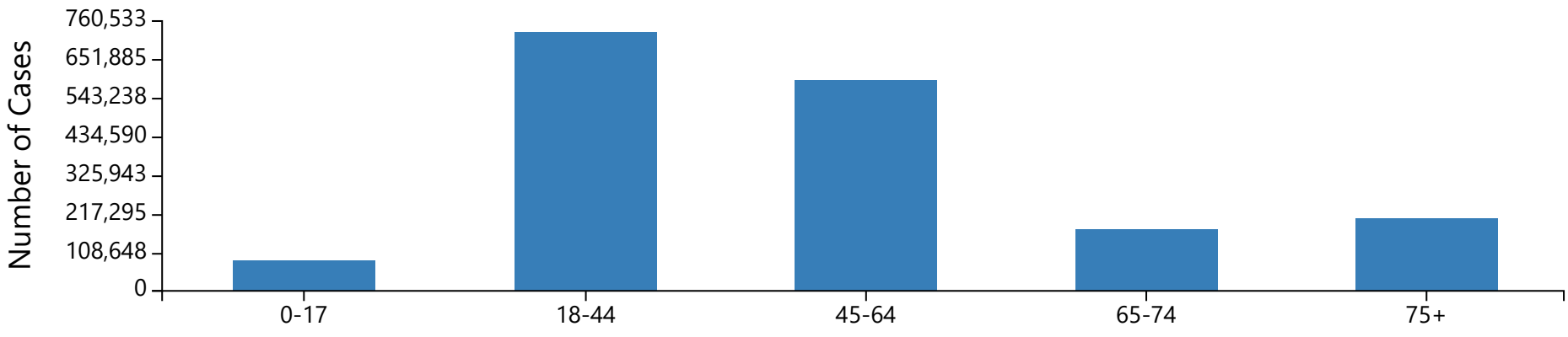


View Data +

Cases by Age

The following chart shows the age of people with COVID-19. Hover over each bar or click on the plus (+) sign below the chart to see the number of cases in each age group.

Data were collected from 1,785,008 people, and age was available for 1,782,664 (99.9%) people.

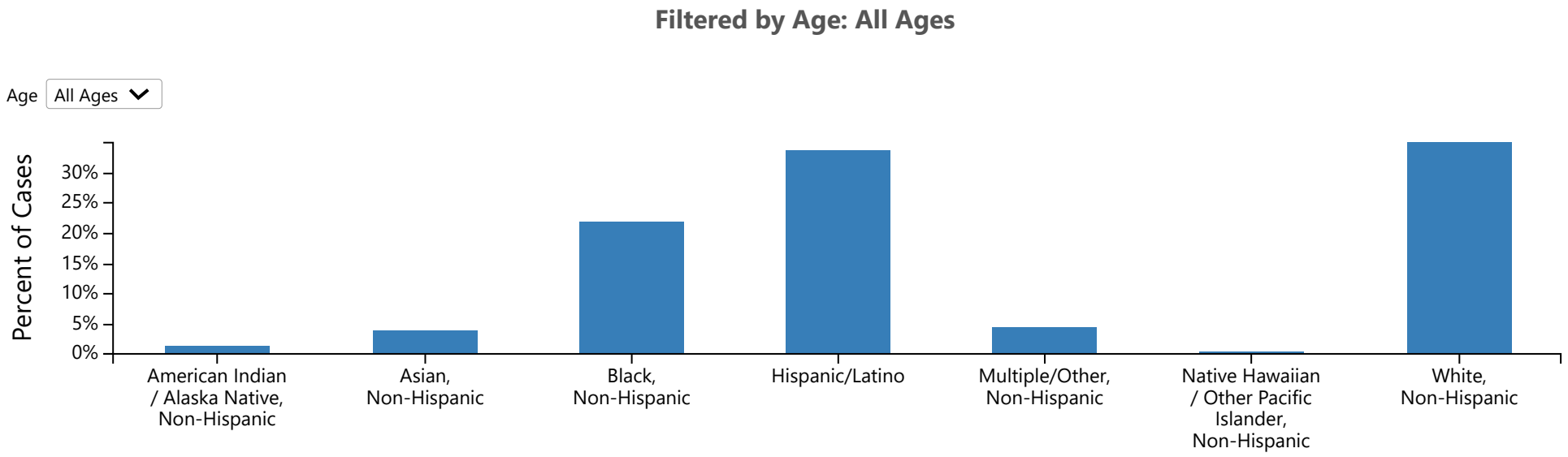


View Data +

Cases by Race/Ethnicity

The following chart shows the race/ethnicity of people with COVID-19. Hover over each bar or click on the plus (+) sign below the chart to see the percentage for each race/ethnicity group. Select from the “Age” dropdown list to see the percentage for each age group.

Data were collected from 1,785,008 people, but race/ethnicity was only available for 859,772 (48.2 %) people. CDC is working with states to provide more information on race/ethnicity for reported cases. The percent of reported cases that include race/ethnicity data is increasing.



View Data +

These data only represent the geographic areas that contributed data on race/ethnicity. Every geographic area has a different racial and ethnic composition. These data are not generalizable to the entire U.S. population.

If cases were distributed equally across racial and ethnic populations, one would expect to see more cases in those populations that are more highly represented in geographic areas that contributed data.

Cases & Deaths among Healthcare Personnel

Data were collected from 1,785,007 people, but healthcare personnel status was only available for 379,858 (21.3%) people. For the 77,186 cases of COVID-19 among healthcare personnel, death status was only available for 48,748 (63.2%).

CASES AMONG HCP	DEATHS AMONG HCP
77,186	412

Previous Data +

CDC has moved the following information to the Previous U.S. COVID-19 Case Data page.

- Level of community transmission by jurisdiction — last updated May 18, 2020

- Total number of cases by day — last updated April 28, 2020
- Number of cases by source of exposure — last updated April 16, 2020
- Number of cases from Wuhan, China and the Diamond Princess cruise — last updated April 16, 2020
- Number of cases by illness start date — last updated April 15, 2020

About the Data +

Updated Daily

This page is updated daily based on data confirmed at 4:00pm ET the day before.

Reported by Jurisdiction's Health Department

Data on this page are reported voluntarily to CDC by each jurisdiction's health department. CDC encourages all jurisdictions to report the most complete and accurate information that best represents the current status of the pandemic in their jurisdiction.

Number of Jurisdictions

There are currently 56 U.S.-affiliated jurisdictions reporting cases of COVID-19. This includes 50 states, District of Columbia, Guam, New York City, the Northern Mariana Islands, Puerto Rico, and the U.S Virgin Islands. New York State's case and death counts do not include New York City's counts as they are separate jurisdictions.

Confirmed & Probable Counts

As of April 14, 2020, CDC case counts and death counts include both confirmed and probable cases and deaths. This change was made to reflect an interim COVID-19 position statement issued by the Council for State and Territorial Epidemiologists on April 5, 2020. The position statement included a case definition and made COVID-19 a nationally notifiable disease. Nationally notifiable disease cases are voluntarily reported to CDC by jurisdictions.

A confirmed case or death is defined by meeting confirmatory laboratory evidence for COVID-19.

A probable case or death is defined by one of the following:

- Meeting clinical criteria AND epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19
- Meeting presumptive laboratory evidence AND either clinical criteria OR epidemiologic evidence
- Meeting vital records criteria with no confirmatory laboratory testing performed for COVID19

Not all jurisdictions report confirmed and probable cases and deaths to CDC. When not available to CDC, it is noted as N/A.

Accuracy of Data

CDC does not know the exact number of COVID-19 illnesses, hospitalizations, and deaths for a variety of reasons. COVID-19 can cause mild illness, symptoms might not appear immediately, there are delays in reporting and testing, not everyone who is infected gets tested or seeks medical care, and there may be differences in how jurisdictions confirm numbers.

Changes & Fluctuations in Data

Health departments may update case data over time when they receive more complete and accurate information.

The number of new cases reported each day fluctuates. There is generally less reporting on the weekends and holidays.

Differences between CDC and Jurisdiction Data

If the number of cases or deaths reported by CDC is different from the number reported by jurisdiction health departments, data reported by jurisdictions should be considered the most up to date. The differences may be due

More Information

- COVIDView – A Weekly Surveillance Summary of U.S. COVID-19 Activity
- Previous U.S. COVID-19 Case Data
- FAQ: COVID-19 Data and Surveillance
- Testing Data in the U.S.
- World Map
- Health Departments

Page last reviewed: June 14, 2020

Exhibit A-10

What law enforcement personnel need to know about coronavirus disease 2019 (COVID-19)

Coronavirus disease 2019 (COVID-19) is a respiratory illness that can spread from person to person. The outbreak first started in China, but cases have been identified in a growing number of other areas, including the United States.

Patients with COVID-19 have had mild to severe respiratory illness.

- Data suggests that symptoms may appear in as few as 2 days or as long as 14 days after exposure to the virus that causes COVID-19.
- Symptoms can include fever, cough, difficulty breathing, and shortness of breath.
- The virus causing COVID-19 is called SARS-CoV-2. It is thought to spread mainly from person-to-person via respiratory droplets among close contacts. Respiratory droplets are produced when an infected person coughs or sneezes and can land in the mouths or noses, or possibly be inhaled into the lungs, of people who are nearby.
  - Close contact increases your risk for COVID-19, including:
    - » Being within approximately 6 feet of an individual with COVID-19 for a prolonged period of time.
    - » Having direct contact with body fluids (such as blood, phlegm, and respiratory droplets) from an individual with COVID-19.

To protect yourself from exposure

- **If possible, maintain a distance of at least 6 feet**.
- **Practice proper hand hygiene**. Wash your hands with soap and water for at least 20 seconds. If soap and water are not readily available and illicit drugs are NOT suspected to be present, use an alcohol-based hand sanitizer with at least 60% alcohol.
- Do not touch your face with unwashed hands.
- Have a trained Emergency Medical Service/Emergency Medical Technician (EMS/EMT) assess and transport anyone you think might have COVID-19 to a healthcare facility.
- Ensure only trained personnel wearing appropriate personal protective equipment (PPE) have contact with individuals who have or may have COVID-19.
- Learn your employer's plan for exposure control and participate in all-hands training on the use of PPE for respiratory protection, if available.

Recommended Personal Protective Equipment (PPE)

Law enforcement who must make contact with individuals confirmed or suspected to have COVID-19 should follow CDC's Interim Guidance for EMS. https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-for-ems.html.

Different styles of PPE may be necessary to perform operational duties. These alternative styles (i.e., coveralls) must provide protection that is at least as great as that provided by the minimum amount of PPE recommended.

The minimum PPE recommended is:

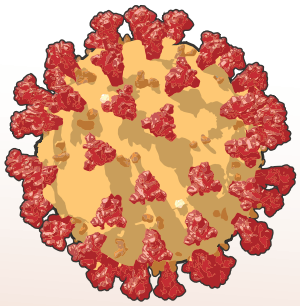
- A single pair of disposable examination gloves,
- Disposable isolation gown or single-use/disposable coveralls*,
- Any NIOSH-approved particulate respirator (i.e., N-95 or higher-level respirator); facemasks are an acceptable alternative until the supply chain is restored, and
- Eye protection (i.e., goggles or disposable face shield that fully covers the front and sides of the face).

*If unable to wear a disposable gown or coveralls because it limits access to duty belt and gear, ensure duty belt and gear are disinfected after contact with individual.

If close contact occurred during apprehension

- Clean and disinfect duty belt and gear prior to reuse using a household cleaning spray or wipe, according to the product label.
- Follow standard operating procedures for the containment and disposal of used PPE.
- Follow standard operating procedures for containing and laundering clothes. Avoid shaking the clothes.

For law enforcement personnel performing daily routine activities, the immediate health risk is considered low. Law enforcement leadership and personnel should follow CDC's Interim General Business Guidance. Search "Interim Guidance for Businesses" on www.cdc.gov.

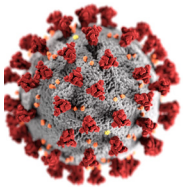


cdc.gov/COVID-19

CS 315526-A 03/16/2020

Exhibit A-11

What you should know about COVID-19 to protect yourself and others



Know about COVID-19

- Coronavirus (COVID-19) is an illness caused by a virus that can spread from person to person.
- The virus that causes COVID-19 is a new coronavirus that has spread throughout the world.
- COVID-19 symptoms can range from mild (or no symptoms) to severe illness.

Know how COVID-19 is spread

- You can become infected by coming into close contact (about 6 feet or two arm lengths) with a person who has COVID-19. COVID-19 is primarily spread from person to person.
- You can become infected from respiratory droplets when an infected person coughs, sneezes, or talks.
- You may also be able to get it by touching a surface or object that has the virus on it, and then by touching your mouth, nose, or eyes.

Protect yourself and others from COVID-19

- There is currently no vaccine to protect against COVID-19. The best way to protect yourself is to avoid being exposed to the virus that causes COVID-19.
- Stay home as much as possible and avoid close contact with others.
- Wear a cloth face covering that covers your nose and mouth in public settings.
- Clean and disinfect frequently touched surfaces.
- Wash your hands often with soap and water for at least 20 seconds, or use an alcohol-based hand sanitizer that contains at least 60% alcohol.

Practice social distancing

- Buy groceries and medicine, go to the doctor, and complete banking activities online when possible.
- If you must go in person, stay at least 6 feet away from others and disinfect items you must touch.
- Get deliveries and takeout, and limit in-person contact as much as possible.

Prevent the spread of COVID-19 if you are sick

- Stay home if you are sick, except to get medical care.
- Avoid public transportation, ride-sharing, or taxis.
- Separate yourself from other people and pets in your home.
- There is no specific treatment for COVID-19, but you can seek medical care to help relieve your symptoms.
- If you need medical attention, call ahead.

Know your risk for severe illness

- Everyone is at risk of getting COVID-19.
- Older adults and people of any age who have serious underlying medical conditions may be at higher risk for more severe illness.

cdc.gov/coronavirus

CS 314937A 04/15/2020

Exhibit A-12

Determination that a Public Health Emergency Exists

As a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV), on this date and after consultation with public health officials as necessary, I, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby determine that a public health emergency exists and has existed since January 27, 2020, nationwide.

01/31/2020	/s/
Date	Alex M. Azar II

More Emergency and Response Information

- Declarations of a Public Health Emergency
- Public Health Emergency Determinations to Support an Emergency Use Authorization
- Section 1135 Waivers
- Emergency Use Authorizations

This page last reviewed: January 31, 2020

Exhibit A-13

THE PRESIDENT'S **CORONAVIRUS GUIDELINES** FOR AMERICA

30 DAYS TO SLOW THE SPREAD

Listen to and follow the directions of your **STATE AND LOCAL AUTHORITIES.**

IF YOU FEEL SICK, stay home. Do not go to work. Contact your medical provider.

IF YOUR CHILDREN ARE SICK, keep them at home. Do not send them to school. Contact your medical provider.

IF SOMEONE IN YOUR HOUSEHOLD HAS TESTED POSITIVE for the coronavirus, keep the entire household at home. Do not go to work. Do not go to school. Contact your medical provider.

IF YOU ARE AN OLDER PERSON, stay home and away from other people.

IF YOU ARE A PERSON WITH A SERIOUS UNDERLYING HEALTH CONDITION that can put you at increased risk (for example, a condition that impairs your lung or heart function or weakens your immune system), stay home and away from other people.

THE WHITE HOUSE

CDC

For more information, please visit

CORONAVIRUS.GOV

THE PRESIDENT'S **CORONAVIRUS GUIDELINES** FOR AMERICA

DO YOUR PART TO SLOW THE SPREAD OF THE CORONAVIRUS

Even if you are young, or otherwise healthy, you are at risk and your activities can increase the risk for others. It is critical that you do your part to slow the spread of the coronavirus.

Work or engage in schooling **FROM HOME** whenever possible.

IF YOU WORK IN A CRITICAL INFRASTRUCTURE INDUSTRY, as defined by the Department of Homeland Security, such as healthcare services and pharmaceutical and food supply, you have a special responsibility to maintain your normal work schedule. You and your employers should follow CDC guidance to protect your health at work.

AVOID SOCIAL GATHERINGS in groups of more than 10 people.

Avoid eating or drinking at bars, restaurants, and food courts — **USE DRIVE-THRU, PICKUP, OR DELIVERY OPTIONS.**

AVOID DISCRETIONARY TRAVEL, shopping trips, and social visits.

DO NOT VISIT nursing homes or retirement or long-term care facilities unless to provide critical assistance.

PRACTICE GOOD HYGIENE:

- *Wash your hands, especially after touching any frequently used item or surface.*
- *Avoid touching your face.*
- *Sneeze or cough into a tissue, or the inside of your elbow.*
- *Disinfect frequently used items and surfaces as much as possible.*

CORONAVIRUS.GOV

School operations can accelerate the spread of the coronavirus. Governors of states with evidence of community transmission should close schools in affected and surrounding areas. Governors should close schools in communities that are near areas of community transmission, even if those areas are in neighboring states. In addition, state and local officials should close schools where coronavirus has been identified in the population associated with the school. States and localities that close schools need to address childcare needs of critical responders, as well as the nutritional needs of children.

Older people are particularly at risk from the coronavirus. All states should follow Federal guidance and halt social visits to nursing homes and retirement and long-term care facilities.

In states with evidence of community transmission, bars, restaurants, food courts, gyms, and other indoor and outdoor venues where groups of people congregate should be closed.

Exhibit A-14

ECONOMY & JOBS

An In-Depth Look at COVID-19's Early Effects on Consumer Spending and GDP

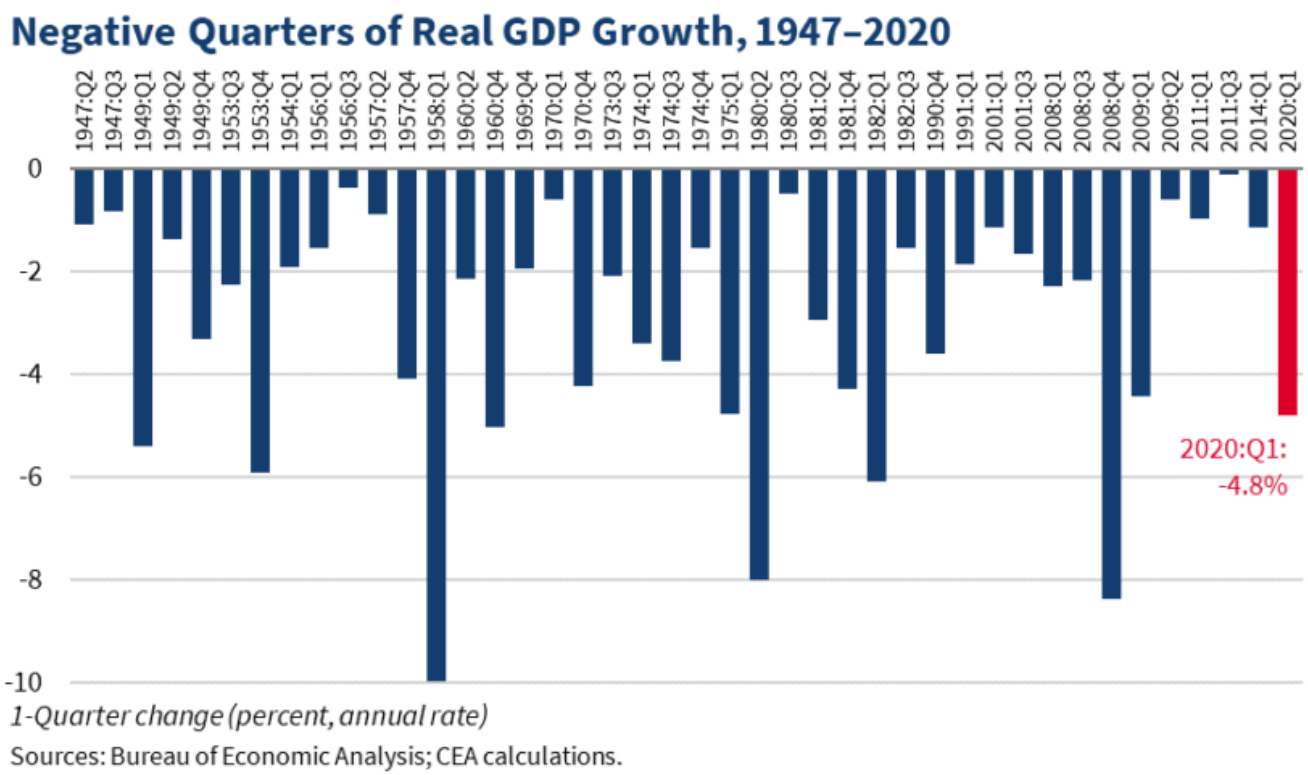
April 29, 2020 | 4 minute read

Council of Economic Advisers

Today, the Bureau of Economic Analysis (BEA) released its advance estimate of U.S. GDP for the first quarter of 2020. BEA estimates that real GDP contracted 4.8 percent at an annual rate in the first quarter of 2020, the first decline in six years. In comparison, real GDP expanded 2.5 percent annually over the first three years of the Trump Administration.

This release confirms that COVID-19's unprecedented adverse shock to the economy brought an end to the longest economic expansion in U.S. history. Consumer spending declined sharply, contributing -5.3 percentage points to the first quarter's contraction. This rapid shift in consumer spending shows that Americans are dramatically curtailing expenditures as the Nation responds to COVID-19. But just as consumers cutting back drove the first quarter's GDP decline, they will also contribute to the economic recovery—showing the importance of policies that support American workers and businesses.

This drop in GDP serves as an early indicator of the costs of the American and global economies shutting down in response to COVID-19. To put a 4.8 percent contraction in perspective, the figure below plots quarters with negative annual GDP declines since the series began in 1947.



Falling consumer spending has major effects on overall GDP growth, as it accounts for roughly 68 percent of GDP. The sharp decline in consumer spending was driven by suppressed spending on services and durable goods, with a partial offset from positive spending on nondurable goods. The service sector alone contributed -5.0 percentage points to overall real GDP growth, with particularly sharp annualized declines in household spending on healthcare services (-18.0 percent), transportation (-29.2 percent), recreation (-31.9 percent), and food services and accommodations (-29.7 percent).

Consumers also sharply curtailed spending on durable goods, which contributed -1.2 percentage points to overall GDP growth. Annualized declines in household spending on motor vehicles and parts (-33.2 percent) and furnishings and household equipment (-6.4 percent) were particularly steep. The declines in both services and durable goods spending were partially offset by growth in spending on nondurable goods, which was entirely driven by the largest ever quarterly surge in consumer spending on at-home food and beverages (25.1 percent). Given COVID-19's risks, it is not surprising that these spending patterns were observed.

Despite the major challenges posed by COVID-19, the United States is in a strong position to recover as the public health threat recedes. Prior to COVID-19's spread, GDP and job growth were exceeding pre-2016 election expectations, the strong job market was pulling Americans off the labor market's

sidelines, measures of business and consumer optimism were at or near historic highs, and wages were rising—especially for lower-income Americans. Furthermore, among G7 countries, the United States had the strongest real GDP growth from the fourth quarter of 2016 to the fourth quarter of 2019. Over that period, the U.S. rate of growth was more than a full percentage point above the other G7 countries' average.

While a sharp decline in household spending takes a toll on the economy, consumers can also respond to positive economic changes as they respond to public health risks. Last year, when consumer confidence reached a 20-year high, elevated consumer spending accounted for roughly 80 percent of real GDP growth. The potential for and necessity of a strong rebound is one reason why the Trump Administration has worked with Congress to keep people attached to their work, and enacted financial supports for those who lost their jobs or were temporarily furloughed.

COVID-19 has also led to a whole-of-government response to bridge the current gap between a historically strong economy and the coming economic recovery. Federal policies that support workers and job creators should help limit negative effects on the economy in the second quarter as States restart their economies and let their residents return safely to work.

Exhibit A-15

ECONOMY & JOBS

April's Job Losses Show Many Workers Are Still Connected to Their Employers

May 8, 2020 | 5 minute read

Council of Economic Advisers

Over the past weeks, Americans' efforts to slow COVID-19's spread have helped flatten the curve. As a result of this action, the Bureau of Labor Statistics' (BLS) April Employment Situation report shows that nonfarm payroll employment fell by 20.5 million and the unemployment rate (U-3) jumped 10.3 percentage points to 14.7 percent. Both of these monthly changes are the largest in the series' histories, as never before has the United States halted large portions of its economic activity.

While April's jobs numbers may astound Americans, the economy's strength earlier this year put the Nation in a better position to make temporary economic sacrifices to slow COVID-19's spread. After all, the unemployment rate stood at a 50-year low of 3.5 percent only two months ago.

Aided by Federal policy, the connection between many unemployed individuals and their previous employers remains strong—as temporary layoffs account for many of April's job losses and all of the month's unemployment increase. But these connections deteriorate the longer that States continue limiting economic activity. As States start or consider reopening their economies in a responsible way, it is critical that policymakers' focus expands to reviving the health of the United States labor force.

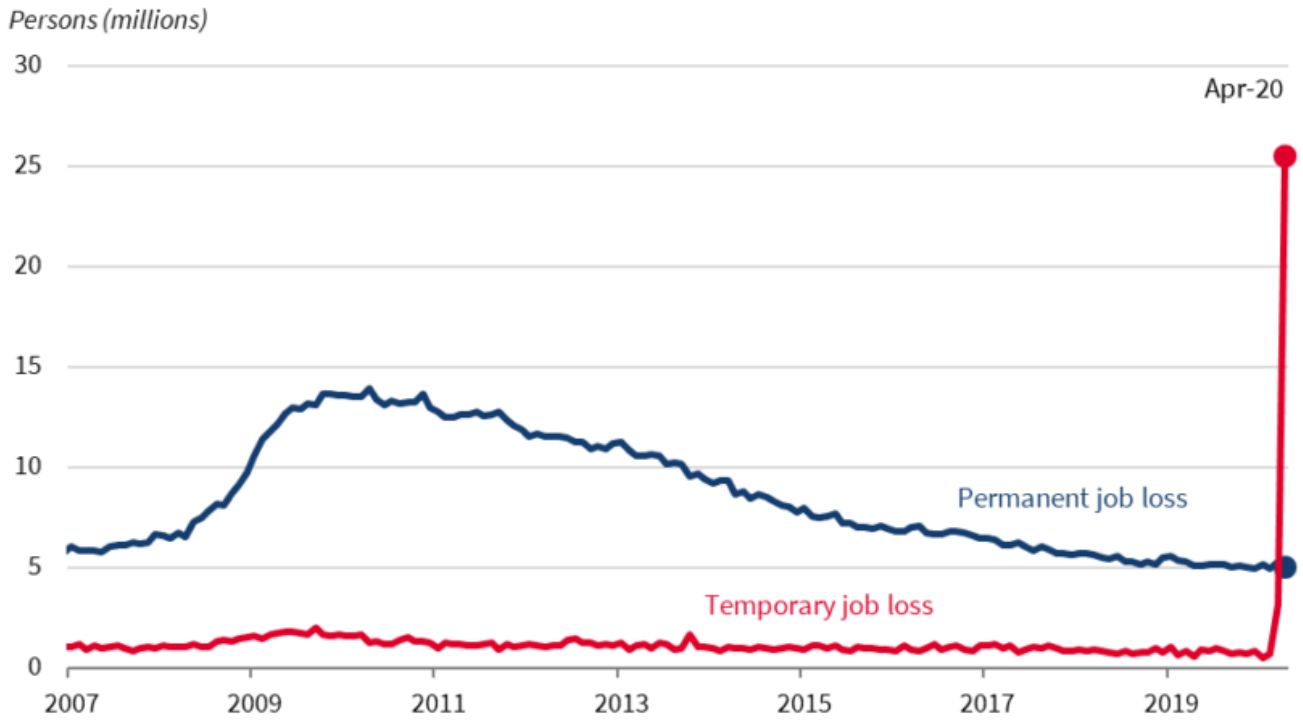
The April report also shows that the African American unemployment rate rose 10.0 percentage points to 16.7 percent, and that the Hispanic American unemployment rate rose 12.9 percentage

points to 18.9 percent. These substantial increases come after unemployment rates for both demographics reached historic lows in 2019. Furthermore, those with lower education levels are experiencing the largest job losses. The unemployment rate for those without a high school diploma rose 14.4 percentage points to 21.2 percent in April, and the unemployment rate for those with only a high school degree rose 12.9 percentage points to 17.3 percent.

Even though April's unemployment rate reached the highest level on record, COVID-19's sudden shock to the labor market has put more people out of work than the top-line number suggests. Those who lost their jobs and are not looking for work do not count as unemployed unless they are temporarily laid off; instead, they count as not in the labor force. Since the U-3 rate is calculated by dividing the number of the unemployed by the size of the labor force, the prevalence of this category of workers substantially changes the unemployment rate calculation. Flows from employment to not in the labor force totaled 9.5 million from March to April, compared with 17.5 million people who moved from employment to unemployment. Adding the increase in the number of Americans who were classified as not in the labor force because they are not searching for work further increases April's unemployment rate.

With the right policies, there is reason to expect a faster labor market recovery than the unemployment rate suggests. The April report shows that temporary layoffs explain the entire increase in the number of unemployed from March to April, meaning these workers could return to their previous jobs as economic activity picks up. Additionally, the number of temporarily laid off workers is likely higher than BLS reports. Compared to the average April value over the previous four years, 7.5 million more workers were classified as employed but not at work for "other reasons" last month. Reclassifying these workers, who may be on temporary layoff and not getting paid, as unemployed would raise April's U-3 rate to 19.5 percent. Figure 1 shows the distribution of types of job loss in April, including the excess workers who claim to be employed but not at work for "other reasons."

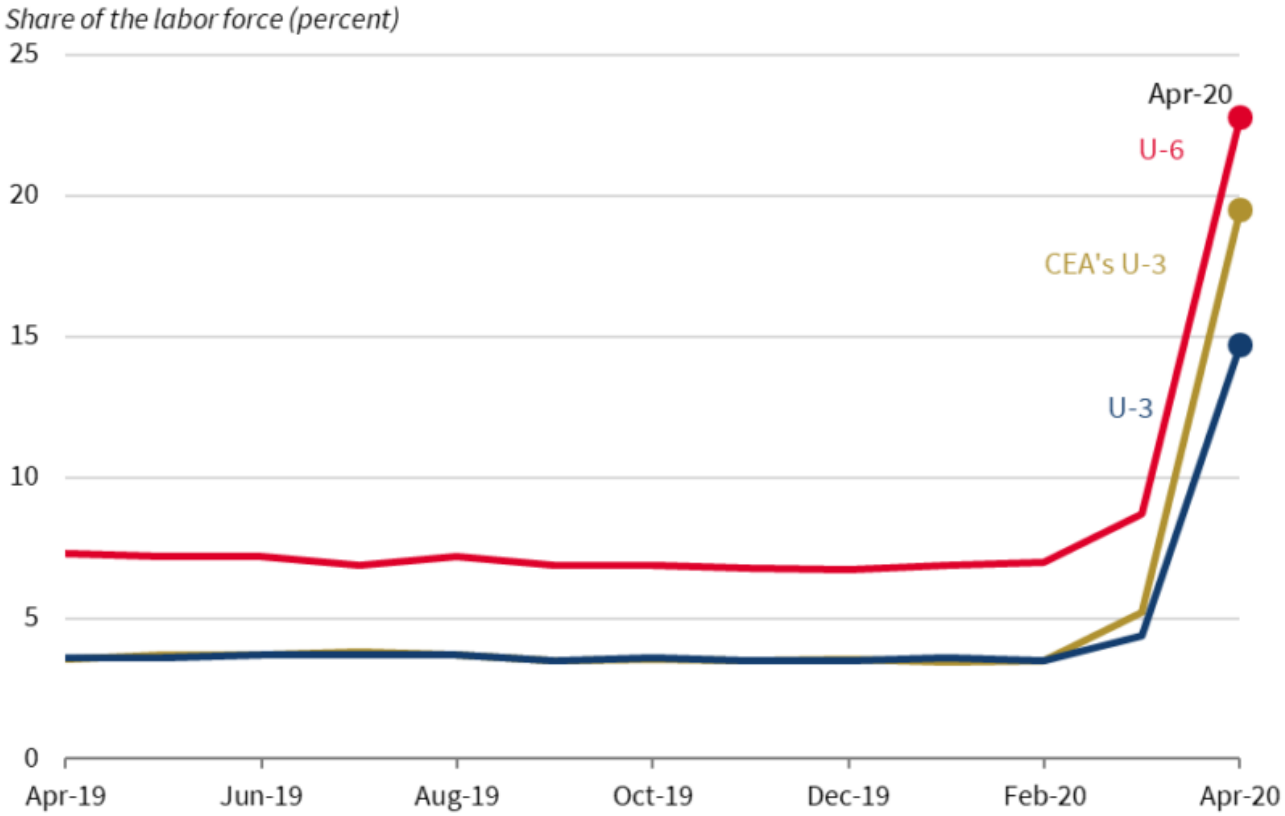
Figure 1. Number of Adjusted Unemployed Persons by Type of Job Loss, 2007–20



Sources: Bureau of Labor Statistics; CEA calculations.

BLS has other unemployment metrics to help capture this unprecedented labor market situation. While not the same as CEA's modified U-3 rate of 19.5 percent shown in Figure 2, the more comprehensive U-6 rate captures workers who are part-time for economic reasons, as well as discouraged or marginally attached workers who were unemployed prior to the crisis and stopped searching for work. After hitting a series low of 6.7 percent in December 2019, the U-6 rate increased to 22.8 percent in April.

Figure 2. Measures of Unemployment, 2019–20



Sources: Bureau of Labor Statistics; CEA calculations.
Note: CEA's U-3 was calculated by adding the excess employed but not at work for other reasons to the number of unemployed, and then dividing the result by the number in the labor force.

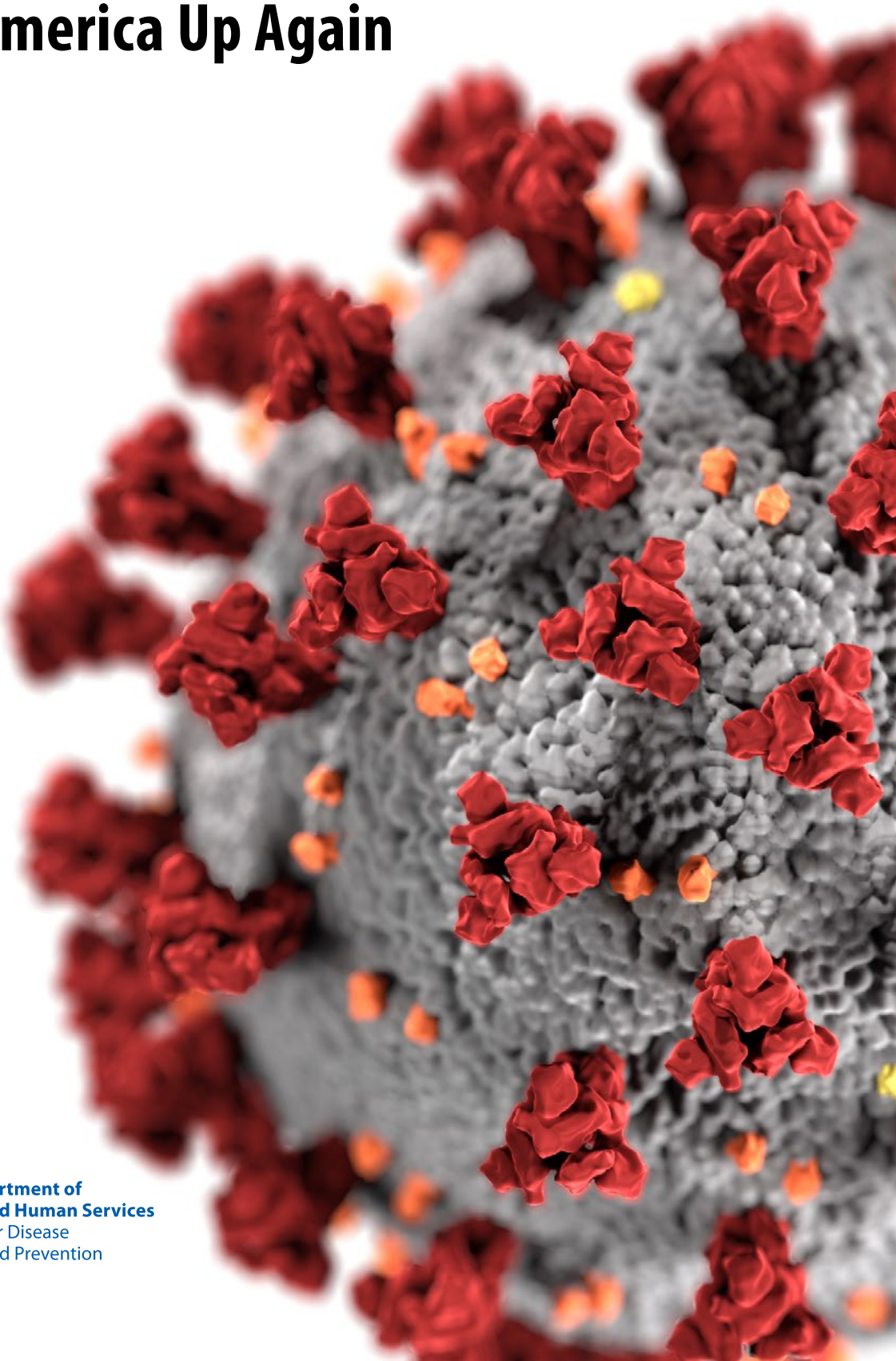
The April jobs report shows that the key to the labor market's rebound—bonds between employers and employees—remains even while many Americans are not working. Looking ahead to next month, with many States reopening their economies, the May report may show early signs of the economic comeback. However, given the 7 million initial unemployment insurance claims filed since the April report's reference period, and that the May report's household survey covers next week, further indications of recovery may not be shown until the June report—even if they are already underway.

Workers' economic sacrifices allowed the United States to keep healthcare capacity from being exceeded in most of the Nation. But temporarily shutting down large portions of the economy to ensure adequate healthcare capacity and create systems to protect the most vulnerable came at a high cost—especially for minority and lower-income workers. While Federal responses have enabled more workers to remain attached to their jobs for now, these critical attachments will weaken the longer that State-imposed shutdowns are in effect. As April's jobs report shows, the

declining health of America's labor force needs to be considered as the Nation continues responding to COVID-19.

Exhibit A-16

CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again



May 2020

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CRITICAL INITIATIVES AND ACTIVITIES

A. Expanding Testing and Advising Testing Practices

Extensive, rapid, and widely available COVID-19 testing is essential. CDC is working within the "All-of-Government and All-of-America Approach" to increase testing capacity and availability to improve case detection and contact tracing though all phases of the US plan to Opening Up America Again. As the supply and nature of tests expand, testing criteria have been broadened to include a wider range of people and situations.

Prioritizing Patients for Testing: Current recommendations for testing: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

Focusing Testing Efforts: CDC is working across the US government to support diverse efforts to increase testing in multiple settings to support diagnosis, surveillance, and outbreak control:

- **Testing for Diagnosis and Clinical Management:** CDC is working with federal government partners to support hospitals, healthcare systems, clinics, and public health departments to ensure the capability to diagnose COVID-19 infections with a turnaround time needed for appropriate clinical care and public health decision-making. CDC is:
  - » Working with federal government partners to provide a wide range of technical assistance resources to each state to help them develop a state-specific testing plan that meets their unique needs.
  - » Equipping state public health laboratories with sufficient quantities of devices, reagents, and testing supplies in the International Reagent Resource (IRR).
  - » Working with the White House Coronavirus Task Force to enhance the national supply of reagents and testing supplies so that the commercial market is able to supply state efforts. This supply should be sufficient to achieve a rate of less than 10% positive tests for COVID-19 among symptomatic, asymptomatic, and pre-symptomatic individuals.
- **Testing for Surveillance and Outbreak Control:** Identify newly emergent cases or clusters of COVID-19 among symptomatic and asymptomatic individuals who are prioritized by public health officials and clinicians, and improve reporting of COVID-19 cases to public health systems. CDC is:
  - » Utilizing established, nationwide surveillance systems to identify any areas of potential COVID-19 outbreaks, including use of CDC's Influenza-Like Illness Network and the National Syndromic Surveillance Program.
  - » Enabling public health systems at state, local, territorial, and tribal levels to develop a robust system to identify COVID-19 infections, particularly among vulnerable populations such as residents of nursing homes, people of racial and ethnic minority groups (e.g., African Americans, American Indians, Alaska Natives) at higher risk of disease, and those in areas of high social vulnerability, closed settings, and congregate housing.
  - » Supporting existing case-based surveillance efforts for identifying infections through routine testing of persons in clinical encounters.
  - » Enhancing case investigation and contact tracing efforts through increased public health staff and rapid testing capability.
  - » Working with point-of-care diagnostic test manufacturers and state health departments to improve reporting of results from rapid, point-of-care devices
  - » Evaluating various serologic assays for use in surveillance and for potential use for returning to work.

Defining Usage: CDC is working with state, local, and other partners to define the circumstances where testing of asymptomatic persons is likely to be helpful in controlling the pandemic, as well as the best application of surveillance serologic testing.

- Emerging evidence suggests that asymptomatic infections play an important role in the epidemiology of SAR-CoV-2 infections. Testing for asymptomatic infection should focus (1) on persons with an increased likelihood of infection and (2) on settings with particularly vulnerable populations.
- CDC is working to identify indications for serologic testing. Broadly, the purpose of serologic test falls into two categories: serologic surveillance of populations and serologic testing of individuals to determine if they have had a prior infection. This current CDC COVID-19 test is not currently designed for individual use (i.e., to test people who want to know if they have been previously infected with SARS-CoV-2). Serologic surveillance has the potential to provide important insights into the transmission dynamics of disease, as well as a more complete picture of total burden of COVID-19 infections in a community or among first responders and front-line health providers. More information is needed to determine how the results of serologic testing correlate with possible immunity.
- See Appendix D and https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html for additional details on testing strategies, testing of asymptomatic infections, and serologic testing.

Augmenting Existing Infrastructure and Technology to Improve Data Flow and Reporting:

CDC is supporting the improvement of current data infrastructure, and the development and integration of digital/technology solutions to augment state and community-wide sites to ensure timely and transparent communication to all citizens inclusive of daily new cases, hospitalizations, use of intensive care units (ICU), and mortality by county and or zip code. To ensure geographic relevant information is continuously available to state and local governments and the public in those communities, this should also include laboratory and potential immunization data systems. Activities include:

- Working with state and local officials and web development groups to develop and support interactive web-based platforms that allow open and transparent data visibility to all communities, such as the Florida Public Health COVID-19 website.
- Working with manufacturers for point-of-care diagnostic tests, commercial laboratories, state and local health departments, testing locations (providers, hospitals, pharmacies), and public health partners (Association of Public Health Laboratories [APHL], Council of state and Territorial Epidemiologists [CSTE]) to improve data quality, integration, and electronic reporting.
- Developing, integrating, and testing the ability for laboratories to securely share data with digital platforms selected by public health, including platforms that may be used for testing, or to support state and local contract tracing.
- Exploring digital solutions to share laboratory results with patients directly and sharing tested best practices with state and local partners. This could also extend to immunization record access.
- Developing recommendations for minimum requirements of platforms to integrate, store, and manage personal laboratory information on digital platforms (what states should consider before investing or having additional standards for platforms handling these data).

B. Phased Plan and Indicators for Reopening America

The plan for reopening America outlines a three-phased approach for reducing community mitigation measures while protecting vulnerable populations. The phased approach can be implemented statewide or community-by-community at governors' discretion. The guidelines propose the use of six "gating" indicators to assess when to move through from one mitigation phase to another.

Table 1. Gating Criteria and Phase-specific Thresholds

Gating Criteria	Threshold for entering Phase 1	Threshold for entering Phase 2	Threshold for entering Phase 3
Decreases in newly identified COVID-19 cases	Downward trajectory (or near-zero incidence) of documented cases over a 14-day period	Downward trajectory (or near-zero incidence) of documented cases for at least 14 days *after entering Phase 1*	Downward trajectory (or near-zero incidence) of documented cases for at least 14 days *after entering Phase* 2
Decreases in emergency department (ED) and/or outpatient visits for COVID-like illness (CLI)	Downward trajectory (or near-zero incidence) of CLI syndromic cases reported over a 14-day period	Downward trajectory (or near-zero incidence) of CLI syndromic cases reported for at least 14 days *after entering Phase 1*	Downward trajectory (or near-zero incidence) of CLI syndromic cases reported for at least an additional 14 days *after entering Phase 2*
Decreases in ED and/ or outpatient visits for influenza-like illness (ILI)	Downward trajectory (or near-zero incidence) of ILI reported over a 14-day period	Downward trajectory (or near-zero incidence) of ILI reported for at least 14 days *after entering Phase 1*	Downward trajectory (or near-zero incidence) of ILI reported for at least an additional 14 days *after entering Phase 2*
Decreases in percentage of SARS-CoV-2 tests positive	Downward trajectory (or near-zero percent positive) of positive tests as a percentage of total tests over a 14-day period (flat or increasing volume of tests)	Downward trajectory (or near-zero percent positive) of positive tests as a percentage of total tests for 14 days *after entering Phase 1* (flat or increasing volume of tests)	Downward trajectory (or near-zero percent positive) of positive tests as a percentage of total tests for at least 14 days *after entering Phase 2* (flat or increasing volume of tests)
Treat all patients without crisis care	Jurisdiction inpatient & ICU beds <80% full Staff shortage in last week = no PPE supplies adequate for >4 days	Jurisdiction inpatient & ICU beds <75% full Staff shortage in last week = no PPE supplies adequate for >4 days	Jurisdiction inpatient & ICU beds <70% full Staff shortage in last week = no PPE supplies adequate for >15 days
Robust testing program	Test availability such that percentage of positive tests is ≤20% for 14 days Median time from test order to result is ≤4 days	Test availability such that percentage of positive tests is ≤15% for 14 days Median time from test order to result is ≤3 days	Test availability such that the percentage of positive tests is ≤10% for 14 days Median time from test order to result is ≤2 days

Decisions to move between phases should also consider the public health capacity of the jurisdiction based on the criteria listed below. Other epidemiologic data sources available locally can be used to corroborate trends seen in core epidemiologic gating criteria. Special consideration should be given to infections identified in populations and settings such as healthcare personnel, patients in healthcare facilities (e.g., nursing homes, dialysis centers, long-term care facilities), and residents of congregate living settings (e.g., prisons, youth homes, shelters), underserved populations, and people of racial and ethnic minority groups (e.g., African Americans, American Indians, Alaska Natives) at higher risk of disease. Incidence and trajectory (increasing versus decreasing) of COVID-19 illnesses in the surrounding region should also be considered.

Table 2. Assessing Capacity for Case Identification, Follow Up, and Containment

Category	Considerations for Assessing Capacity for Case Identification, Follow Up, and Containment
SARS-CoV-2 testing in jurisdiction	Testing is available as indicated for clinical, public health, and infection prevention needs.
Identification of new COVID-19 cases	All new COVID-19 cases in the jurisdiction can be rapidly identified through active surveillance, including proactive monitoring for asymptomatic cases through surveillance monitoring.
Interviewing new COVID-19 cases	Initial interviews can be conducted for nearly all new COVID-19 cases within one day of health department notification.
Contact tracing	Follow up (isolation, self-monitoring, and rapid testing of selected contacts) can be initiated for nearly all identified contacts of newly identified cases.
Incidence relative to local public health resources	Public health capacity is sufficient to fully perform contact tracing and investigate outbreaks based on local incidence and resources available.

While some communities will progress sequentially through the reopening phases, there is the possibility of recrudescence in some areas. Given the potential for a rebound in the number of cases or level of community transmission, a low threshold for reinstating more stringent mitigation standards will be essential. The decision to reinstate community mitigation strategies will undoubtedly be very difficult and will require careful thought to define an evidence-based monitoring strategy and specific guidance for these decisions.

Technical Support for States

As part of the "Whole-of-Government" public health effort, CDC is providing states and other jurisdictions with technical assistance regarding testing, surveillance data collection and reporting, contact tracing, infection control, and outbreak investigation. Implementation of these activities is supported by the Paycheck Protection Program and Health Care Enhancement Act, which includes $11 billion to be awarded, within 30 days, directly to states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes to develop, purchase, administer, process, and analyze COVID-19 tests, conduct surveillance, trace contacts, and related activities. Listed below are additional strategies CDC is using to strengthen the capacity of state, tribal, local, and territorial (STLT) health departments to fight against COVID-19. This technical assistance is essential to ready the nation to re-open and minimize future COVID-19 outbreaks in jurisdictions across the country.

Exhibit A-17

Centers for Disease Control and Prevention

Coronavirus Disease 2019 (COVID-19)

What to Do If You Are Sick

If you have a fever, cough or other symptoms, you might have COVID-19. Most people have mild illness and are able to recover at home. If you think you may have been exposed to COVID-19, contact your healthcare provider immediately.

- Keep track of your symptoms.
- **If you have an emergency warning sign (including trouble breathing),** get medical attention right away.

Self-Checker

A guide to help you make decisions and seek appropriate medical care

Steps to help prevent the spread of COVID-19 if you are sick

Follow the steps below: If you are sick with COVID-19 or think you might have COVID-19, follow the steps below to care for yourself and to help protect other people in your home and community.

Stay home except to get medical care

- **Stay home.** Most people with COVID-19 have mild illness and can recover at home without medical care. Do not leave your home, except to get medical care. Do not visit public areas.
- **Take care of yourself.** Get rest and stay hydrated. Take over-the-counter medicines, such as acetaminophen, to help you feel better.
- **Stay in touch with your doctor.** Call before you get medical care. Be sure to get care if you have trouble breathing, or have any other emergency warning signs, or if you think it is an emergency.
- **Avoid public transportation**, ride-sharing, or taxis.

Separate yourself from other people

As much as possible, stay in a specific room and away from other people and pets in your home. If possible, you should use a separate bathroom. If you need to be around other people or animals in or outside of the home, wear a cloth face covering.

- Additional guidance is available for those living in close quarters and shared housing.
- See COVID-19 and Animals if you have questions about pets.

Monitor your symptoms

- Symptoms **of COVID-19 include fever, cough, and shortness of breath but other symptoms may be present as well.** Trouble breathing is a more serious symptom that means you should get medical attention.
- **Follow care instructions from your healthcare provider and local health department.** Your local health authorities may give instructions on checking your symptoms and reporting information.

When to Seek Emergency Medical Attention

Look for **emergency warning signs*** for COVID-19. If someone is showing any of these signs, **seek emergency medical care immediately**

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face

*This list is not all possible symptoms. Please call your medical provider for any other symptoms that are severe or concerning to you.

Call 911 or call ahead to your local emergency facility: Notify the operator that you are seeking care for someone who has or may have COVID-19.

Call ahead before visiting your doctor

- **Call ahead.** Many medical visits for routine care are being postponed or done by phone or telemedicine.
- **If you have a medical appointment that cannot be postponed, call your doctor's office,** and tell them you have or may have COVID-19. This will help the office protect themselves and other patients.

If you are sick wear a cloth covering over your nose and mouth

- **You should wear a** cloth face covering, **over your nose and mouth** if you must be around other people or animals, including pets (even at home)
- You don't need to wear the cloth face covering if you are alone. If you can't put on a cloth face covering (because of trouble breathing, for example), cover your coughs and sneezes in some other way. Try to stay at least 6 feet away from other people. This will help protect the people around you.
- Cloth face coverings should not be placed on young children under age 2 years, anyone who has trouble breathing, or anyone who is not able to remove the covering without help.

Note: During the COVID-19 pandemic, medical grade facemasks are reserved for healthcare workers and some first responders. You may need to make a cloth face covering using a scarf or bandana.

Cover your coughs and sneezes

- **Cover your mouth and nose** with a tissue when you cough or sneeze.
- **Throw away used tissues** in a lined trash can.
- **Immediately wash your hands** with soap and water for at least 20 seconds. If soap and water are not available, clean your hands with an alcohol-based hand sanitizer that contains at least 60% alcohol.

Clean your hands often

- **Wash your hands** often with soap and water for at least 20 seconds. This is especially important after blowing your nose, coughing, or sneezing; going to the bathroom; and before eating or preparing food.
- **Use hand sanitizer** if soap and water are not available. Use an alcohol-based hand sanitizer with at least 60% alcohol, covering all surfaces of your hands and rubbing them together until they feel dry.

- **Soap and water** are the best option, especially if hands are visibly dirty.
- **Avoid touching** your eyes, nose, and mouth with unwashed hands.
- Handwashing Tips

Avoid sharing personal household items

- **Do not share** dishes, drinking glasses, cups, eating utensils, towels, or bedding with other people in your home.
- **Wash these items thoroughly after using them** with soap and water or put in the dishwasher.

Clean all “high-touch” surfaces everyday

- **Clean and disinfect** high-touch surfaces in your “sick room” and bathroom; wear disposable gloves. Let someone else clean and disinfect surfaces in common areas, but you should clean your bedroom and bathroom, if possible.
- **If a caregiver or other person needs to clean and disinfect** a sick person’s bedroom or bathroom, they should do so on an as-needed basis. The caregiver/other person should wear a mask and disposable gloves prior to cleaning. They should wait as long as possible after the person who is sick has used the bathroom before coming in to clean and use the bathroom.

High-touch surfaces include phones, remote controls, counters, tabletops, doorknobs, bathroom fixtures, toilets, keyboards, tablets, and bedside tables.

- **Clean and disinfect areas that may have blood, stool, or body fluids on them**.
- **Use household cleaners and disinfectants.** Clean the area or item with soap and water or another detergent if it is dirty. Then, use a household disinfectant.
    - Be sure to follow the instructions on the label to ensure safe and effective use of the product. Many products recommend keeping the surface wet for several minutes to ensure germs are killed. Many also recommend precautions such as wearing gloves and making sure you have good ventilation during use of the product.
    - Most EPA-registered household disinfectants should be effective. A full list of disinfectants can be found here .
    - Complete Disinfection Guidance

How to discontinue home isolation

People with COVID-19 who have stayed home (home isolated) can leave home under the following conditions**:

- **If you have not had a test** to determine if you are still contagious, you can leave home after these three things have happened:
    - You have had no fever for at least 72 hours (that is three full days of no fever **without** the use of medicine that reduces fevers)
      AND
    - other symptoms have improved (for example, when your cough or shortness of breath have improved)
      AND
    - at least 10 days have passed since your symptoms first appeared

- **If you have had a test** to determine if you are still contagious, you can leave home after these three things have happened:
  - You no longer have a fever **(without** the use of medicine that reduces fevers)
    AND
  - other symptoms have improved (for example, when your cough or shortness of breath have improved)
    AND
  - you received two negative tests in a row, at least 24 hours apart. Your doctor will follow CDC guidelines.

People who DID NOT have COVID-19 symptoms, but tested positive and have stayed home (home isolated) can leave home under the following conditions**:

- **If you have not had a test** to determine if you are still contagious, you can leave home after these two things have happened:
  - At least 10 days have passed since the date of your first positive test
    AND
  - you continue to have no symptoms (no cough or shortness of breath) since the test.

- **If you have had a test** to determine if you are still contagious, you can leave home after:
  - You received two negative tests in a row, at least 24 hours apart. Your doctor will follow CDC guidelines.

Note: if you develop symptoms, follow guidance above for people with COVID19 symptoms.

In all cases, **follow the guidance of your doctor and local health department. The decision to stop home isolation should be made in consultation with your healthcare provider and state and local health departments. Some people, for example those with conditions that weaken their immune system, might continue to shed virus even after they recover.

Find more information on when to end home isolation.

For any additional questions about your care, contact your healthcare provider or state or local health department.

For healthcare professionals

There is no specific antiviral treatment recommended for COVID-19. People with COVID-19 should receive supportive care to help relieve symptoms. For severe cases, treatment should include care to support vital organ functions.

- Evaluating and Testing Patients for COVID-19
- Infection Prevention and Control in Healthcare Settings
- Discontinuing Isolation Guidance

Print Resources

Caring for yourself at home: 10 things to manage your health

What you can do if you have possible or confirmed COVID-19:

- English [1 page]

- Spanish

- Chinese
- Vietnamese
- Korean

More information

Travelers	Businesses
Households	Healthcare Professionals
People Who Need Extra Precautions	Health Departments
People Who Are Sick	Laboratories
Caregivers	ASL Video Series: Use the Coronavirus Self Checker
Schools	

Page last reviewed: May 8, 2020

Exhibit A-18

Silver State Health Insurance announces exceptional circumstance enrollment period

by News 4 & Fox 11 Digital Team | Tuesday, March 17th 2020

<p>Following Governor Sisolak's Emergency Declaration on March 12, the Silver State Health Insurance Exchange has announced a limited-time Exceptional Circumstances Special Enrollment Period for qualified Nevadans who missed the Open Enrollment Period. (Graphic per Nevada Health Link){/p}

CARSON CITY, Nev. (News 4 & Fox 11) — Following Governor Sisolak's Emergency Declaration on March 12, the Silver State Health Insurance Exchange has announced a limited-time Exceptional Circumstances Special Enrollment Period for qualified Nevadans who missed the Open Enrollment Period.

This Special Enrollment Period is available from March 17 through May 15, 2020 and will allow eligible individuals to enroll in a qualified health plan through Nevada Health Link.

“The comprehensive insurance plans on Nevada Health Link are designed to protect you and your family from financial ruin if a medical issue or accident occurs, and they cover the ten essential health benefits mandated by the Affordable Care Act, including but not limited to pre-existing conditions. This is an incredibly important time to ensure you and your family are covered,” said Exchange Executive Director, Heather Korbulic. “Nevadans deserve to have peace of mind to take care of all their health needs, and given today’s exceptional circumstances, we are enabling those who are qualified to enroll and gain access to the vital services they may need.”

Individuals seeking a special enrollment are encouraged to contact the Customer Assistance Call Center between 9 a.m. to 5 p.m. Monday through Friday at 1-800-547-2927; TTY: 711.

The Call Center will extend its hours on Saturdays and Sundays (except for Easter Sunday) from March 21 through April 15 from 10 a.m. to 2 p.m.

MORE TO EXPLORE

Gov. Sisolak: Stay-at-home order will be extended, casinos to open in '3rd or 4t...

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TRENDING

One taken to hospital after crash at Kietzke Lane and Mill Street

Local law enforcement speak out in response to death of George Floyd in Minneapolis

Allegations of illegal campaign donations to Gov. Sisolak under review

Gov. Sisolak: Nevada 'ready to begin Phase 2 of reopening'; casinos on track for June 4

Some Reno gyms to reopen as as soon as Friday

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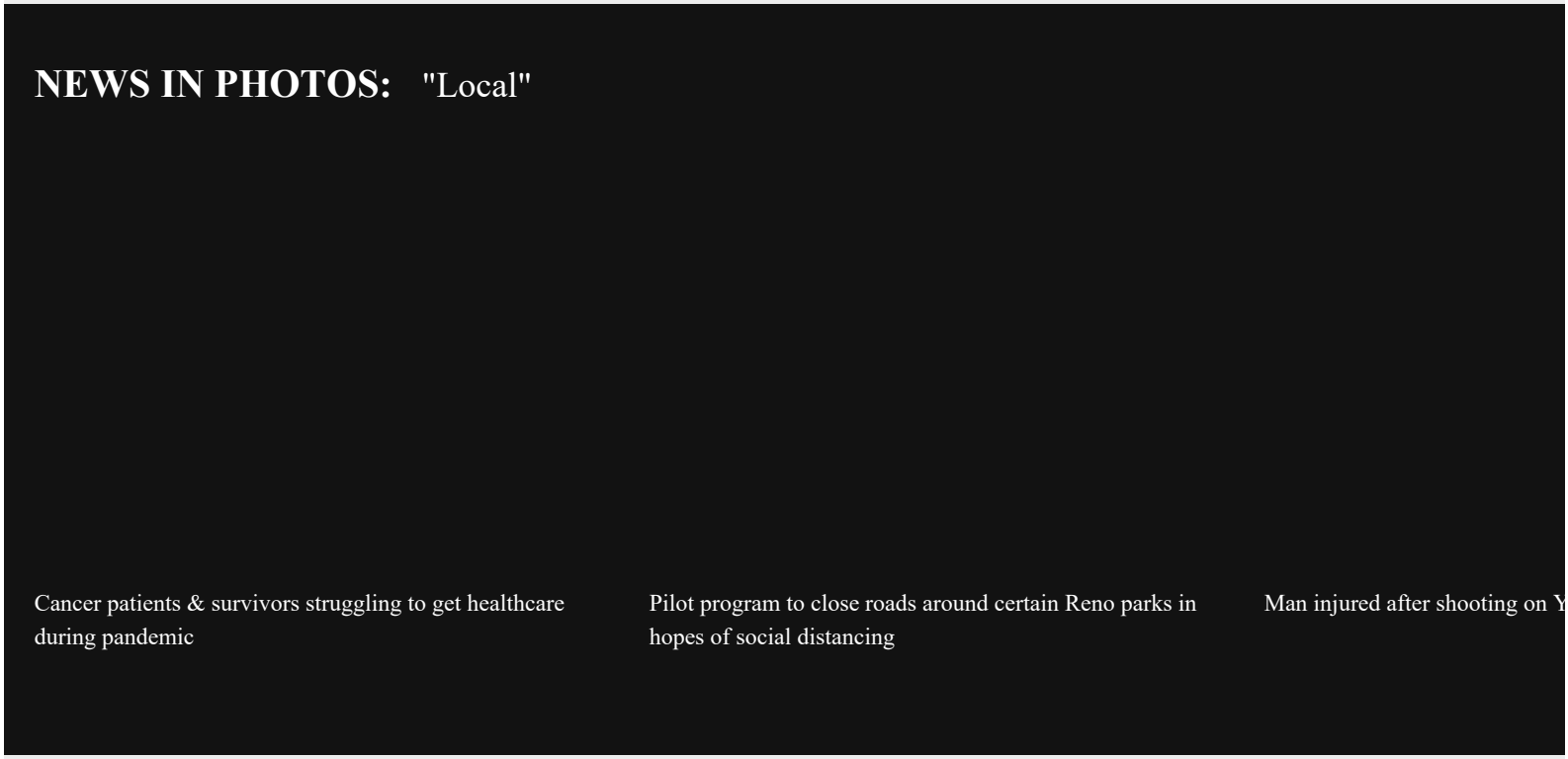

Cancer patients & survivors struggling to get healthcare during pandemic

Pilot program to close roads around certain Reno parks in hopes of social distancing

Man injured after shooting on Y

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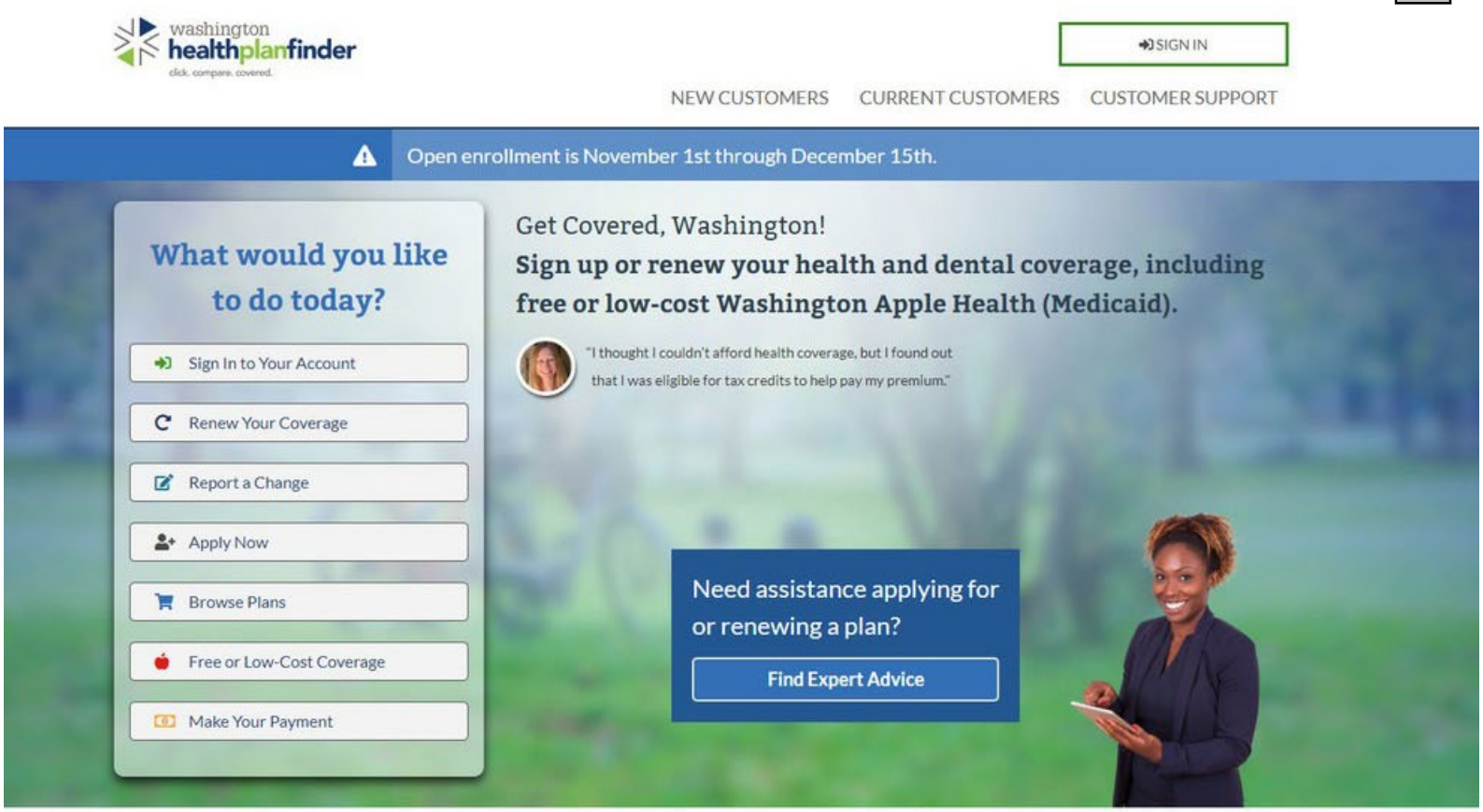
Exhibit A-19

State health exchange offers special enrollment period due to virus

by KOMO News Staff | Wednesday, March 11th 2020



Screenshot of Washington Healthplanfinder web page

OLYMPIA, Wash. - The coronavirus outbreak has prompted the state Health Benefit Exchange to offer a limited-time special enrollment period for qualified individuals who are currently without insurance.

The special enrollment period runs through April 8 and will allow uninsured individuals 30 days to enroll in health insurance coverage through Washington Healthplanfinder.

Until April 8, individuals seeking a special enrollment must contact the Customer Support Center between 7:30 a.m. to 5:30 p.m. Monday-Friday at 1-855-923-4633; TTY: 1-855-627-9604, or a local certified broker or navigator.

Those individuals can then request the special enrollment period and select a plan by April 8 for a coverage start date beginning April 1.

“It is apparent that many in our state have been exposed to this virus and that health insurance will be critical to those seeking treatment,” said Exchange Chief Executive Officer Pam MacEwan.

“Individuals need to have peace of mind to take care of all health needs, especially if they are at a high risk. Given today’s exceptional circumstances we are enabling those who are uninsured to enroll and gain access to the vital services they may need," McEwan added.

Customers who experience another qualifying event, such as marriage, birth of a child or a move, are also eligible to shop for coverage and/or those who qualify for Medicaid through Washington Apple Health is available year

round on Washington Healthplanfinder.

In addition, enrollment is offered year-round to individuals and families through Medicaid, known in this state as Washington Apple Health. Free or low-cost coverage is available year-round for those who qualify.

Washington Healthplanfinder is an online marketplace for individuals and families in Washington to compare and enroll in health insurance coverage and gain access to tax credits, reduced cost sharing and public programs such as Medicaid.

The next regular health and dental plans open enrollment period for Washington Healthplanfinder begins on Nov. 1, 2020.

TRENDING

Bethel wrestling coach fired after post defending Minneapolis police

State recovers $300M in stolen unemployment money, but many jobless still waiting for help

Snohomish County officials push to enter phase 2 of reopening

COVID-19: New rules announced for nursing homes testing, farm workers' safety

Suspected burglar fatally shot by homeowner in Everett

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NEW Democrats charge OSHA isn't protecting front-line workers

NEW Lives Lost: Veteran guarded Nazis during war crimes trial

NEW North Carolina governor: plan

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Exhibit A-20

Governor Lamont Provides Update on Connecticut's Coronavirus Response Efforts

Published on Sunday, 05 April 2020 17:31
Written by Office of the Governor.

As the State of Connecticut continues taking actions in response to the global spread of coronavirus disease (COVID-19), Governor Ned Lamont provided the following updates as of 4:00 p.m. on Sunday, April 5, 2020:

Data updates on testing in Connecticut

Since yesterday's update, an additional **399** Connecticut residents have tested positive for COVID-19, bringing the statewide total to **5,675**. To date, more than **23,270** tests have been conducted in Connecticut among both state and private laboratories. Approximately **1,142** patients have been hospitalized. The total statewide total number of COVID-19 associated fatalities is **189**.

A county-by-county breakdown includes:

County	Laboratory-Confirmed COVID-19 Cases	Laboratory-Confirmed COVID-19 Hospitalizations	Laboratory-Confirmed COVID-19-Associated Deaths
Fairfield County	3,050	531	96
Hartford County	751	189	29
Litchfield County	197	15	6
Middlesex County	110	19	5
New Haven County	1,162	372	36
New London County	57	10	4

Tolland County	94	3	11
Windham County	32	3	1
Pending address validation	*222*	*0*	*1*
Total	**5,675**	**1,142**	**189**

For several additional graphs and tables containing more data, including a list of cases in every municipality and data broken down by age, gender, race, and other factors, visit ct.gov/coronavirus.

Governor Lamont signs 22nd executive order to mitigate the spread of COVID-19

Governor Lamont today signed another executive order – the 22nd since he enacted the emergency declarations – that builds upon his efforts to encourage mitigation strategies that slow down transmission of the virus.

Governor Lamont's Executive Order No. 7U enacts the following provisions:

- **Protection from civil liability for actions or omissions in support of the state's COVID-19 response**: Protects health care professionals and health care facilities, including nursing homes and field hospitals, from lawsuits for acts or omissions undertaken in good faith in support of the state's COVID-19 response. State statutes already provide similar protections for other first responders, including police, firefighters, and EMS.
- **Financial protections for the uninsured and people covered by insurance who receive out-of-network health care services during the public health emergency**: Protects those who are uninsured and those who are insured and are treated by an out-of-network emergency services health care provider from surprise bills and other significant costs. This will ensure that individuals receiving care are not being financially burdened.

***Download*: Governor Lamont's Executive Order No. 7U**

Access Health CT continues enrolling residents in health insurance plans under new special enrollment period

Access Health CT – Connecticut's health insurance marketplace – is continuing to enroll uninsured residents in health plans under a new special enrollment period that was created due to the exceptional circumstances surrounding the COVID-19 pandemic. The special enrollment period began on March 19 and was initially scheduled to end on April 2 but was recently extended to April 17.

To date, Access Health CT has processed 3,530 enrollments into qualified health plans during this period. A total of 1,498 of those enrollments were made possible by the new special enrollment period offered in partnership with Connecticut's health insurance companies. This is in addition to 15,518 HUSKY enrollments during the same period.

Coverage for anyone who enrolled during between March 19 and April 2 began on April 1. Anyone who enrolls between April 3 and April 17 will have coverage that takes effect May 1. Customers are reminded that anyone currently enrolled in qualified health plans through Access Health CT may be able to update their income and increase the amount of financial assistance for which they qualify.

To learn more about how to enroll, visit learn.accesshealthct.com.

Providing information to Connecticut residents

For the most up-to-date information from the State of Connecticut on COVID-19,

including an FAQ and other guidance and resources, residents are encouraged to visit ct.gov/coronavirus.

Individuals who have general questions that are not answered on the website can also call 2-1-1 for assistance. The hotline is available 24 hours a day and has multilingual assistance and TDD/TTY access. It intended to be used by individuals who are not experiencing symptoms but may have general questions related to COVID-19. Anyone experiencing symptoms is strongly urged to contact their medical provider.

Next article

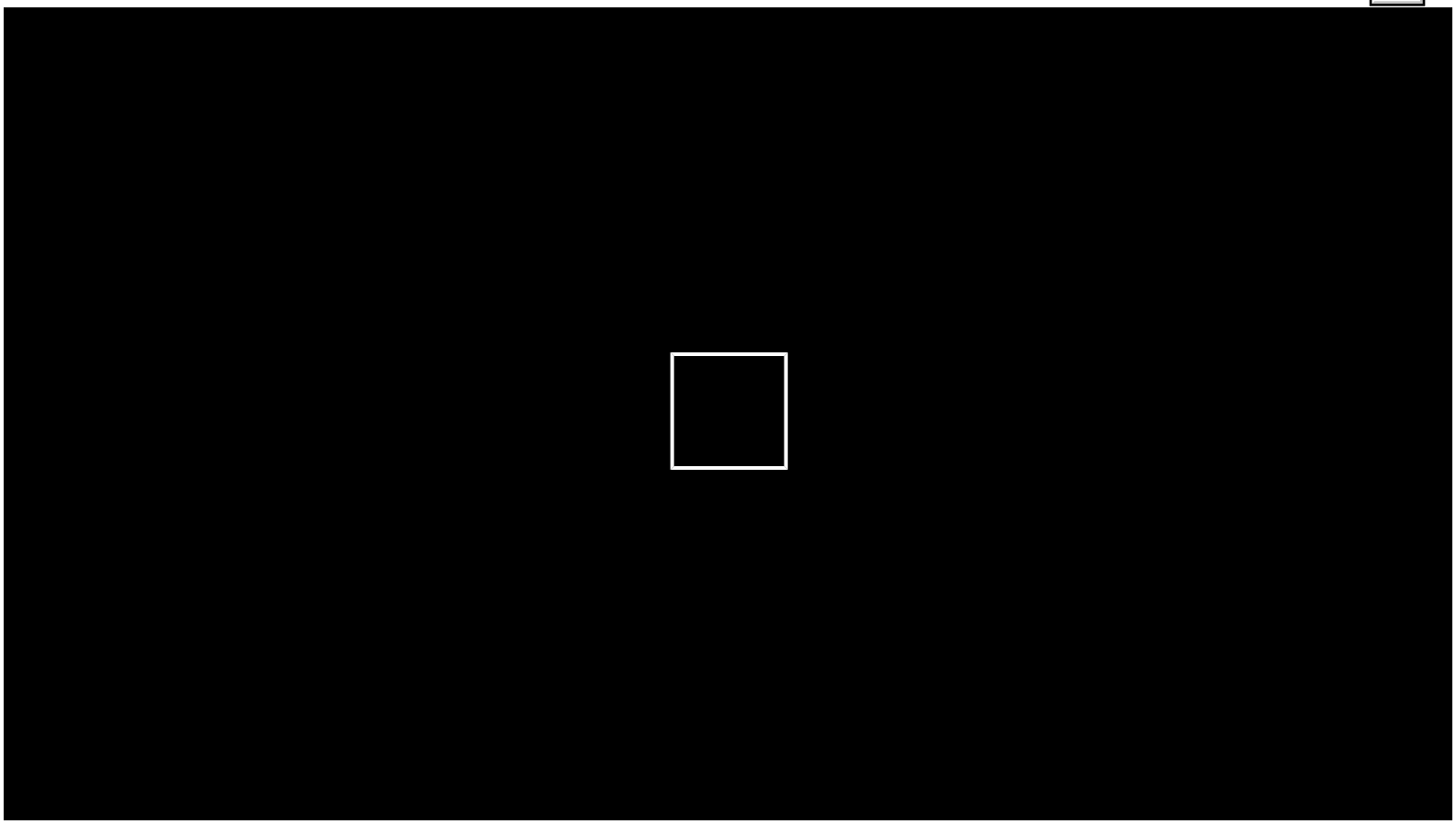
Quarantine Concert Series" from...

MORE STORIES

Exhibit A-21

Coronavirus cases in RI reach 20; Health benefits available for uninsured

by JESSICA A. BOTELHO, NBC 10 NEWS | Saturday, March 14th 2020

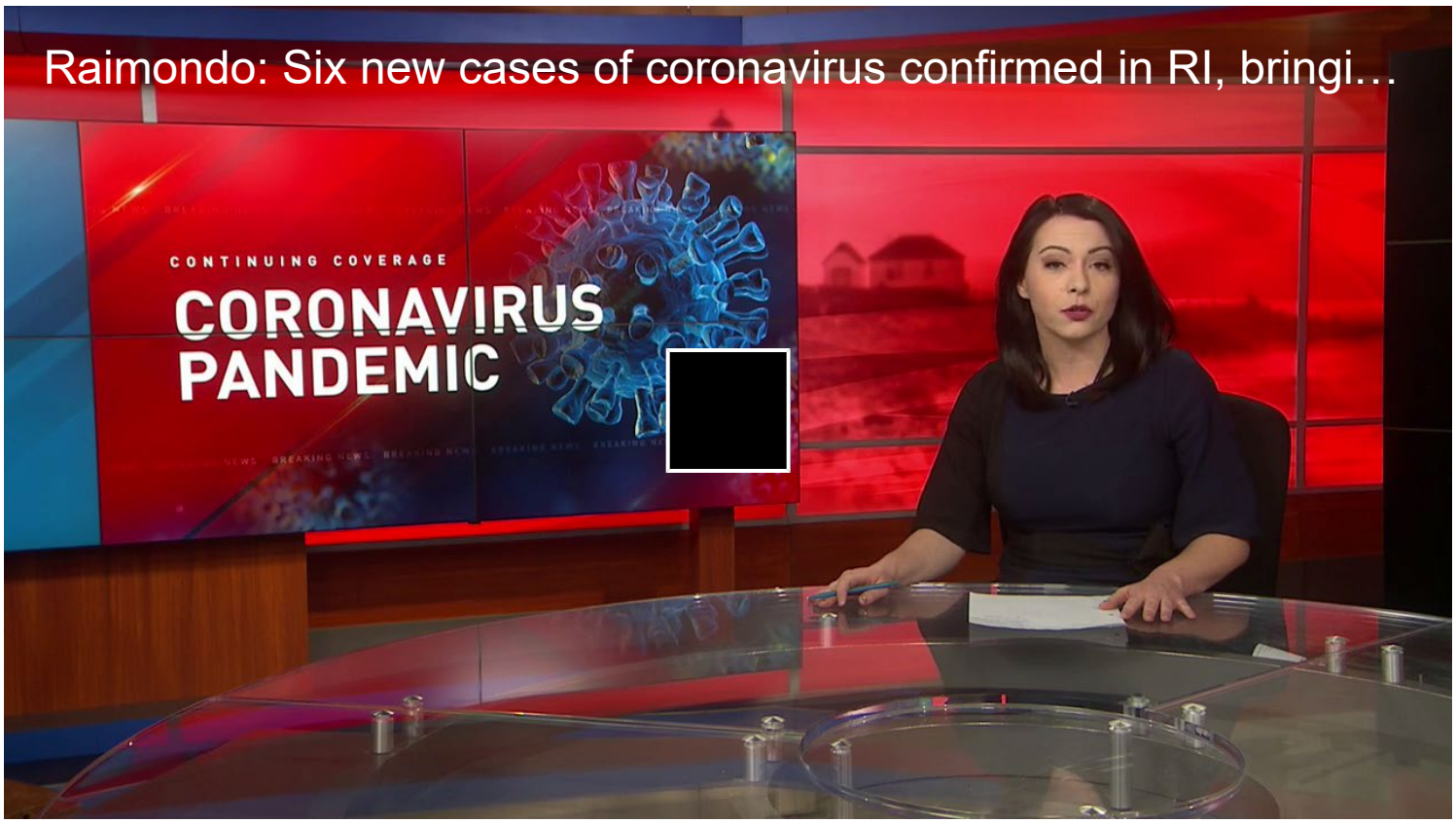


As of Saturday, March 14, 2020, Gov. Gina Raimondo says there are six new cases of coronavirus in Rhode Island. (WJAR)

PROVIDENCE, R.I. (WJAR) — Gov. Gina Raimondo said there are six new cases of coronavirus in Rhode Island, bringing the total to 20.

The governor made the announcement during a press conference on Saturday just before 12:30 p.m., also issuing new orders for health insurers and reminded the public to remain vigilant.

“There will be more cases,” she said. “Rhode Islanders should know that.”



As of Saturday, March 14, 2020, Gov. Gina Raimondo says there are six new cases of coronavirus in Rhode Island. (WJAR)

Raimondo went on to tell residents, including students who have been released from school for the next week, to stay home.

"Avoid going out," she said. “You have to stay home -- for your health and the health of everyone around you.”

Dr. Nicole Alexander-Scott, who is the director of the Rhode Island Department of Health, shared similar sentiments, saying going out “defeats the purpose” of self-quarantining.

They said the total cases in the Ocean State is now 20, with the news cases including four males and two females, with their ages ranging from 30s to 70s.

All six individuals are recovering at home, said Alexander-Scott.

“These are the results of late last night, so we are still investigating these cases,” Alexander-Scott said, also noting that three of them reported recent travel, including two separate domestic trips, and one trip to Lisbon.

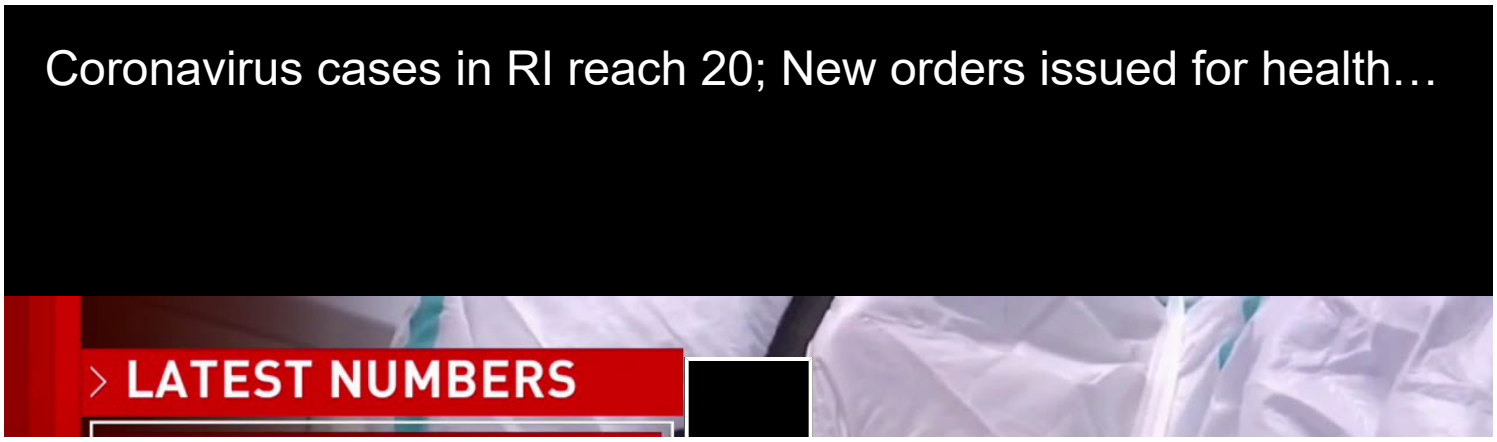
The governor also continued to remind the public to practice social distancing, which means avoiding large gatherings.

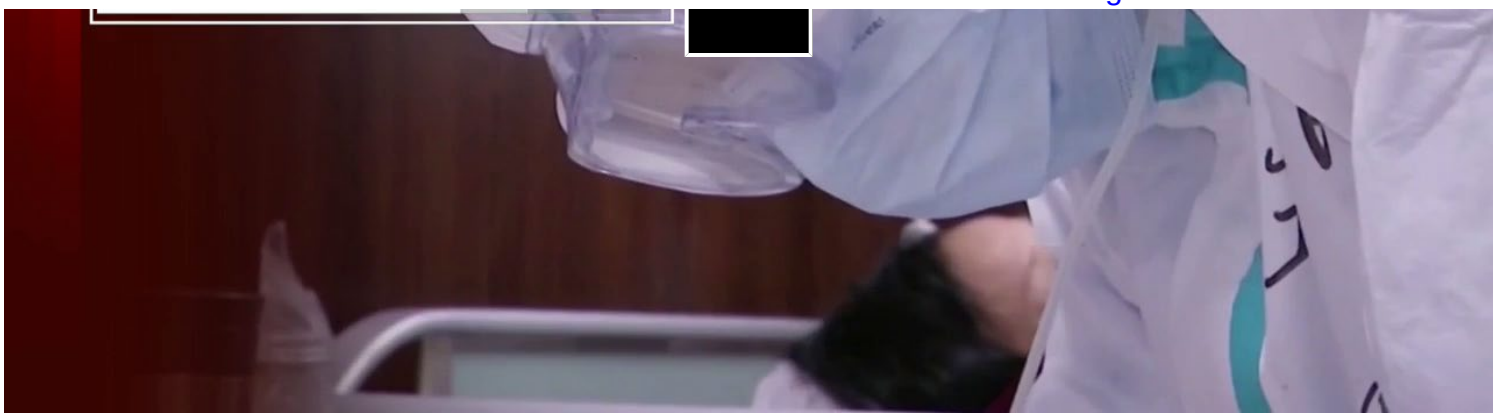
In fact, she advised venues to post-pone or cancel large gathering of 250 people or more.

“Shut them down,” Raimondo said. “These next two weeks are absolutely critical as we try to stay ahead of this virus.”

She, along with Alexander-Scott, again said to follow other safety protocols, such as hand-washing, covering your mouth when coughing or sneezing, working from home, as well as avoiding handshakes and hugs.

“Everyone heeding these guidelines makes a difference,” Alexander-Scott said.





As of Saturday, March 14, 2020, Gov. Gina Raimondo says there are six new cases of coronavirus in Rhode Island. (WJAR)

Alexander-Scott also said everyone who has been infected is recovering. She said while there has been one hospitalization, that patient has since been released.

So far, 198 people have tested negative at RIDOH's State Health Laboratories, while 57 tests are pending.

Approximately 600 have been instructed to self-quarantine in Rhode Island because they had direct contact with a person with COVID-19.

"The quicker we react, the better we will be," Raimondo said. "This weekend in particular in an especially important weekend and it is crucial for everyone to stay home."

Raimondo and Rhode Island Health Commissioner Marie Ganim also issued the following instructions for health insurers:

- Update telemedicine policies to include telephone-only services for primary care and behavioral health providers
- Ensure testing and screening for COVID-19 can be done without prior authorization and without any cost to the patient
- Cover prescription refills even if the prescription has yet to run out, provided that the prescription itself would remain valid beyond the refill date. This will allow people to shelter in place, while ensuring that they have adequate supplies on hand for continuity of care and medication compliance
- Work to remove barriers to access to services related to COVID-19 that may delay necessary care, including requirements for specialist referrals and prior authorizations
- In the event a federally-approved vaccine becomes available for COVID-19, cover the cost of the immunization for all enrollees

Raimondo also noted that that HealthSource RI is opening a special enrollment period for the three percent of

Rhode Islanders who don't have insurance right now.

The enrollment period will remain open until April 15.

"Ensuring Rhode Islanders have access to health coverage is critical to our mission and is especially important during this time," HealthSource RI Director Lindsay Lang said in a statement. "Due to these unexpected and exceptional circumstances, and under the leadership of Governor Raimondo's administration, HealthSource RI was able to work with the health insurance carriers offering plans through the exchange to develop a plan to make this special enrollment period available for residents who may be in need of health coverage."

Rhode Islanders who want obtain coverage should visit HealthSourceri.com to enroll online, or contact the Healthsource RI call center Monday through Friday from 8 a.m. to 6 p.m. at 1-855-840-4774.

Meanwhile, a spokesman for Raimondo later issued a statement, noting that the governor, along with the Rhode Island Emergency Management Agency, will hold another press conference with updates on Sunday at noon.

MORE TO EXPLORE

Four Stop & Shop employees test positive for COVID-19

White House health leader discusses concern over Rhode Island

Raimondo plans to make announcement about RI public schools this week

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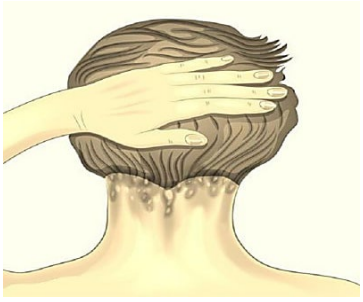

TRENDING

Raimondo says youth sports now possible as phase two kicks off

Rhode Island releases phase two guidelines for indoor dining

RI Board of Education lays out potential plans for summer, fall learning

New rules for hair salons, barbershops in RI

South Kingstown High School senior beats all odds against him, graduates

The WW3 strategy game!

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NEWS IN PHOTOS: "Coronavirus"

Exhibit A-22

arrows book broker browser building calculator-cash calculator-sm calculator calendar cart chat checkmark clipboard clock doctor document dollar-sign download eye handshake info letter links math medical-trio medical money-scissors person phone-book phone-left phone-right piggy-bank pill question-mark search speaker tooth

If you've recently experienced a job loss or loss of income, you might qualify for a 60-day Special Enrollment period, which will allow you to sign up for a new health insurance plan or to change your current plan. Visit the When Can I Buy Insurance Page under Get Started to learn more.

- Special Group Financial Help
- Find Answers
  - Before You Buy
    - Health Insurance Companies
    - Types of Health Plans
    - Bronze, Silver & Gold Plans
  - Tips for Choosing a Plan
  - Health Insurance 101
    - Who can sign up?
    - Health Services Covered
    - Insurance Costs Explained
  - After You Buy
    - Submit Documents
    - 2019 Tax Forms and Information
  - FAQs
  - Glossary
- We Can Help
  - Assisters
  - Brokers
  - Events
  - Customer Service
  - Enrollment Center
- I AM A ...
  - New Customer
  - Returning Customer
  - Small Group Employer
- GET COVERAGE NOW

- About Us
  - Who we are
    - Leadership Team
  - Board and Stakeholders
    - Connect for Health Colorado Board
    - Committees & Groups
      - Executive Committee
      - Finance & Operations Committee
      - Policy & Regulations Committee
      - Board Advisory Group
    - Archives
      - Board Meeting Archives
      - Board Advisory Group Archives
      - Former Committees
      - Joint Committees

CONNECT for HEALTH COLORADO

olorado's Official Health Insurance Marketplace

Health First Colorado
- Explore Plans
  - Compare Costs & Plans
  - Dental & Vision Insurance
- Special Enrollment Groups
  - Young Adults
  - Native Americans
- When can I buy insurance?
- Options for Small Business Owners

- Financial Help
  - Get Financial Help
  - Lower Your Monthly Premiums
  - Estimate Your Savings
  - Healthcare Discounts
  - Special Group Financial Help
- Find Answers
  - Before You Buy
    - Health Insurance Companies
    - Types of Health Plans
    - Bronze, Silver & Gold Plans
  - Tips for Choosing a Plan
  - Health Insurance 101
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  - Glossary
- We Can Help
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  - Brokers
  - Events
  - Customer Service
  - Enrollment Center

ore than 14,000 Coloradans gain health coverage ɹring emergency Special Enrollment Period; arketplace reports higher enrollments and lower

osts in 2020

Website Breadcrumbs

Home

category

press-release

More than 14,000 Coloradans gain health coverage during emergency Special Enrollment Period; Marketplace reports higher enrollments and lower costs in 2020

ontact: Monica Caballeros, 720-496-2574

ENVER — A total of **14,263 Coloradans gained health insurance coverage** during Connect for Health Colorado's nergency Special Enrollment Period, which ran from March 20 to April 30. The Marketplace opened the Special Enrollment eriod in response to the outbreak of the coronavirus (COVID-19), to ensure as many Coloradans as possible have access to ealth care.

We've seen a tremendous response to the emergency Special Enrollment Period and need for affordable health coverage," id Chief Executive Officer Kevin Patterson. "As always, we are here to help Coloradans get covered and stay covered as they avigate life changes this year."

overing more than 14,000 previously uninsured Coloradans during the emergency Special Enrollment Period was a milestone a successful year for the state's official health insurance marketplace. We received strong support promoting the Special nrollment Period from community partners and our statewide network of Brokers and Assisters. The new Open Enrollment eport for Plan Year 2020, released today, includes additional highlights for the 2020 plan year, including:

- 166,850 Coloradans enrolled for 2020 health coverage during the Open Enrollment period.
- 74 percent of customers qualified for financial help to reduce the monthly cost of health insurance.
- Statewide rates for full price premiums dropped by 20 percent, which lead to an uptick in new enrollments in many rural counties.
- 46 percent of our customers enrolled with the help of a trained and certified Broker, and another 6 percent enrolled with the help of a community-based Assister.

he new report includes more detailed information about changes to premium costs and financial help by county, the

ıproved customer experience and our outreach tactics. Preliminary enrollment totals at the close of the Marketplace's seventh ɔen Enrollment period were released in Jan. The Marketplace publishes monthly updates on total medical enrollments, as we ıntinue to enroll Coloradans throughout the year who have life-change events.

ɔloradans who have had a change in job, income or living situation should contact Connect for Health Colorado to find what ɛalth care coverage and financial help could be available. There are many ways to contact us to find out if you qualify for a ı-day Special Enrollment Period and get enrolled:

- Online: ConnectforHealthCO.com
- By phone: 855-752-6749
- Virtual or phone appointment with an enrollment expert: ConnectforHealthCO.com/we-can-help/

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ɔout Connect for Health Colorado

ɔnnect for Health Colorado is a public, non-profit entity established by the Colorado General Assembly in 2011 to create a ɛalth insurance Marketplace. Since 2013, we've been helping individuals, families and small employers compare plans, apply r financial help and buy health insurance. As Colorado's official health insurance marketplace, we are the only place to apply r financial help to lower the monthly cost of premiums. Customers can shop online; get help by phone or online chat from ıstomer Service Center representatives; and access expert, in-person help from a statewide network of certified Brokers and ımmunity-based Assisters. For more information: ConnectforHealthCO.com

ıthormcaballerosPosted onMonday, May 11, 2020Monday, May 11, 2020CategoriesNews, Press Release

0,000 Coloradans Covered during Emergency ɔpecial Enrollment Period So Far; Marketplace Open to Those with Life Changes

ɔntact: Monica Caballeros, mcaballeros@c4hco.com, 720-496-2574

ENVER– More than 10,000 Coloradans so far have signed up for a health insurance plan through Connect for Health ɔlorado's emergency Special Enrollment period, which ends Thursday, April 30, 2020. The Marketplace opened the Special ırollment period on March 20 in response to the outbreak of the coronavirus (COVID-19). Uninsured residents have nine days ɛt to enroll for coverage that begins on May 1.

Ve created this enrollment opportunity to relieve some stress for thousands of families who are trying to figure out their ɛalth coverage needs during this time." said Chief Executive Officer Kevin Patterson. "I encourage residents who are uninsured sign up before the April 30 deadline."

ɔloradans who have had a change in job, income or living situation should contact Connect for Health Colorado to find what ɛalth care coverage and financial help could be available. In addition to the COVID-19 Special Enrollment period, residents ight qualify for a 60-day Special Enrollment period that allows them to sign up for a new health insurance plan or to change eir current plan.

ısiness owners who are looking for options as employee insurance benefits end can direct employees to Connect for Health olorado to enroll. Our plans are often far more affordable than COBRA, and we offer financial help.

; a reminder, Connect for Health Colorado only sells health insurance plans with a full package of benefits, known as ualified Health Plans. Plans sold outside of the Marketplace may only cover a limited number of injuries or diseases. The olorado Division of Insurance is warning consumers about marketing organizations and agents using misleading tactics to sell oducts that are not Qualified Health Plans. Connect for Health Colorado encourages residents to contact our trained and rtified brokers and assisters, who continue to provide virtual and/or phone appointments.

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uthormcaballerosPosted onTuesday, April 21, 2020Tuesday, April 21, 2020CategoriesNews, Press Release

Connect for Health Colorado Extends Emergency Special Enrollment Period until April 30 in Response to COVID-19 Outbreak

ontact: Monica Caballeros, mcaballeros@c4hco.com

ENVER — Due to the growing number of coronavirus (COVID-19) cases and increased need for health coverage, Connect r Health Colorado will extend an Emergency Special Enrollment period for uninsured Coloradans until Thursday, April 30, 020.

nce March 20, approximately 5,500 individuals protected their health and safety by signing up for a health insurance plan rough this Special Enrollment period. People who enroll during the extended timeframe will have coverage as of May 1.

y extending the Special Enrollment period, we are doing our part to help Coloradans get the health coverage they need," id Chief Executive Officer Kevin Patterson. "If you are experiencing an unexpected loss of health coverage or a change in nployment, we are ready to help you explore your options."

; a reminder, Coloradans can sign up for a plan throughout the year if they experience other qualifying life change events, cluding loss of job-based coverage. Individuals may also be eligible to enroll in a new plan if they experience a loss in come. Those who qualify for Health First Colorado (Medicaid) or the Child Health Plan *Plus* program can enroll online rough the PEAK application any time during the year.

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uthormcaballerosPosted onThursday, April 2, 2020Thursday, April 2, 2020CategoriesNews, Press Release

Jninsured Coloradans Can Enroll during a Special :nrollment Period in Response to COVID-19 Outbreak

ENVER — To help as many people as possible protect their health and safety during the COVID-19 outbreak, Connect for ealth Colorado® announces a new Special Enrollment period that starts **Friday, March 20, 2020 and ends Friday, April 3,)20. Coloradans who are uninsured qualify to enroll in a health insurance plan for coverage that starts April 1, 2020.**

) sign up for coverage through the Marketplace- the only place where residents can qualify for financial help to lower costs- oloradans can complete an application and select a health insurance plan:

- Online at ConnectforHealthCO.com.
- Over the phone at **855-752-6749**, Monday through Friday from 8 a.m. to 6 p.m. We're also extending Customer Service Center hours this weekend and next, from 9 a.m. to 5 p.m. Saturday and Sunday.
- Working with a certified enrollment expert. Many local experts continue to provide virtual and/or phone appointments.

pplicants should select the enrollment reason as, **"Will lose or lost health insurance and/or have no other health verage during the COVID-19 outbreak"** and input the application date as the qualifying life change event date. Residents no take these steps will not be asked by health insurance companies to provide documentation to verify their eligibility for the ecial Enrollment period.

; always, Coloradans can sign up for a plan if they experience other qualifying life change events, including loss of job-based id Health First Colorado (Medicaid) coverage. Coloradans may be eligible to enroll in a new plan if they experience changes losses in income, which should be reported to Connect for Health Colorado. Residents who qualify for Health First Colorado Medicaid) or the Child Health Plan *Plus* program can enroll online through the PEAK application any time during the year.

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ustomer Service Center representatives; and access expert, in-person help from a statewide network of certified Brokers and mmunity-based Assisters. For more information: ConnectforHealthCO.com

uthormcaballerosPosted onThursday, March 19, 2020Thursday, March 19, 2020CategoriesNews, Press Release

Connect for Health Colorado® Supports the Colorado Affordable Health Care Option Plan

enver– On Monday, Connect for Health Colorado's Board of Directors voted in support of House Bill 20-1349, which details e Colorado Affordable Health Care Option plan. The bill creates an advisory board, of which Connect for Health Colorado's hief Executive Officer is named as a member, to guide development and implementation of the plan.

olorado continues to lead the nation in developing innovative solutions for our health care challenges," said Connect for ealth Colorado's CEO Kevin Patterson. "I am confident this legislation is headed in the right direction and we stand ready to lvise and implement. I look forward to a thoughtful discussion with policy makers and our state partners about how we use is proposal to lower health care costs for Coloradans."

oard members for Connect for Health Colorado continually explore options to increase competition and lower health care sts for residents," said Board Chair Adela Flores-Brennen. "We will continue to prioritize issues of access and affordability, pecially for Coloradans who receive financial assistance to lower costs, as we monitor the bill's progress this session."

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onnect for Health Colorado is a public, nonprofit entity established by the Colorado General Assembly in 2011 to create a ealth insurance marketplace. Since 2013, we've been helping individuals, families, and small employers compare plans, apply r financial help, and buy health insurance. As Colorado's official health insurance marketplace, we are the only place to apply r financial help to lower the monthly cost of premiums. Customers can shop online; get help by phone or online chat from ustomer Service Center representatives; and access expert, in-person help from a statewide network of certified Brokers and mmunity-based Assisters. For more information: ConnectforHealthCO.com

uthormcaballerosPosted onTuesday, March 10, 2020Tuesday, March 10, 2020CategoriesNews, Press Release

Statement from Connect for Health Colorado® CEO Kevin Patterson regarding the Colorado Affordable Health Care Option

arch 5, 2020

ontact: Monica Caballeros
caballeros@c4hco.com, 720-496-2574

enver– Connect for Health Colorado® Chief Executive Officer Kevin Patterson released the following statement on the nouncement of the *Colorado Affordable Health Care Option*:

/e are evaluating the bill in depth to ensure we are ready to implement the Colorado Affordable Health Care Option. We are pecially focused on evaluating the bill's impact to financially-assisted Coloradans and whether their needs are suitably ldressed in this bill. I'm confident that our Marketplace and our partners position us well to implement the program should e bill pass. We are eager to increase access, affordability, and plan choice to Coloradans and are prepared to support our ate partners as they strive to maximize coverage and affordability."

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uthormcaballerosPosted onThursday, March 5, 2020Thursday, March 5, 2020CategoriesNews, Press Release

tatement from Connect for Health Colorado® Regarding Supreme Court Decision on the Public Charge Rule

n. 27, 2020

enver – Connect for Health Colorado® Chief Executive Officer Kevin Patterson released the following statement in response today's Supreme Court decision on the Public Charge Rule:"I am disappointed about the overall impact this ruling will have all of us, but especially on our friends, neighbors and co-workers seeking a permanent residency status. This rule will force eople to get health care in more expensive ways and will cause worse health outcomes for Coloradans; exactly the opposite our mission and the work our state has led to increase access, affordability and choice in health. I'd like to remind our stomers that the financial help they may receive through the Marketplace does not count negatively against them if going rough the public charge review process. Our Assisters, Brokers and Customer Service Center can answer questions about ancial help. We also developed a resource that includes immigration lawyers who can answer questions more directly about e public charge process."

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bout Connect for Health Colorado

onnect for Health Colorado is a public, nonprofit entity established by the Colorado General Assembly in 2011 to create a health surance marketplace. Since 2013, we've been helping individuals, families and small employers compare plans, apply for ancial help and buy health insurance. As Colorado's official health insurance marketplace, we are the only place to apply for ancial help to lower the monthly cost of health insurance. Customers can shop online; get help by phone or online chat from ustomer Service Center representatives; and access expert, in-person help from a statewide network of certified brokers and mmunity-based assisters. For more information: ConnectforHealthCO.com

uthorlchadwickPosted onMonday, January 27, 2020Wednesday, February 5, 2020CategoriesNews, Press Release

Nearly 167,000 Coloradans Signed Up for 2020 Health Insurance Coverage

ENVER — Nearly 167,000 Coloradans signed up for a health insurance plan through the state's official Marketplace by the id of the Open Enrollment period, according to preliminary data released today by Connect for Health Colorado®.

nong the 2020 plan selections, about 20 percent are by customers who are new to Connect for Health Colorado and 80 ercent are returning customers.

his has been another successful Open Enrollment period," said Chief Executive Officer Kevin Patterson. "Now the work ntinues to increase access, affordability and choice for residents. We are fully engaged with partners at the state and in the gislature to advise and help implement innovative approaches to lower the cost of health care and increase choice."

utside of the Open Enrollment period, Coloradans can only sign up for a health insurance plan through the Marketplace if ey experience a "Qualified Life Event," like losing job-based insurance, losing Medicaid, or certain family changes. Coloradans n continue to get help signing up for coverage from certified brokers and community-based assisters during their Special rollment period.

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uthormcaballerosPosted onFriday, January 17, 2020Friday, January 17, 2020CategoriesNews, Press Release

More than 153,000 Coloradans Enrolled in Health nsurance So Far; Less than Four Weeks Remain to nroll for 2020 Coverage

ENVER — More than 153,000 Coloradans signed up for a health insurance plan through Connect for Health Colorado's arketplace by Dec. 18, 2019. Approximately 68 percent of applicants qualify for financial help to lower monthly premium sts.

am encouraged by the pace of sign-ups so far," said Connect for Health Colorado® CEO Kevin Patterson. "However, it's not o late to get covered for 2020. I urge you to take advantage of the final deadline and all the support we offer by visiting our e, giving us a call, or finding local help in your community."

ıe Open Enrollment period in Colorado ends Wednesday, Jan. 15, 2020. Residents who sign up for a health insurance plan by e deadline will receive a Feb. 1, 2020 coverage start date.

ıtside of the Open Enrollment period, Coloradans can **only** sign up for a health insurance plan through the Marketplace if ey experience a "Qualified Life Event," like losing job-based insurance, losing Medicaid, or certain family changes.

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ɔout Connect for Health Colorado

ɔnnect for Health Colorado is a public, non-profit entity established by the Colorado General Assembly in 2011 to create a ealth insurance Marketplace. Since 2013, we've been helping individuals, families and small employers compare plans, apply r financial help and buy health insurance. As Colorado's official health insurance marketplace, we are the only place to apply r financial help to lower the monthly cost of premiums. Customers can shop online; get help by phone or online chat from ıstomer Service Center representatives; and access expert, in-person help from a statewide network of certified Brokers and ımmunity-based Assisters. For more information: ConnectforHealthCO.com

ıthormcaballerosPosted onFriday, December 20, 2019Friday, December 20, 2019CategoriesNews, Press Release

ɜtatement from Connect for Health Colorado® ℜegarding the Fifth Circuit Texas v. Azar Decision

ecember 18, 2019

enver – Connect for Health Colorado® Chief Executive Officer Kevin Patterson released the following statement in response the Fifth Circuit decision on the *Texas v. Azar* lawsuit:

want to reassure our customers that regardless of the ruling by the Fifth Circuit Court of Appeals, the marketplace in ɔlorado is stable, strong and open for business. The steady pace of 2020 enrollments shows that Coloradans continue to rely ı the health insurance coverage and the financial help our marketplace provides. The Affordable Care Act has withstood a riety of challenges since it became law nine years ago and remains unchanged while the case moves through the expected ɔpeals, which will take some time. Colorado has also passed state laws that protect those with pre-existing conditions. You n rest assured that your financial help and plan protections and benefits remain in place."

###

ɔout Connect for Health Colorado

ɔnnect for Health Colorado is a public, nonprofit entity established by the Colorado General Assembly in 2011 to create a ealth insurance marketplace. Since 2013, we've been helping individuals, families and small employers compare plans, apply r financial help and buy health insurance. As Colorado's official health insurance marketplace, we are the only place to apply r financial help to lower the monthly cost of health insurance. Customers can shop online; get help by phone or online chat ɔm Customer Service Center representatives; and access expert, in-person help from a statewide network of certified brokers ıd community-based assisters. For more information: ConnectforHealthCO.com

ıthormcaballerosPosted onWednesday, December 18, 2019Wednesday, December 18, 2019CategoriesNews, Press Release

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observance of Independence Day, our Customer Service Center is closed Thursday July 4.

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ur Marketplace will be unavailable for shopping from 5:30 pm, Sept. 21 through 7 am, Sept. 24. Thank you for your patience.

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Exhibit A-23

May 28, 2020 | 4:05 pm
Information on Novel Coronavirus

Coronavirus is still spreading in New York. New Yorkers are required to wear a mask and maintain 6 feet distance in public.

GET THE FACTS

NY State of Health and New York State Department of Financial Services Announce Special Enrollment Period for Uninsured New Yorkers, as Novel Coronavirus Cases Climb

Remind New Yorkers That There is No Cost Sharing for COVID-19 Testing Across Medicaid, Child Health Plus, Essential Plan, and Qualified Health Plans

ALBANY, N.Y. (March 16, 2020) - NY State of Health, together with the New York State Department of Financial Services (DFS), today announced that New York will make a Special Enrollment Period available to New Yorkers during which eligible individuals will be able to enroll in insurance coverage through NY State of Health, New York's official health plan Marketplace, and directly through insurers. This step is being taken in light of the COVID-19 public health emergency to further protect the public health of New Yorkers. NY State of Health, DFS, and New York State health insurers are taking this action due to the exceptional nature of the public health emergency posed by the COVID-19 so that individuals do not avoid seeking testing or medical care for fear of cost. The open enrollment period for coverage in 2020 had previously ended on February 7, 2020.

Individuals who enroll in Qualified Health Plans through NY State of Health or directly through insurers between March 16 and April 15, 2020 will have coverage effective starting April 1, 2020. Individuals who are eligible for other NY State of Health programs – Medicaid, Essential Plan and Child Health Plus – can enroll year-round. As always, consumers can apply for coverage through NY State of Health on-line at nystateofhealth.ny.gov, by phone at 855-355-5777, and working with enrollment assistors.

As directed by Governor Cuomo, all New York insurers will have waived cost-sharing for a COVID-19 testing,

"With a pandemic spreading through the U.S., it's important to ensure that healthcare is available to everyone who needs it," **said NY State of Health Executive Director, Donna Frescatore**. "This special enrollment period will provide New Yorkers with another opportunity to sign up for high-quality, affordable health insurance."

"Ensuring access to affordable and quality medical care for all New Yorkers is a top priority during this state of emergency," **said Superintendent of Financial Services Linda A. Lacewell.** "Under Governor Cuomo's leadership, we have established a special enrollment period, providing uninsured New Yorkers an opportunity to select a New York State health insurance provider to access diagnostic testing and care they may need."

For additional information on COVID-19:

- The Department of Health provides public health information and guidance here: https://www.health.ny.gov/diseases/communicable/coronavirus/, and has implemented a Novel Coronavirus Hotline at 1-888-364-3065.
- The Centers for Disease Control's website offers up to date information at: https://www.cdc.gov/coronavirus/2019-ncov/
- Governor Cuomo has issued a directive regarding access and cost sharing for COVID-19 testing and treatment available at: https://www.governor.ny.gov/news/governor-cuomo-announces-new-directive-requiring-new-york-insurers-waive-cost-sharing

The Department of Financial Services has issued a circular letter on COVID-19 for health insurers here:
https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_03

Revised: March 2020

Department of Health

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Howard Zucker, M.D., Commissioner
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Current Issues

1-866-NY-QUITS - NYS Smokers' Quit Line
Addressing the Opioid Epidemic in New York State
Become an Organ Donor - Enroll Today
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Ending the Epidemic
Learn About the Dangers of "Synthetic Marijuana"
Medicaid Redesign
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New York State Breast Cancer Programs
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Exhibit A-24

VERMONT HEALTH CONNECT
Find the plan that's right for you.

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2018 Plan Comparison Tool is Here!

Health Insurance Basics

Educational Materials

Eligibility, Policy and Evaluation

Help for Small Business Owners

Advisory Committee

For Brokers

Paper Applications

Medicaid & Dr. Dynasaur

The Blueprint

Federal Grants

About Vermont Health Connect

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APPLY NOW

News and Events

Important Messages

- Please call Vermont Health Connect between the hours of 8AM-4:30PM Monday-Friday.
- Due to the COVID-19 emergency, Vermont Health Connect has opened a **Special Enrollment Period until June 15, 2020**. During this time, any uninsured Vermonter can sign up for a Qualified Health Plan through Vermont Health Connect. Qualified families can also get financial help paying for coverage.. Please call us at 1-855-899-9600 to learn more.
- Need to report a life change? Find out how.

Vermont Health Connect Updates

February 2020 Updates

- Individual and Small Group Enrollment Data

June 2019 Updates

- 2019 Health Coverage Map

May 2019 Updates

- Individual and Small Group Enrollment Report

March 2019 Updates

- 2019 Health Coverage Map

February 2019 Updates

- Vermont's 2019 Individual Enrollment in Five Graphs
- Operational Key Performance Indicators (KPI) February 2019

January 2019 Updates

- Operational Key Performance Indicators (KPI) January 2019

December 2018 Updates

UPCOMING EVENTS

Medicaid and Exchange Advisory Committee monthly meeting
06/22/20 - 10:00am to 12:00pm

Medicaid and Exchange Advisory Committee monthly meeting
07/27/20 - 10:00am to 12:00pm

Medicaid and Exchange Advisory Committee monthly meeting
09/28/20 - 10:00am to 12:00pm

Medicaid and Exchange Advisory Committee monthly meeting
10/26/20 - 10:00am to 12:00pm

Medicaid and Exchange Advisory Committee monthly meeting
11/23/20 - 10:00am to 12:00pm

more

VERMONT

Vermont Health Connect is Vermont's Health Insurance Marketplace

- Open Letter on End of 2019 Open Enrollment

November 2018 Updates

- Happy Thanksgiving, Happy Open Enrollment Halftime
- 2nd Quarter 2018 Health Coverage Map
- Operational Key Performance Indicators (KPI) November 2018
- Changes in Financial Help and Plan Options - Frequently Asked Questions (FAQ) about what's new in 2019, including Reflective Silver plans

October 2018 Updates

- 2019 Plan Comparison Tool is Live!
- Operational Key Performance Indicators (KPI) October 2018

September 2018 Updates

- 2019 Open Enrollment Countdown

July 2018 Updates

- Operational Key Performance Indicators (KPI) July 2018
- 1st Quarter 2018 Health Coverage Map

June 2018 Updates

- Heat Advisory June 29, 2018
- Operational Key Performance Indicators (KPI) June 2018

April 2018 Updates

- Operational Key Performance Indicators (KPI) April 2018

March 2018 Updates

- Operational Key Performance Indicators (KPI) March 2018

January 2018 Updates

- Operational Key Performance Indicators (KPI) January 2018

December 2017 Updates

- Operational Key Performance Indicators (KPI) December 2017
- Dec. 11 - More than 20,000 sessions on 2018 Plan Comparison Tool.
- Dec. 11 - Customer Support Center is open extended hours (8am-8pm) for the

Contact Us

Do you have a question about your online account and/or health plan?

Login here.

Do you have a general question that our website doesn't answer?

Click here.

Do you have questions about employer-sponsored insurance?

Click here.

Do you have feedback for Vermont Health Connect?

Click here.

Would you like to apply for an Exceptional Circumstance Special Enrollment Period?

Click here

Department of Vermont Health Access

280 State Dr.
Waterbury, Vermont 05671
Click here for additional contact information

Mail Payments to:

Vermont Health Connect
PO Box 2060
Omaha, NE 68103-2060

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last four days of Open Enrollment (12/12-12/15).

- Dec. 11 - 2018 Open Enrollment Q+A - the Sequel on Facebook Live

November 2017 Updates

- Nov. 30 - Customer Support Center to Open Next Two Saturdays
- Nov. 30 - 2018 Open Enrollment Q+A on Facebook Live
- Nov. 29 - Operational Key Performance Indicators (KPI) November 2017
- Nov. 2 - 11 Fast Facts about Open Enrollment

October 2017 Updates

- 2018 Open Enrollment to run November 1, 2017 through December 15, 2017.
- Oct. 17 - 2018 Plan Comparison Tool is now live - read announcement or use tool
- Vermonters who want to get a jump start on Open Enrollment can also download a "Getting Started" worksheet, learn about key health insurance terms with a "Health Insurance 101" flyer, and find additional resources in the "Health Insurance Basics" section of this site.
- Sign up for 2018 Plan Comparison webinars on November 9th.
- Operational Key Performance Indicators (KPI) October 2017

September 2017 Updates

- Operational Key Performance Indicators (KPI) September 2017

August 2017 Updates

- Operational Key Performance Indicators (KPI) August 2017

July 2017 Updates

- Operational Key Performance Indicators (KPI) July 2017

June 2017 Updates

- New payment mailing address! If your bank mails your checks for you, please inform them of the new address.
- Health Coverage Dashboard May 2017
- Operational Key Performance Indicators (KPI) June 2017

May 2017 Updates

- Operational Key Performance Indicators (KPI) May 2017

March 2017 Updates

- Health Coverage Dashboard February 2017

January 2017 Updates

- Health Coverage Dashboard December 2016

December 2016 Updates

- Health Coverage Dashboard October 2016

October 2016 Updates

- 2017 Plan Comparison Tool is now available

September 2016 Updates

- 2017 Broker Compensation Schedule.
- See where to find help filling out the 202-Med to apply for Medicaid for the Aged, Blind and Disabled

August 2016 Updates

Health Coverage Dashboard July 2016

June 2016 Updates

Health Coverage Dashboard May 2016

May 2016 Updates

- The 2017 Navigator Organization Grant Request for Application is now available!
  - Application will close on June 3, 2016
- Health Coverage Dashboard April 2016

January 2016 Updates

- Open Enrollment is November 1st - January 31st. Click here to learn more.
- Health Coverage Dashboard December 2015
- January 30, 2016 - Navigator Open Enrollment Event at BROC - Community Action in SW Vermont

December 2015 Updates

- New Plan Comparison Tool launched, helping Vermonters understand total costs
- November 2015 Dashboard

November 2015 Updates

- October 2015 Dashboard

October 2015 Updates

- 2016 Health Plans, including plan designs, rates, and additional information
- Use the 2016 Subsidy Estimator to see if you qualify for financial help to lower the cost of health insurance.
- Dental Plans, including stand-alone plans and dental details that are embedded in health plans
- Fact sheet: "8 Things to Know about Full-Cost Individual Direct Enrollment."
- September 2015 Dashboard

September 2015 Updates

- August 2015 Dashboard (9/21/15)
- 2016 Broker Compensation Schedule (9/18/15)
- 2015 Customer Experience Evaluation (9/17/15)

2015 and 2014 Updates

- End-of-May Systems Update FAQ (5/14/15)
- While Open Enrollment has ended, you may still be able to sign up. Learn about Special Enrollment Periods and Qualifying Events (2/16/15)
- Resources to help with Filing Taxes (1/19/15)
- Public Notice: 2016 Qualified Health Plans on Vermont Health Connect (12/16/14)
- New Dental Tier for 2015: Tier VI covers multiple children for the price of two children (11/15/14
- If you've had a "qualifying event" such as a marriage, new baby, or loss of health insurance, you don't need to wait until 2015 to get covered. Call 1-855-899-9600. (9/10/14)
- Info Sheet: Tips for Enrolling Online (7/2/14)
- Report: Enrollment Update (5/2/14)
- Notice of Application: 2014-2015 Navigator Organization Grants (4/1/14)
- Info Sheet: Moving from Catamount/VHAP to Medicaid (3/11/14)
- Tips: Using VermontHealthConnect.gov to Find a Health Plan (1/21/14)

October 2017 Updates

- 2018 Open Enrollment to run November 1, 2017 through December 15, 2017.
- 2018 Plan Comparison Tool is now live!
- Vermonters who want to get a jump start on Open Enrollment can also download a "Getting Started" worksheet, learn about key health insurance

terms with a "Health Insurance 101" flyer, and find additional resources in the "Health Insurance Basics" section of this site.

- Sign up for 2018 Plan Comparison Tool webinars on November 9th.
- Operational Key Performance Indicators (KPI) October 2017

February 2019 Updates

- Vermont's 2019 Individual Enrollment in Five Graphs
- Operational Key Performance Indicators (KPI) February 2019

Exhibit A-25

Press Release

Previous Next

Massachusetts Health Connector offers extended enrollment for uninsured individuals to ease coronavirus fears

On March 30, the special enrollment deadline was extended an additional month to May 25, 2020. Learn more →

BOSTON – March 11, 2020 – To ensure everyone who wants access to covered coronavirus services has it, the Massachusetts Health Connector announced today that uninsured residents can apply and get into coverage through a 45-day window running until April 25.

On March 6, the Division of Insurance announced that Massachusetts health insurers are now required to cover the cost of testing and treatment for members who may be affected by the Coronavirus (COVID-19), including not charging co-pays or deductibles for those services. The Health Connector's decision to open enrollment to anyone without coverage ensures Massachusetts residents concerned about contracting coronavirus can access necessary services without cost barriers.

Additionally, the Health Connector will be delivering to current members information about the Division of Insurance guidance, reassuring members that coronavirus-related services are available at no cost.

"The coronavirus represents a significant and growing public health threat, and the Massachusetts Health Connector is committed to making sure residents have access to testing, treatment and other related services as necessary," said Louis Gutierrez, the Executive Director of the Massachusetts Health Connector. "With 97 percent of residents covered, almost everyone in Massachusetts understands the ongoing value and need for coverage, but if anyone is considering signing up now, we encourage them to do."

Typically, the only time of year anyone can newly access coverage is during Open Enrollment, which runs from November through January. However, because of the public health threat created by the coronavirus and the increased public interest in prevention and treatment, the Health Connector is opening enrollment for uninsured residents through April 25. For people wanting coverage starting April 1, the deadline to apply, pick a plan and pay the first month's premium is March 23.

Residents who need health insurance can call 1-877-MA-ENROLL (1-877-623-6765) to gain access to the enrollment period, and go to MAhealthconnector.org to complete an application. From the website, people who qualify for Health Connector coverage may be in the ConnectorCare program, which offers subsidized plans with low premiums and co-pays, and no deductibles for all services. Those who do not qualify for ConnectorCare can pick plans from nine carriers, with as many as 50 plans available. Applicants can also seek out assistance from local Navigator organizations or Certified Application Counselors.

About the Massachusetts Health Connector

The Massachusetts Health Connector is the Commonwealth's health insurance exchange, and currently serves 325,000 individuals and small-employer members with health and dental insurance. Massachusetts residents who do not have health insurance from an employer or other entity can use

the exchange to gain coverage. Through the ConnectorCare program, income-qualifying residents can access coverage that includes low-cost premiums and co-pays, and no deductibles. Access to health coverage for individuals and small businesses can be found at the Health Connector's website, MAhealthconnector.org.

###

Wednesday, March 11th, 2020

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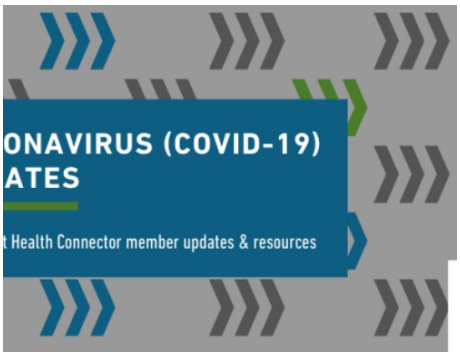

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Exhibit A-26

March 20, 2020

California Responds to COVID-19 Emergency by Providing Path to Coverage for Millions of Californians

- Effective immediately, anyone uninsured and eligible to enroll in health care coverage through Covered California can sign up through the end of June.
- The Department of Health Care Services announces new steps to help those eligible for Medi-Cal sign up easily and get immediate coverage.
- The moves come amid widespread disruption in the lives and livelihoods of Californians as public health officials seek to reduce the spread of COVID-19.
- All medically necessary screening and testing for COVID-19 are free of charge, and all health plans available through Medi-Cal and Covered California offer telehealth options.
- These actions build on increased state subsidies and the implementation of a state penalty, both of which took effect in January 2020.

Covered California Expands Special Enrollment and Medi-Cal Seeks Waivers to Foster Coverage

SACRAMENTO, Calif. — As the state of California is taking action on many fronts to respond to the COVID-19 pandemic, Covered California and the Department of Health Care Services (DHCS) joined together to make sure that those losing employment would have a ready path to coverage — whether through Medi-Cal or the plans offered through Covered California.

Effective Friday, March 20, Covered California opened the health insurance exchange to any eligible uninsured individuals who need health care coverage amid the COVID-19 national emergency. Anyone who meets Covered California's eligibility requirements, which are similar to those in place during the annual open-enrollment period, can sign up for coverage through June 30.

"We want to get as many people covered as possible to ensure they have access to the health care they need," said Peter V. Lee, executive director of Covered California. "Having more people insured is the right thing to do, and this action builds on our efforts to leave no one behind in California."

People who sign up through Covered California will have access to private health insurance plans with monthly premiums that may be lowered due to federal and new state financial help that became effective in 2020. After selecting a plan, their coverage would begin on the first of the following month — meaning individuals losing job-based coverage will not face a gap in coverage.

In addition, consumers who sign up through CoveredCA.com may find out that they are eligible for no-cost or low-cost coverage through Medi-Cal, which they can enroll in online. Those eligible for Medi-Cal can have coverage that is immediately effective.

California has put a 90-day hold on Medi-Cal renewal reviews, ensuring those already enrolled can continue their coverage and freeing up resources to quickly process the expected new enrollments. DHCS also is seeking expanded authority to expedite enrollment for seniors and other vulnerable populations, expand the use of telehealth, and take other steps to make care easier to access.

"The extraordinary challenges posed by COVID-19 demand an equally extraordinary response, and the Medi-Cal and Covered California systems are stepping up to meet the need for health coverage and ease access to services," said Dr. Bradley P. Gilbert, Director of the Department of Health Care Services.

DHCS oversees Medi-Cal, California's version of Medicaid, which provides coverage for about 13 million Californians.

The California Department of Managed Health Care (DMHC) and the California Department of Insurance will provide guidance to health plans on the special-enrollment period, which will also include off-exchange health plans. This will ensure consumers enrolling in the entire individual market in California will have access to coverage during the pandemic emergency.

"We are working together to protect the health and safety of Californians during this pandemic," said DMHC Director Shelley Rouillard. "This includes making sure that Californians are able to access health care coverage. Opening a special-enrollment period due to COVID-19 offers new coverage options to Californians when they need it most."

All Covered California and Medi-Cal Plans Offering Telehealth Options

All health plans offered through Covered California and by Medi-Cal provide telehealth options for enrollees, giving individuals the ability to connect with a health care professional by phone or video without having to personally visit a doctor's office or hospital.

All medically necessary screening and testing for COVID-19 is free of charge. This includes telehealth or doctor's office visits as well as network emergency room or urgent care visits when necessary for the purpose of screening and testing for COVID-19. In addition, Medi-Cal covers costs associated with COVID-19 in both its managed care plans and with fee for service providers. Covered California health plans will help cover costs that arise from any required treatment or hospitalization.

"A core part of our mission is improving access to high-quality health care, and that has never been

more important than it is right now in California," Lee said.

New Ad Campaign to Get the Word Out

Covered California will be alerting the public about the new special enrollment period through television, radio and digital ads. Covered California is already running ads that highlight the new financial help that is available for the first time this year, the new state individual mandate penalty and ads that make the connection to the COVID-19 pandemic and the ability to get coverage.

Click here to listen to the radio ad currently airing that highlights what consumers can do in face of the COVID-19 epidemic .

Watch the new television ads focusing on the financial help and penalties in English and Spanish here.

New State Subsidies Help Californians Lower Their Health Care Costs

Californians who sign up for coverage may be able to benefit from a new state subsidy program that expanded the amount of financial help available to many people. The subsidies are already benefitting about 625,000 Covered California consumers. Roughly 576,000 lower-income consumers, who earn between 200 and 400 percent of the federal poverty level (FPL), are receiving an average of $608 per month, per household in federal tax credits and new state subsidies (which averages $23 per household). The financial assistance lowers the average household monthly premium from $881 per month to $272, a decrease of 70 percent.

In addition, nearly 32,000 middle-income consumers have already qualified for new state subsidies, with average state subsidy to eligible households is $504 per month, lowering their monthly premium by nearly half.

Many of those eligible for the new middle-income state subsidies are an estimated 280,000 Californians who are likely eligible for new state or existing federal subsidies but kept their "off-exchange" coverage. They are also eligible to switch to Covered California and benefit from the financial help. During this special enrollment period, Covered California, its health plans and certified agents will be reaching out to these Californians to let them know how they can save money on their premiums – which will help them keep their coverage in challenging financial times.

California's Success in Expanding Coverage Strengthens Pandemic Response

The policies announced today build on the success of the Affordable Care Act in California. Since the law was signed 10 years ago, California's uninsured rate has dropped to a record low of 7.2 percent thanks to the expansion of Medi-Cal and the creation of Covered California.

"California's policy makers made important choices ten years ago to build the Covered California exchange and dramatically expand the state's Medi-Cal program. Those choices — as well as new efforts by Gov. Newsom and the Legislature to bolster financial support to buy coverage — mean many millions of people have coverage today and can get it tomorrow for this critical moment in time," Lee said. "Our goals now must be to make sure we meet the needs of those without insurance – whether they just lost their coverage or lost their income – while assuring those with coverage get the care they need, when then need it. The urgency of this public health crisis calls on all of us to do everything we can to help Californians."

Staying Safe While Getting Help Enrolling

With the just announced order for Californians to stay home if they are not engaged in essential work or travel, Covered California is working with the more than 10,000 Certified Insurance Agents that help Californians sign up and understand their coverage options through phone-based service models.

“We are in a different world right now, but social distance does not mean you cannot get personal help,” Lee said. “Our agents and staff are stepping up to help people by phone and support them to enroll online.”

Consumers can easily find out if they are eligible Medi-Cal or other forms of financial help and see which plans are available in their area by using the CoveredCA.Com Shop and Compare Tool and entering their ZIP code, household income and the ages of those who need coverage.

Those interested in learning more about their coverage options can also:

- Visit www.CoveredCA.com.
- Get free and confidential assistance over the phone, in a variety of languages, from a certified enroller.
- Have a certified enroller call them and help them for free.
- Call Covered California at (800) 300-1506.

About Covered California

Covered California is the state’s health insurance marketplace, where Californians can find affordable, high-quality insurance from top insurance companies. Covered California is the only place where individuals who qualify can get financial assistance on a sliding scale to reduce premium costs. Consumers can then compare health insurance plans and choose the plan that works best for their health needs and budget. Depending on their income, some consumers may qualify for the low-cost or no-cost Medi-Cal program.

Covered California is an independent part of the state government whose job is to make the health insurance marketplace work for California’s consumers. It is overseen by a five-member board appointed by the governor and the Legislature. For more information about Covered California, please visit www.CoveredCA.com.

About the Department of Health Care Services

The California Department of Health Care Services (DHCS) is the backbone of California’s health care safety net. It provides access to affordable, integrated, high-quality health care, including medical, dental, mental health, substance use treatment services and long-term care. DHCS funds health care services for about 13 million Medi-Cal beneficiaries and is the largest health care purchaser in California. It collaborates with the federal government and other state agencies, counties, and partners to invest more than $100 billion for the care of low-income families, children, pregnant women, seniors, and persons with disabilities. For more information about DHCS, please visit www.dhcs.ca.gov.

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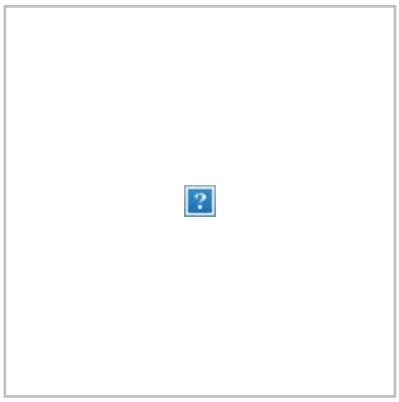

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CoveredCA.com is sponsored by Covered California and the Department of Health Care Services, which work together to support health insurance shoppers to get the coverage and care that's right for them.

Exhibit A-27

DC Health Link Expands Opportunities to Get Covered During Public Health Emergency

Monday, April 6, 2020

Responding to COVID-19 pandemic, DC Health Link permits uninsured employees of DC small businesses that offer health insurance through DC Health Link to get covered now

Washington, DC – In responding to the COVID-19 public health emergency in the District of Columbia, the DC Health Benefit Exchange Authority (DCHBX) Executive Board unanimously voted to create a special enrollment period (SEP) for employees of small businesses currently covered through DC Health Link. Through this special enrollment period, employees of small businesses that purchase health insurance coverage through DC Health Link can enroll in health insurance or enroll their dependents now, rather than being required to wait for their employer's next annual open enrollment period.

Outside of their employer's annual open enrollment period, an employee is required to have a qualifying life event such as marriage, birth of a child, or loss of other healthcare coverage—to be able to enroll in their employer's health insurance plan. The DCHBX Executive Board expanded qualifying life events to include COVID-19. This action permits any current employee of a small business that purchases health insurance through DC Health Link to enroll in their employer's health plan.

This new SEP will run through September 15, 2020, which mirrors action previously taken by DCHBX to provide uninsured individuals and families the opportunity to enroll in health insurance through DC Health Link. Anyone who is uninsured in the District, should visit DCHealthLink.com and sign up for coverage now. Depending on income, residents may qualify for Medicaid or premium reductions for private health insurance.

All DC Health Link health insurers cover COVID-19 diagnosis, testing, and treatment without any cost-sharing (no deductibles, no coinsurance, and no copays). This applies to all levels of coverage including catastrophic plans and HSA-compatible high deductible health plans.

For more information about DC Health Link and Coronavirus, visit https://www.dchealthlink.com/coronavirus. DC Health Link enrollees can find a useful and easy to read summary chart on this dedicated webpage highlighting how DC Health Link health insurers cover COVID-19 related services.

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(855) 532-5465
TTY: 711
Mon-Fri 8am-6pm

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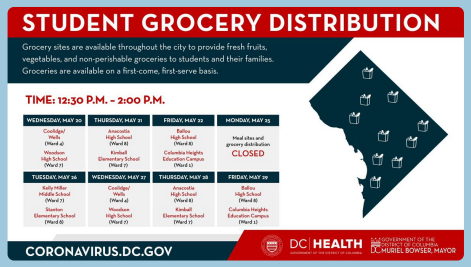
FAQs
Glossary

DC Health Link #StayHomeDC @DCHealthLink

During the week, students and families can receive fresh fruits, vegetables, and non-perishable groceries at grocery sites across the District. Learn more: bit.ly/DCGrocerySites
Coronavirus.dc.gov



27 May

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NEWS | DC Health Link Expands Opportunities to Get Covered During Public Heal…

Exhibit A-28

Coronavirus emergency extends special enrollment period until June 15

As part of the state's overall response to the coronavirus, and in an effort to prioritize health and safety, Maryland Health Connection opened a new special enrollment period for uninsured Marylanders.

What you need to know

When will the special enrollment period begin?

The coronavirus emergency special enrollment period will begin in March and ends Monday, June 15. Here are the dates coverage will begin, depending on what day you enrolled in a health plan:

- Enroll by April 15, 2020, coverage starts April 1, 2020
- Enroll April 16-May 15, 2020, coverage starts May 1, 2020
- Enroll May 16-June 15, 2020, coverage starts June 1, 2020

How do I enroll?

To enroll, visit MarylandHealthConnection.gov or download the free "Enroll MHC" mobile app. When enrolling, you should request or select "Coronavirus Emergency Special Enrollment Period."

Trained navigators and brokers can help you enroll by phone.

This enrollment period is for new enrollments of uninsured Marylanders who are eligible, not an opportunity for currently enrolled consumers to change plans.

Can I get help enrolling?

Free consumer assistance is available by calling 855-642-8572 weekdays from 8 a.m. to 6 p.m. Deaf and hard of hearing use Relay. Help is available in more than 200 languages.

We encourage you to follow the Centers for Disease Control and Prevention (CDC) and the Maryland Department of Health (MDH) for all health-related coronavirus questions.

What do I need to apply?

- Birthdates
- Social Security numbers (or document numbers for legal immigrants)
- Proof of citizenship or immigration status

- Tax returns for previous years
- Employer and income info (pay stubs, W-2 forms)
- Policy numbers for any current health insurance
- Information about any job-related coverage you or someone in your household is eligible for

Is Coronavirus covered under a Maryland Health Connection plan or Medicaid?

Yes. Health insurance companies are required to waive cost-sharing, including lab fees, co-payments, coinsurance, and deductibles for any visit to test for coronavirus at a doctor's office, urgent care center, or emergency room.

Can I qualify for the Coronavirus Emergency Special Enrollment Period even if I'm not sick?

Yes. All eligible, uninsured Marylanders may qualify for this emergency special enrollment period.

Do the insurance companies on Maryland Health Connection cover the costs of coronavirus?

Yes, both **Kaiser Permanente** and **CareFirst** cover testing, visits relating to testing, and treatment of COVID-19. You won't be billed for a copay, coinsurance or deductible for services to test, diagnose and treat COVID-19.

Resources

Glossary

Privacy

Nondiscrimination & Accessibility

Need Assistance?

Consumer Support Center
1-855-642-8572

Deaf and Hard of Hearing
Use Relay Service

Interpreter Services

Connect with us

Maryland Health Connection
P.O. Box 857
Lanham, MD 20703

Exhibit A-29

Coronavirus (COVID-19) Emergency Special Enrollment Period

This special enrollment period ended Tuesday, April 21, but you may still have coverage options through MNsure:

- If you lost or will you lose your employer-sponsored health insurance you may qualify for a special enrollment period.
- If you have had a decrease or loss of income and are currently enrolled through MNsure: make sure to keep your account updated by reporting your current income to MNsure. You may be eligible for low- or no-cost coverage, or increased financial help toward paying for your current plan.

Other qualifying life events—such as marriage, birth or adoption of a child, or a move—may make you eligible to enroll now. Year-round enrollment is also open to those who qualify.

Help is Available

- We have a statewide network of **expert assisters** who can help you apply and enroll, free of charge.
- **Get online help** to access frequently requested services.
- The **MNsure Contact Center** is open 8 a.m. to 4 p.m. Monday-Friday at 651-539-2099 (855-366-7873 outside the Twin Cities).

Small Business

Stay Informed

Connect with us

Contact Center:
651-539-2099 or 855-366-7873

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Exhibit A-30

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Donald J. Trump
@realDonaldTrump

3 Republicans and 48 Democrats let the American people down. As I said from the beginning, let ObamaCare implode, then deal. Watch!

2:25 AM · Jul 28, 2017 · Twitter for iPhone

22.3K Retweets **80.4K** Likes

This Tweet is from a suspended account. Learn more

This Tweet is from a suspended account. Learn more

1 more reply

BlueNovember2020 #VoteOutGOP @deejay… · Jul 28, 2017
Replying to @realDonaldTrump
#TheFailingPresident & the #EvilGop are LOSERS & the American people are the WINNERS! Many Thanks to Democrats McCain Murkowski & Collins

25 298 760

Michael Banach @m1db · Jul 28, 2017
And there is a special place in hell for @LindseyGrahamSC after the speech he gave today, to then vote for the GOP Skinny Final Solution.

6 17 171

1 more reply

Khanoisseur @Khanoisseur · Jul 28, 2017
Replying to @Khanoisseur and @realDonaldTrump
Yeah, everyone's shocked that all that work you put into attacking your own attorney general and bullying senators didn't get you the win

23 190 1.5K

Khanoisseur @Khanoisseur · Jul 28, 2017
Some things never change eh?

> **Khanoisseur** @Khanoisseur · Jul 27, 2017

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Relevant people

Donald J. Trump
@realDonaldTrump
45th President of the United States of America
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What's happening

COVID-19 · LIVE
COVID-19: China commits $2 billion to fight the pandemic

#EpicMegaSale
GTAV free on PC until 5/21. Keep it forever, only on Epic Games Store.
Promoted by Epic Games Store

COVID-19 · LIVE
COVID-19 updates for the US

Trending in United States
#timmylovespocs

Politics · Trending
Saudi Arabia
78.9K Tweets

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9 115 497

What's the crime? @suziferg0806 · Jul 29, 2017
Replying to @realDonaldTrump
Let it implode? Did you consider the people who would be hurt if that happens?
16 4 75

What's the crime? @suziferg0806 · Jul 29, 2017
A good leader would have this taken care of by now. But you were too busy giving them childish nicknames...
7 57

6 more replies

northierthanthou.com @Brimshack · Jul 29, 2017
Replying to @realDonaldTrump
This is the perspective of a wealthy man who couldn't care less if those fr whom he is responsible live, die or suffer in pain.
40 22 302

This Tweet is from a suspended account. Learn more

1 more reply

Shane @monolith5S · Jul 28, 2017
Replying to @321Amanda75 @MtnChippewa and 3 others
Couldn't like your tweet more Matt.. It made me feel like I just saw a unicorn. There are some of you out there!
9 13 579

Circe @Circe74 · Jul 28, 2017
We're out here! With what we see in DC, though, it's hard to say I'm an R anymore. The GOP in DC does NOT represent MY beliefs.
16 29 619

1 more reply

Craig Stone @craigstone_ · Jul 28, 2017
Replying to @realDonaldTrump
Nothing passed in 6 months cos your ideas are poison. Biggest presidential loser in history. You know the most losses. All the losses. SAD!
90 328 4.1K

David Pepper @DavidPepper · Jul 28, 2017
Replying to @realDonaldTrump
If you purposely let Obamacare fail, you are violating your oath to faithfully execute the laws of the United States
66 271 1.7K

MissMolecular @20to1Devotchka · Jul 28, 2017
Replying to @RobertMaguire_ and @realDonaldTrump
Lmao, the crowd behind him must have been paid actors... A woman holding an lgbtq sign, multiple poc and a doctor with a stethoscope?
8 4 196

Eugene Gu, MD @eugenegu · Jul 28, 2017
Must have been this type of doctor...

4 10 74

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Exhibit A-31

REMARKS

Remarks by President Trump at the 2017 Values Voter Summit

Issued on: **October 13, 2017**

★ ★ ★

Omni Shoreham Hotel
Washington, D.C.

10:22 A.M. EDT

THE PRESIDENT: Thank you very much, Tony. (Applause.) Thank you. Thank you very much. (Applause.)

AUDIENCE: USA! USA! USA!

THE PRESIDENT: Thank you very much. You know, I've been here before. (Laughter.) You do know that. Before the big day on November 8th, I was here. I want to thank Mark Meadows and all of the folks that have really made this possible. And, Tony, tremendous guy.

We have some incredible people that we love and that we're involved with. So we all know that. And I'm being followed by Mr. Bennett — you know that, right? And I've been watching him say nice things about me before I knew him. Those are the ones I like — (laughter) — where they speak well of you before you know them. Right?

But I really want to thank everybody, and, Tony, for your extraordinary leadership of this organization. And I want to thank, also, Lawana, for your dedication to the faith community and to our nation. Work so hard.

It's great to be back here with so many friends at the 2017 Values Voter Summit, and we know what that means. (Applause.) We know what that means. America is a nation of believers, and together we are strengthened and sustained by the power of prayer. (Applause.)

As we gather for this tremendous event, our hearts remain sad and heavy for the victims of the horrific mass murder last week in Las Vegas. It was an act of pure evil.

But in the wake of such horror, we also witnessed the true character of our nation. A mother laid on top of her daughter to shield her from gunfire. A husband died to protect his beloved wife. Strangers rescued strangers, police officers — and you saw that, all of those incredible police officers, how brave they were, how great they were running into fire. (Applause.) And first responders, they rushed right into danger.

Americans defied evil and hatred with courage and love.
The men and women who risked their lives to save their fellow citizens gave proof to the words of this scripture: "The light shines in the darkness, and the darkness has not overcome it." (Applause)

All of America is praying for the wounded and the grieving, and we will be with them today and we will be with them forever. (Applause.) Just want to finish by saying that — really, and we understand it was so horrific to watch and so terrible — but to those who lost the ones they love: We know that we cannot erase your pain, but we promise to never, ever leave your side. We are one nation, and we all hurt together, we hope together, and we heal together. (Applause.)

We also stand with the millions of people who have suffered from the massive fires, which are right now raging in California, and the catastrophic hurricanes along the Gulf Coast, in Puerto Rico, the U.S. Virgin Islands. And I will tell you, I left Texas, and I left Florida, and I left Louisiana, and I went to Puerto Rico, and I met with the president [governor] of the Virgin Islands.

These are people that are incredible people. They've suffered gravely, and we'll be there. We're going to be there. We have, really — it's not even a question of a choice. We don't even want a choice. We're going to be there as Americans, and we love those people and what they've gone through. And they're all healing, and their states and territories are healing, and they're healing rapidly.

In the wake of the terrible tragedies of the past several weeks, the American people have responded with goodness and generosity, and bravery. You've seen it. The heroism of everyday citizens reminds us that the true strength of our nation is found in the hearts and souls of our people.

When America is unified, no force on Earth can break us apart. (Applause.) We love our families. We love our neighbors. We love our country. Everyone here today is brought together by the same shared and timeless values. We cherish the sacred dignity of every human life. (Applause.)

We believe in strong families and safe communities. We honor the dignity of work. (Applause.) We defend our Constitution. We protect religious liberty. (Applause.) We treasure our freedom. We are proud of our history. We support the rule of law and the incredible men and women of law enforcement. (Applause.) We celebrate our heroes, and we salute every American who wears the uniform. (Applause.)

We respect our great American flag. (Applause.) Thank you. Thank you. Thank you.

And we stand united behind the customs, beliefs and traditions that define who we are as a nation and as a people.

George Washington said that "religion and morality are indispensable" to America's happiness, really, prosperity and totally to its success. It is our faith and our values that inspires us to give with charity, to act with courage, and to sacrifice for what we know is right.

The American Founders invoked our Creator four times in the Declaration of Independence — four times. (Applause.) How times have changed. But you know what, now they're changing back again. Just remember that. (Applause.)

Benjamin Franklin reminded his colleagues at the Constitutional Convention to begin by bowing their heads in prayer.

Religious liberty is enshrined in the very first amendment of the Bill of Rights. And we all pledge allegiance to — very, very beautifully — "one nation under God." (Applause.)

This is America's heritage, a country that never forgets that we are all — all, every one of us — made by the same God in Heaven. (Applause.)

When I came to speak with you last year, I made you a promise. Well, one of the promises I made you was that I'd come back. See? (Applause.) And I don't even need your vote this year, right? That's even nicer. (Laughter.)

But I pledged that, in a Trump administration, our nation's religious heritage would be cherished, protected, and defended like you have never seen before. That's what's happening. That's what's happening. You see it every day. You're reading it.

So this morning I am honored and thrilled to return as the first sitting President to address this incredible gathering of friends — so many friends. (Applause.) So many friends. And I'll ask Tony and all our people that do such a great job in putting this event together — can I take next year off or not? (Laughter.) Or do I have to be back? I don't know.

AUDIENCE: No!

THE PRESIDENT: He's saying — they're saying no. Lawana is saying no. That's means no. (Laughter.)

So I'm here to thank you for your support and to share with you how we are delivering on that promise, defending our shared values, and in so doing, how we are renewing the America we love.

In the last 10 months, we have followed through on one promise after another. (Applause.) I didn't have a schedule, but if I did have a schedule, I would say we are substantially ahead of schedule. (Applause.)

Some of those promises are to support and defend the Constitution. I appointed and confirmed a Supreme Court Justice in the mold of the late, great Justice Antonin Scalia, the newest member of the Supreme Court, Justice Neil Gorsuch. (Applause.)

To protect the unborn, I have reinstated a policy first put in place by President Ronald Reagan, the Mexico City Policy. (Applause.) To protect religious liberty, including protecting groups like this

one, I signed a new executive action in a beautiful ceremony at the White House on our National Day of Prayer — (applause) — which day we made official. (Applause.)

Among many historic steps, the executive order followed through on one of my most important campaign promises to so many of you: to prevent the horrendous Johnson Amendment from interfering with your First Amendment rights. (Applause.) Thank you. We will not allow government workers to censor sermons or target our pastors or our ministers or rabbis. These are the people we want to hear from, and they're not going to be silenced any longer. (Applause.)

Just last week, based on this executive action, the Department of Justice issued a new guidance to all federal agencies to ensure that no religious group is ever targeted under my administration. It won't happen. (Applause.)

We have also taken action to protect the conscience rights of groups like the Little Sisters of the Poor. You know what they went through. (Applause.) What they went through — they were going through hell. And then all of the sudden they won. They said, how did that happen? (Laughter.)

We want to really point out that the Little Sisters of the Poor and other people of faith, they live by a beautiful calling, and we will not let bureaucrats take away that calling or take away their rights. (Applause.)

We are stopping cold the attacks on Judeo-Christian values. (Applause.) Thank you. Thank you very much. And something I've said so much during the last two years, but I'll say it again as we approach the end of the year. You know, we're getting near that beautiful Christmas season that people don't talk about anymore. (Laughter.) They don't use the word "Christmas" because it's not politically correct. You go to department stores, and they'll say, "Happy New Year" and they'll say other things. And it will be red, they'll have it painted, but they don't say it. Well, guess what? We're saying "Merry Christmas" again. (Applause.)

And as a Christmas gift to all of our hardworking families, we hope Congress will pass massive tax cuts for the American people. (Applause.) That includes increasing the child tax credit and expanding it to eliminate the marriage penalty. (Applause.) Because we know that the American family is the true bedrock of American life. So true. (Applause.) This is such an exciting event because we are really working very hard, and hopefully Congress will come through.

You saw what we did yesterday with respect to healthcare. It's step by step by step. (Applause.) And that was a very big step yesterday. Another big step was taken the day before yesterday. And one by one it's going to come down, and we're going to have great healthcare in our country. We're going to have great healthcare in our country. (Applause.) We're taking a little different route than we had hoped, because getting Congress — they forgot what their pledges were. (Laughter.) So we're going a little different route. But you know what? In the end, it's going to be just as effective, and maybe it will even be better. (Applause.)

For too long, politicians have tried to centralize the authority among the hands of a small few in our nation's capital. Bureaucrats think they can run your lives, overrule your values, meddle in your faith, and tell you how to live, what to say, and how to pray. But we know that parents, not bureaucrats, know best how to raise their children and create a thriving society. (Applause.)

We know that faith and prayer, not federal regulation — and, by the way, we are cutting regulations at a clip that nobody has ever seen before. Nobody. (Applause.) In nine months, we have cut more regulation than any President has cut during their term in office. So we are doing the job. (Applause.) And that is one of the major reasons, in addition to the enthusiasm for manufacturing and business and jobs — and the jobs are coming back.

That's one of the major reasons — regulation, what we've done — that the stock market has just hit an all-time historic high. (Applause.) That just on the public markets we've made, since Election Day, $5.2 trillion in value. Think of that: $5.2 trillion. (Applause.) And as you've seen, the level of enthusiasm is the highest it's ever been, and we have a 17-year low in unemployment. So we're doing, really, some work. (Applause.)

We know that it's the family and the church, not government officials, that know best how to create strong and loving communities. (Applause.) And above all else, we know this: In America, we don't worship government — we worship God. (Applause.) Inspired by that conviction, we are returning moral clarity to our view of the world and the many grave challenges we face.

This afternoon, in a little while, I'll be giving a speech on Iran, a terrorist nation like few others. And I think you're going to find it very interesting. (Applause.)

Yesterday, things happened with Pakistan, and I have openly said Pakistan took tremendous advantage of our country for many years, but we're starting to have a real relationship with

Pakistan and they're starting to respect us as a nation again, and so are other nations. They're starting to respect the United States of America again, and I appreciate that. (Applause.) And I want to thank the leaders of Pakistan for what they've been doing.

In this administration, we will call evil by its name. (Applause.) We stand with our friends and allies, we forge new partnerships in pursuit of peace, and we take decisive action against those who would threaten our people with harm. (Applause.) And we will be decisive — because we know that the first duty of government is to serve its citizens. We are defending our borders, protecting our workers, and enforcing our laws. You see it every single day like you haven't seen it in many, many years — if you've seen it at all. (Applause.)

In protecting America's interests abroad, we will always support our cherished friend and partner, the State of Israel. (Applause.) We will confront the dangers that imperil our nation, our allies, and the world, including the threat of radical Islamic terrorism. (Applause.)

We have made great strides against ISIS — tremendous strides. I don't know if you've seen what's going on, but tremendous strides against ISIS. They never got hit like this before. (Laughter.)

AUDIENCE MEMBER: (Inaudible.)

THE PRESIDENT: Stand up. Stand up. Let me see — he's a rough guy. I can see it.

But they've been just ruthless and they've ruthlessly slaughtered innocent Christians, along with the vicious killing of innocent Muslims and other religious minorities. And we've made their lives very, very difficult — believe me. (Applause.)

We've done more against ISIS in nine months than the previous administration has done during its whole administration — by far, by far. (Applause.) And ISIS is now being dealt one defeat after another. We are confronting rogue regimes from Iran to North Korea, and we are challenging the communist dictatorship of Cuba and the socialist oppression of Venezuela. And we will not lift the sanctions on these repressive regimes until they restore political and religious freedom for their people. (Applause.)

All of these bad actors share a common enemy, the one force they cannot stop, the force deep within our souls, and that is the power of hope. That is why, in addition to our great military might,

our enemies truly fear the United States. Because our people never lose faith, never give in, and always hope for a better tomorrow.

Last week, Melania and I were reminded of this in a powerful way when we traveled to Las Vegas. We visited a hospital where some of the survivors were recovering from absolutely horrific wounds. We met a young man named Brady Cook. He's 22 and a brand-new police officer. That night was Brady's second day in field training — his second day as a policeman, can you believe that? But when the shooting began, he did not hesitate. He acted with incredible courage, rushing into the hail of bullets, and he was badly shot in the shoulder.

This is what Brady said: "I didn't expect it, but it's what I signed up for. When stuff goes down, I want to be there to face evil and to protect the good, innocent people that need it." And here's a young guy, great guy — and second day. I said, Brady, don't worry about it, it's going to be easier from here. (Laughter and applause.) Brady is a hero, and he can't wait to get back on the job.

Several weeks before, when Hurricane Harvey hit Houston, a local furniture storeowner, who's known in Texas as "Mattress Mack," decided he had to help. When the rain began to flood the streets of the city, he sent out his furniture trucks to rescue the stranded. He brought them back to his stores, and gave them food and a clean, dry place to stay, even if it meant ruining countless dollars' worth of furniture.

As "Mattress Mack" put it, "My faith defines me, it's who I am." "We can afford [the cost]…what we can't afford" — we can't — and he said this very strongly, "what we can't afford is to cause people to lose hope."

In Brady and Mack, we see the strength of the American spirit. This spirit of courage and compassion is all around us, every day. It is the heartbeat of our great nation. And despite certain coverage, that beat is stronger than it's ever been before. You see right through it. (Applause.) That beat is stronger than it's ever been.

We see this spirit in the men and women who selflessly enlist in our armed forces and, really, who go out and risk their lives for God and for country. And we see it in the mothers and the fathers who get up at the crack of dawn; they work two jobs and sometimes three jobs. They sacrifice every day for the furniture and — future of their children. They have to go out. They go out. They work. The

future of their children is everything to them. They put it before everything. And they make sure that the future of their children has God involved in it. So important to them. (Applause.)

We see it in the church communities that come together to care for one another, to pray for each other, and to stand strong with each other in times of need.

The people who grace our lives, and fill our homes, and build our communities are the true strength of our nation, and the greatest hope for a better tomorrow.

As long as we have pride in our country, confidence in our future, and faith in our God, then America will prevail.

We will defeat every evil, overcome every threat, and meet every single challenge. We will defend our faith and protect our traditions. We will find the best in each other and in ourselves. We will pass on the blessings of liberty, and the glories of God, to our children. Our values will endure, our nation will thrive, our citizens will flourish, and our freedom will triumph.

Thank you to the Value Voter Summit. Such an incredible group of people you are. Thank you to all of the faithful here today. And thank you to the people of faith all across our nation and all over the world.

May God bless you. May God bless the United States of America. Thank you very much, everybody. (Applause.)

END

10:51 A.M. EDT

Exhibit A-32

REMARKS

Remarks by President Trump at S.204, "Right to Try" Bill Signing

HEALTHCARE

Issued on: **May 30, 2018**

★ ★ ★

South Court Auditorium
Eisenhower Executive Office Building

12:31 P.M. EDT

THE PRESIDENT: Thank you very much, everybody. I really appreciate it. This is — to me, this is a very important moment, a very important day. Been looking forward to this for a long time, along with Senator Ron Johnson. And I will tell you, we worked hard on this. I never understood why it was hard.

They've been trying to have it passed for years. I never understood why. Because I'd see people — friends of mine, and other people I'd read about, where they'd travel all over the world looking for a cure. And we have the best medical people in the world, but we have trials and we long time — 12 years, 15 years. Even when things look really promising, so many years. And I never understood why they didn't do this. And we worked very hard.

And I want to thank Vice President Pence for helping us so much. Mike was in there, and I'd say, "Mike, how we doing? We got to get it approved." And he was — he was really working it. And in my State of the Union Address, four months ago, I called on Congress to pass Right to Try. It's such a great name. Some bills, they don't have a good name. (Laughter.) Okay? They really don't. But this is such a great name, from the first day I heard it. It's so perfect. Right to Try.

And a lot of that trying is going to be successful. I really believe that. I really believe it.

So we did it. And we went through the Senate, we went through the House. The House had a bill. The Senate had a bill. We'd go and mesh them together. We got to go back and take votes. And I said, do me a favor — tell me, which is the better bill for the people? Not for the insurance company, not for the pharmaceutical companies. I don't care about them. I really don't. I couldn't care less. (Applause.)

And that's the bill I — I won't tell you which one. But I took the one that was — (laughter) — they said one in particular was great for the people. Not so good for the others, but great for the people. We don't care about the others right now. And it's giving terminally ill patients the right to try experimental lifesaving treatments. And some of these treatments are so promising.

And we're moving that timeline way up anyway, beyond this. We're moving it way up. But it's still a process that takes years. Now it takes up to 15 years; even 20 years, some of these treatments are going. But for many years, patients, advocates, and lawmakers have fought for this fundamental freedom. And as I said, incredibly, they couldn't get it. And there were reasons. A lot of it was business. A lot of it was pharmaceuticals. A lot of it was insurance. A lot of it was liability. I said, so you take care of that stuff. And that's what we did.

Today I'm proud to keep another promise to the American people as I sign the Right to Try legislation into law. (Applause.)

Right? (Speaks to participant on stage.) You're so beautiful. So beautiful.

If I looked like that, I would have been President 10 years earlier. (Laughter.) If I had that face, if I had that head of hair, I would have been President so long ago. (Laughter.) That's great.

So I want to thank a couple of people. Secretary Azar is here. Where's the Secretary? Secretary? Please stand up. You have worked so hard on this. (Applause.) Thank you very much. You've really done a great job. And we're going to have another exciting news conference over the next, what, three weeks? Four weeks? Two weeks? What do you think? On healthcare. We're going to have great healthcare. We'll get rid of the individual mandate. Without that, we couldn't be doing what we're doing in a few weeks. We're going to have great, inexpensive, but really good healthcare.

And we have two plans coming out. We also have, through our great Secretary of Labor, we have a great plan coming out, and that's through associations. We're going to have two plans coming out. For the most part, we will have gotten rid of a majority of Obamacare. Gotten tremendous — (applause) — yeah. Could have had it done a little bit easier, but somebody decided not to vote for it, so it's one of those things.

I want to thank Secretary Azar, and I want to thank Commissioner Gottlieb. Where's Scott? Scott, stand up. (Applause.) Ooh, I like those — I like those socks, Scott. And, Scott, let me ask you. So it takes years and years to get this approved, right? You're bringing down — beyond this, you're bringing down that period of time. What is the average time now it takes for, you know, a major medicine or cure? What's the average time it takes to go through the system and get an approval?

COMMISSIONER GOTTLIEB: Depends on the medicine. Probably three to seven years.

THE PRESIDENT: Three to seven. And some go long over 10, right?

COMMISSIONER GOTTLIEB: Some can go much longer.

THE PRESIDENT: And you're bringing that down? You're trying to bring that down? You know, for safety. Very good. And you, in particular, you're very happy with this. Aren't you?

COMMISSIONER GOTTLIEB: We are.

THE PRESIDENT: You have a lot of good things in the wings that, frankly, if you moved them up, a lot of people would have a great shot. Right?

COMMISSIONER GOTTLIEB: We're trying to get (inaudible), Mr. President, under your leadership.

THE PRESIDENT: Right. That's fantastic. Well, thank you, Scott. We're very proud of the job you're doing.

We're also working very hard in getting the cost of medicine down. And I think people are going to see, for the first time ever in this country, a major drop in the cost of prescription drugs. Right? (Applause.) And, Mr. Secretary, that's already happening. Right? That's already happening. You were telling me yesterday that we're seeing a big — a tremendous improvement. And you're going

to have some big news. I think we're going to have some big — some of the big drug companies in two weeks. And they're going to announce — because of what we did, they're going to announce voluntary massive drops in prices. So that's great. That's going to be a fantastic thing.

You know, we're working on some really great things. Aren't we? When you think about it. Ron, pretty good. Huh? We could do some of those — healthcare, drug prices. But this is the baby. Right now.

We would not be here today without the tireless efforts of dedicated members of Congress. That's so true. I want to especially thank Senator Ron Johnson — stand up please, Ron — (applause) — for his tremendous leadership. You know, I just tell you, he doesn't stop. He doesn't give up. You know, it's good. It's good for all of us. This guy, Ron, very capable, very — he just doesn't give up. So when we started working, I knew this was going to happen.

I also want to thank Senator Donnelly. Senator Donnelly, thank you very much. That's really great. Appreciate it. Thank you. Thank you. (Applause.) A fantastic young gentleman, Brian Fitzpatrick of Pennsylvania. Brian, congratulations. And I know how hard you work, Brian. (Applause.) And Dr. Michael Burgess. Do you like being called "Doctor" or "Congressman"? I think "Doctor" is better. I like "Doctor." (Laughs.) So we'll call him Doctor. (Applause.) Thank you, Michael, very much. Great job. You worked — I know how hard everybody worked, and I really appreciate it. Everybody appreciates it. The country appreciates it. Because nobody understood why this wasn't happening. You know, they've been talking about this for how long, Ron? Twenty-five years?

SENATOR JOHNSON: A long time.

THE PRESIDENT: A long time. A lot of talk. Politicians. It's a lot of talk.

I also want to thank Energy and Commerce Committee Chairman Greg Walden, who's not here. But he really worked hard with us. He really did. (Applause.) And thanks, as well, to state and local officials here today who fought for this important cause. They fought so hard, so many of them. I want to thank you for the incredible work that you've done on behalf of these and all wonderful Americans. I mean, anybody can be there someday. Anybody can be there. Could you all stand up — the state, local people that worked so hard on this? Because you really have been — thank you. Yep. Thank you, fellas. (Applause.) Couldn't have done it without the state and local, and I appreciate it. Really great job. Thank you.

Most of all, we're honored to be joined by several brave Americans for whom this bill is named. Matthew Bellina, who is battling ALS, and his incredible wife Caitlin. Matthew. Right? (Applause.) Thank you. Thank you. Laura McLinn and her son, Jordan, who is battling muscular dystrophy. Some good answers. (Applause.) That's so great. Thanks. Thanks for being with us, Jordan. We're going to have some good answers for you. (Laughter.) Matthew, you're going to be happy. You are happy. Frank Mongiello, who's battling ALS, and who's joined by his wife, Marylin, and their six children. Wow. That's fantastic. That's fantastic. (Applause.) Thank you. Six children. And finally, I want to thank for being here and introduce Tim Wendler, who tragically lost his wife Trickett to ALS, and joined also by their three children. So, Tim, thank you very much. Thank you, Tim. (Applause.)

I want to thank you all for being here. You have extraordinary courage, determination, and love. You have love. Real love. And thanks to you, the countless American lives will ultimately be saved. We will be saving — I don't even want to say thousands, because I think it's going to be much more — thousands and thousands, hundreds of thousands. We're going to be saving tremendous numbers of lives. And it's so great that you're up here with us and that we're all on this front line together.

Each year, thousands of terminally ill patients suffer while waiting for new and experimental drugs to receive final FDA approval. It takes a long time, and the time is coming down. While we were streamlining and doing a lot of streamlining, the current FDA approval process can take, as Scott just said, many years — many, many years. And for countless patients, time, it's not what they have. They don't have an abundance of time.

With the Right to Try law I'm signing today, patients with life-threatening illnesses will finally have access to experimental treatments that could improve or even cure their conditions. These are experimental treatments and products that have shown great promise, and we weren't able to use them before. Now we can use them. And oftentimes they're going to be very successful. It's an incredible thing.

The Right to Try also offers new hope for those who either don't qualify for clinical trials or who have exhausted all available treatment options. There were no options, but now you have hope. You really have hope.

Matthew Bellina, who is here with us, is just one example of many Americans who today has new cause for hope. Due to the late progression of Matt's ALS, he doesn't qualify for any clinical trials in the United States. He wouldn't qualify; couldn't do it. They tried; he didn't qualify.

Despite his limited mobility and budget, he was planning on traveling thousands of miles away, to Israel, to receive a treatment that is still awaiting FDA approval in America. No one in Matt's position should ever have to travel from our great country to another continent or another country to receive a treatment.

Now, with the passage of this bill, Americans will be able to seek cures right here at home, close to their family and their loved ones. We are finally giving these wonderful Americans the right to try. So important. (Applause.)

America has always been a nation of fighters who never give up. Right? We never give up, ever. Right? Never give up. We're fighters, like the amazing patients and families here today.

Now, as I proudly sign — and this is very personal for me. But as I proudly sign this bill, thousands of terminally ill Americans will finally have the help, the hope, and the fighting chance — and I think it's going to be better than chance — that they will be cured, that they will be helped, that they'll be able to be with their families for a long time or maybe just for a longer time. But we're able to give them the absolute best, as to what we have at this current moment, at this current second. And now, we're going to help a lot of people. We're going to help a lot of people.

So it's an honor to be signing this. And if I might, I think I'll present — I think I have to do this, Ron. I have to present this good-looking guy with the first pen. Is that okay? You don't mind, right? Okay, good. I'm going to do that. (Applause.)

(The bill is signed.) (Applause.)

So I want to thank — (laughter) — it's going to be fantastic.

Thank you all very much. This, to me, is very exciting. And you're going to see some tremendous results. We're going to have some incredible, incredible results.

So thank you all for being here. And all of the people in the audience who have been so helpful, thank you very much. It's going to be something very, very special. Thank you. (Applause.)

END

12:49 P.M. EDT

Exhibit A-33

REMARKS

Remarks by President Trump at a Fox News Town Hall | Scranton, PA

Issued on: **March 6, 2020**

★ ★ ★

Scranton Cultural Center
Scranton, Pennsylvania

March 5, 2020
6:32 P.M. EST

Q You've got a great crowd here.

THE PRESIDENT: Nice audience. Nice crowd. (Applause.)

Q Terrific crowd here tonight. Thank you so much, everybody.

Q We'd love to get to a lot of questions tonight, and there are a lot of good questions from residents here in Scranton who want to talk about big issues.

Q So we're going to jump right in with the first questioner from our audience. Thank you again, Mr. President, for being here tonight.

THE PRESIDENT: Thank you. Thank you very much.

Q Catherine Pugh (ph) is joining us. She is an undecided voter and she has a question for President Trump. Catherine?

And what we'd like to do is totally kill it, but come up — before we do that — with something that's great. What we've done is we've really managed Obamacare — the remaining portion — we get rid of the bad part, but the remaining portion — really well. And you know, before I got involved, you know what was happening with the rates and Obamacare: They were going up at levels that nobody has ever seen before. We are managing it.

And I had a decision to make. This was very important. I said to my people — and we have great people: Seema, Azar — I mean, great people that are so good at it. I said, "You know, I have a little problem: Do we manage it great until we get something much better or do we manage it poorly and say Obamacare is horrible?" And I said, "We've got to do the right thing. We've got to manage it really, really good."

So it's not great healthcare, but we're managing it fantastically. And you don't see all those stories about the rates going through the roof anymore because we know what we're doing.

At the same time, we want to get you really fantastic healthcare. If we can win back the House, we'll be able to do that. We have to win back the House, keep the Senate, keep the White House. (Applause.) We'll be able to do that.

Thank you. Thanks for the question.

Q So, Mr. President, I just want to follow up quickly on that because the issue of preexisting conditions, you say you're going to protect them —

THE PRESIDENT: Right.

Q — but your administration is also fighting Obamacare in the courts. So how do you — how do you promise people that you're going to protect them —

THE PRESIDENT: Well, that's what I said —

Q — based on that?

THE PRESIDENT: Yeah. That's what I said. We want to terminate Obamacare because it's bad. Look, we're running it really well, but we know it's defective. It's very defective. We got rid of the

Exhibit A-34

Remarks by President Trump on Protecting Seniors with Diabetes

HEALTHCARE | Issued on: May 26, 2020

ALL NEWS

Rose Garden

4:30 P.M. EDT

THE PRESIDENT: You definitely have plenty of distancing. I've never seen distancing like that. That's really — that's really very impressive.

And welcome to the Rose Garden as we take powerful action to lower healthcare costs for America's seniors. Today, I'm proud to announce that we have reached a breakthrough agreement to dramatically slash the out-of-pocket cost of insulin. You know what's happened to insulin over the years, right? Through the roof. Insulin — so many people, so necessary.

For hundreds and thousands of seniors enrolled in Medicare — that's a big deal — participating plans will cap cost at just $35 a month per type of insulin, and some plans may offer it free. So for everybody that was getting ripped off and paying tremendous prices — senior citizens — and, Seema, I want to thank you because you brought this to my attention a long time ago, and you worked very hard on this day. And the press won't even cover it, but they'll cover things that are unimportant.

But this is a big day for seniors. This is a tremendous saving. And it allows people that — you know, if you don't take insulin — I just wrote this down — go blind, stroke, amputation,

kidney failure, and other things. So we're getting it down — $35 per month. And it would be anywhere from $50 to $150 to over $200 a month. So it's a massive cut — I guess, 60, 70 percent. Nobody has seen anything like this for a long time.

Sleepy Joe can't do this — that, I can tell you. In fact, it was his problem with Obamacare that caused part of your problem. This will save impacted Americans an average of minimum $446, just on insulin costs a year.

We're pleased to be joined by Vice President Mike Pence and Surgeon General Jerome Adams. I also want to thank Seema again. Thank you very much for the job you've done helping achieve the incredible victory for Medicare patients nationwide.

In the past, Obamacare prevented insurance providers from competing to offer lower costs for seniors. There was no competition, there was no anything, and they ran away with what took place, and the seniors were horribly hurt. Many people couldn't take insulin; they couldn't even think about it.

As a result, Medicare beneficiaries with prescription drug coverage paid an average of $675 for a year's supply of insulin, and sometimes as high as $1,500. Harmful laws also meant that seniors often paid a different amount almost every single month. They had no idea what they were paying — they were billed. Every month, they were billed a different amount, and it was a massive amount.

One in every three seniors on Medicare has diabetes, and over 3.3 million beneficiaries use at least one type of insulin. Over the past 10 years, these seniors have seen their out-of-pocket costs for this lifesaving treatment almost double.

I don't use insulin. Should I be? Huh? I never thought about it. But I know a lot of people are very — very badly affected, right? Unbelievable.

That's why my administration acted decisively. We slashed Obamacare's crippling requirements and opened up competition like they've never seen before. They've never seen competition like this. Between transparency and all of the other things we're doing,

nobody has ever had a competitive — competitive situation created like we've done it. And the prices, you will see very soon, they're going to come tumbling down.

Then we brought all the parties to the table — insurers, manufacturers, and other key players — and reached an agreement to deliver insulin at stable and drastically lower out-of-pocket costs for our seniors.

I hope the seniors are going to remember it, because Biden is the one that put us into the jam because they didn't know what they were doing. They were incompetent.

Soon, nearly half of all eligible Part D and Medicare Advantage prescription drug plans will offer this low-cost option — and when you say "low-cost," you're really talking low cost — giving seniors the freedom and choice to pick the plan that's right for them.

Nothing will ever stop me from fulfilling my solemn duty to America's seniors. I'll use every power at my disposal to lower drug prices, and my administration will always protect Medicare and Social Security — and, by the way, preexisting conditions.

And we got rid of the individual mandate, which is a disaster. The worst part of Obamacare was the individual mandate. When we got rid of the individual mandate, essentially we got rid of Obamacare, if you want to know the truth. You can say that in the truest form. But we got rid of a horrible, horrible condition called the "individual mandate." But we'll always protect you on preexisting conditions, much more so than the Democrats.

Here with us today is Bruce Broussard, president and C- — CEO of a big, powerful healthcare company: Humana. And I'd like to have Bruce come up and say a few words, please. Bruce? Thank you. That's a big company. You — look how young he is, too. That's very young to be running such a big company, huh?

MR. BROUSSARD: Well, thank you very much, Mr. President.

THE PRESIDENT: Thank you, Bruce.

Exhibit A-35

QuickFacts

United States; Chicago city, Illinois

What's New & FAQs

QuickFacts provides statistics for all states and counties, and for cities and towns with a ***population of 5,000 or more***.

Enter state, county, city, town, or zip code

-- Select a fact --

TABLE

Table

All Topics

	United States	Chicago
PEOPLE		
Population		
Population estimates, July 1, 2019, (V2019)	**328,239,523**	**2,693,976**
Population estimates base, April 1, 2010, (V2019)	308,758,105	2,695,652
Population, percent change - April 1, 2010 (estimates base) to July 1, 2019, (V2019)	6.3%	-0.1%
Population, Census, April 1, 2010	308,745,538	2,695,598
Age and Sex		
Persons under 5 years, percent	6.1%	6.5%
Persons under 18 years, percent	22.4%	21.2%
Persons 65 years and over, percent		
Female persons, percent		
Race and Hispanic Origin		

White alone, percent	76.5%	49.4%
Black or African American alone, percent (a)	13.4%	30.1%
American Indian and Alaska Native alone, percent (a)	1.3%	0.3%
Asian alone, percent (a)	5.9%	6.4%
Native Hawaiian and Other Pacific Islander alone, percent (a)	0.2%	0.0%
Two or More Races, percent	2.7%	2.7%
Hispanic or Latino, percent (b)	18.3%	29.0%
White alone, not Hispanic or Latino, percent	60.4%	32.8%
Population Characteristics		
Veterans, 2014-2018	18,611,432	71,067
Foreign born persons, percent, 2014-2018	13.5%	20.6%
Housing		
Housing units, July 1, 2019, (V2019)	139,684,244	X
Owner-occupied housing unit rate, 2014-2018	63.8%	45.0%
Median value of owner-occupied housing units, 2014-2018	$204,900	$246,500
Median selected monthly owner costs -with a mortgage, 2014-2018	$1,558	$1,929
Median selected monthly owner costs -without a mortgage, 2014-2018	$490	$686
Median gross rent, 2014-2018	$1,023	$1,077
Building permits, 2019	1,386,048	X
Families & Living Arrangements		
Households, 2014-2018	119,730,128	1,056,118
Persons per household, 2014-2018	2.63	2.52
Living in same house 1 year ago, percent of persons age 1 year+, 2014-2018	85.5%	84.7%
Language other than English spoken at home, percent of persons age 5 years+, 2014-2018	21.5%	36.0%
Computer and Internet Use		
Households with a computer, percent, 2014-2018	88.8%	85.8%
Households with a broadband Internet subscription, percent, 2014-2018	80.4%	75.9%
Education		
High school graduate or higher, percent of persons age 25 years+, 2014-2018	87.7%	84.5%
Bachelor's degree or higher, percent of persons age 25 years+, 2014-2018	31.5%	38.4%
Health		
With a disability, under age 65 years, percent, 2014-2018	8.6%	6.9%

Persons without health insurance, under age 65 years, percent	10.0%	11.9%
Economy		
In civilian labor force, total, percent of population age 16 years+, 2014-2018	62.9%	66.6%
In civilian labor force, female, percent of population age 16 years+, 2014-2018	58.2%	62.3%
Total accommodation and food services sales, 2012 ($1,000) (c)	708,138,598	8,996,441
Total health care and social assistance receipts/revenue, 2012 ($1,000) (c)	2,040,441,203	20,064,843
Total manufacturers shipments, 2012 ($1,000) (c)	5,696,729,632	26,503,402
Total merchant wholesaler sales, 2012 ($1,000) (c)	5,208,023,478	33,134,983
Total retail sales, 2012 ($1,000) (c)	4,219,821,871	22,627,328
Total retail sales per capita, 2012 (c)	$13,443	$8,335
Transportation		
Mean travel time to work (minutes), workers age 16 years+, 2014-2018	26.6	35.0
Income & Poverty		
Median household income (in 2018 dollars), 2014-2018	$60,293	$55,198
Per capita income in past 12 months (in 2018 dollars), 2014-2018	$32,621	$34,775
Persons in poverty, percent	11.8%	19.5%

BUSINESSES

Businesses		
Total employer establishments, 2017	7,860,674	X
Total employment, 2017	128,591,812	X
Total annual payroll, 2017 ($1,000)	6,725,346,754	X
Total employment, percent change, 2016-2017	1.5%	X
Total nonemployer establishments, 2018	26,485,532	X
All firms, 2012	27,626,360	291,007
Men-owned firms, 2012	14,844,597	147,997
Women-owned firms, 2012	9,878,397	123,632
Minority-owned firms, 2012	7,952,386	140,109
Nonminority-owned firms, 2012	18,987,918	142,470
Veteran-owned firms, 2012	2,521,682	19,747
Nonveteran-owned firms, 2012	24,070,685	263,026

GEOGRAPHY

Geography		

Population per square mile, 2010	87.4	11,841.8
Land area in square miles, 2010	3,531,905.43	227.63
FIPS Code	1	1714000

About datasets used in this table

Value Notes

Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources.

Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable. Click the Quick Info icon to the left of each row in TABLE view to learn about sampling error.

The vintage year (e.g., V2019) refers to the final year of the series (2010 thru 2019). *Different vintage years of estimates are not comparable.*

Fact Notes

- **(a)** Includes persons reporting only one race
- **(b)** Hispanics may be of any race, so also are included in applicable race categories
- **(c)** Economic Census - Puerto Rico data are not comparable to U.S. Economic Census data

Value Flags

- **-** Either no or too few sample observations were available to compute an estimate, or a ratio of medians cannot be calculated because one or both of the median estimates falls in the lowest or upper interval of an open ended distribution.
- **D** Suppressed to avoid disclosure of confidential information
- **F** Fewer than 25 firms
- **FN** Footnote on this item in place of data
- **N** Data for this geographic area cannot be displayed because the number of sample cases is too small.
- **NA** Not available
- **S** Suppressed; does not meet publication standards
- **X** Not applicable
- **Z** Value greater than zero but less than half unit of measure shown

QuickFacts data are derived from: Population Estimates, American Community Survey, Census of Population and Housing, Current Population Survey, Small Area Health Insurance Estimates, Small Area Income and Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits.

Exhibit A-36

Economy at a Glance

MIDWEST PRINT:

BROWSE EAG
U.S. ECONOMY
CENSUS REGIONS
ABOUT THE DATA

BROWSE ALL STATES
ALABAMA
ALASKA
ARIZONA
ARKANSAS
CALIFORNIA
COLORADO
CONNECTICUT
DELAWARE
D.C.
FLORIDA
GEORGIA
HAWAII
IDAHO
ILLINOIS
INDIANA
IOWA
KANSAS
KENTUCKY
LOUISIANA
MAINE
MARYLAND
MASSACHUSETTS
MICHIGAN
MINNESOTA
MISSISSIPPI
MISSOURI
MONTANA
NEBRASKA
NEVADA
NEW HAMPSHIRE
NEW JERSEY
NEW MEXICO
NEW YORK
NORTH CAROLINA
NORTH DAKOTA
OHIO
OKLAHOMA
OREGON
PENNSYLVANIA
PUERTO RICO
RHODE ISLAND
SOUTH CAROLINA
SOUTH DAKOTA
TENNESSEE

Chicago-Joliet-Naperville, IL

Chicago-Naperville-Arlington Heights, IL

Data Series	Back Data	Nov 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020	Apr 2020
Labor Force Data							
Civilian Labor Force(1)		(R) 3,693.4	(R) 3,674.8	3,638.8	3,678.1	3,746.5	(P) 3,639.5
Employment(1)		(R) 3,583.4	(R) 3,570.4	3,508.8	3,554.1	3,569.5	(P) 2,999.2
Unemployment(1)		(R) 110.0	(R) 104.4	130.0	123.9	177.0	(P) 640.3
Unemployment Rate(2)		(R) 3.0	(R) 2.8	3.6	3.4	4.7	(P) 17.6
Nonfarm Wage and Salary Employment							
Total Nonfarm(3)		3,835.2	3,829.0	3,750.6	3,752.5	3,723.8	(P) 3,284.2
12-month % change		0.3	0.4	1.0	1.0	-0.5	(P) -12.8
Mining and Logging(3)		1.4	1.3	1.2	1.2	1.3	(P) 1.2
12-month % change		7.7	0.0	0.0	0.0	0.0	(P) -14.3
Construction(3)		135.0	127.8	119.5	119.0	120.8	(P) 114.1
12-month % change		-0.5	-1.9	1.2	1.3	-2.3	(P) -12.8
Manufacturing(3)		282.1	282.1	277.8	279.3	277.3	(P) 251.5
12-month % change		-1.4	-1.7	-2.4	-2.0	-2.8	(P) -11.5
Trade, Transportation, and Utilities(3)		762.8	771.5	748.7	739.2	734.0	(P) 666.8
12-month % change		-0.3	0.0	0.3	0.5	-0.5	(P) -9.9
Information(3)		70.4	72.3	71.1	71.5	71.2	(P) 69.9
12-month % change		0.1	3.6	1.3	1.7	0.8	(P) -0.9
Financial Activities(3)		278.9	279.5	277.3	277.7	276.6	(P) 270.6
12-month % change		2.6	2.6	2.6	2.1	1.4	(P) -1.2
Professional and Business Services(3)		716.4	706.1	687.5	692.2	680.5	(P) 628.2
12-month % change		-0.3	-0.9	0.5	0.5	-1.2	(P) -9.3
Education and Health Services(3)		617.2	617.2	614.8	620.2	617.5	(P) 561.8
12-month % change		1.9	2.2	3.0	3.3	2.2	(P) -7.3
Leisure and Hospitality(3)		384.0	384.3	375.1	371.6	363.2	(P) 185.7
12-month % change		-0.1	0.5	1.5	0.8	-3.4	(P) -51.9
Other Services(3)		160.9	161.6	161.0	159.8	159.8	(P) 133.5
12-month % change		-0.7	-0.6	0.5	-0.1	-0.8	(P) -17.4
Government(3)		426.1	425.3	416.6	420.8	421.6	(P) 400.9
12-month % change		1.0	0.9	1.1	1.0	0.1	(P) -4.5
Consumer Price Index: Chicago-Naperville-Elgin, IL-IN-WI							
CPI-U, All items(4)		242.661	242.079	244.361	244.407	242.655	240.364
CPI-U, All items, 12-month % change(4)		2.2	2.2	2.6	2.0	1.1	0.3
CPI-W, All items(5)		233.945	233.518	235.518	235.557	234.250	231.572
CPI-W, All items, 12-month % change(5)		2.2	2.4	2.8	2.1	1.1	0.0

Footnotes
(1) Number of persons, in thousands, not seasonally adjusted.
(2) In percent, not seasonally adjusted.
(3) Number of jobs, in thousands, not seasonally adjusted. See About the data.
(4) All Urban Consumers, base: 1982-84=100, not seasonally adjusted.
(5) Urban Wage Earners and Clerical Workers, base: 1982-84=100, not seasonally adjusted.
(P) Preliminary
(r) Revised

Data extracted on: May 28, 2020

Source: U.S. Bureau of Labor Statistics
Note: More data series, including additional geographic areas, are available through the "Databases & Tables" tab at the top of this page.

Geographically based survey data available from BLS:

Employment & Unemployment

- Employment, Hours, and Earnings from the CES survey (State and Area)

TEXAS
UTAH
VERMONT
VIRGIN ISLANDS
VIRGINIA
WASHINGTON
WEST VIRGINIA
WISCONSIN
WYOMING

- Local Area Unemployment Statistics
- Create Customized Maps -- Unemployment Rates
- Quarterly Census of Employment and Wages
- Occupational Employment Statistics
- Geographic Profile

Prices & Living Conditions

- Consumer Price Index
- Consumer Expenditure Survey

Compensation & Working Conditions

- National Compensation Survey
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Exhibit A-37

INSURANCE EXPANSION, HOSPITAL UNCOMPENSATED CARE, AND THE AFFORDABLE CARE ACT

March 23, 2015

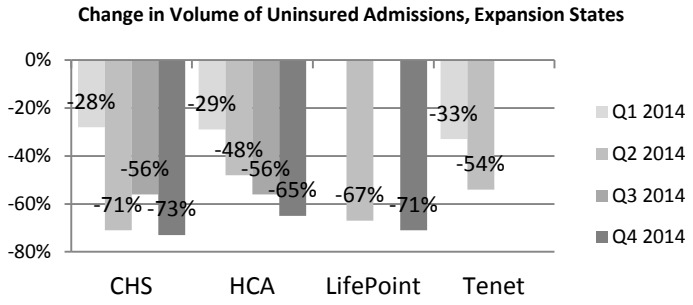
Hospital Uncompensated Care – Uncompensated care is the unreimbursed cost of the care provided by hospitals to people who are uninsured or underinsured. Hospitals provided over $50 billion in uncompensated care in 2013. By greatly reducing the numbers of Americans who are uninsured through the establishment of the Health Insurance Marketplace and by facilitating States' expansions of Medicaid, the Affordable Care Act has reduced hospitals' uncompensated care costs.

Medicaid Expansion –Analysis of hospital financial reporting and member surveys from hospital associations indicates that, through 2014, payor mix is shifting in ways that will likely reduce hospital uncompensated care costs. Moreover, a projection model developed by ASPE suggests that the large observed declines in the uninsured and increases in Medicaid coverage have led to substantial declines in hospital uncompensated care in 2014. Medicaid expansion states account for $5 billion of the estimated $7.4 billion reduction in uncompensated care costs attributed to ACA coverage expansions.

Analysis of Hospital Financial Reports

Hospital financial reporting suggests that payor mix shifted significantly during 2014 in ways that will likely reduce hospital uncompensated care costs. In particular:

- Volumes of uninsured/self-pay admissions (which comprise a major portion of uncompensated care provided by hospitals) have fallen substantially in states that have elected to expand the Medicaid program through the Affordable Care Act; these volumes have fallen slightly in non-expansion states.



CHS = Community Health Systems; HCA = Hospital Corporation of America; CHS, HCA, LifePoint, and Tenet are hospital systems.
Source: Quarterly earnings call transcripts; some data are missing for each system because not all systems report these data each quarter.

- Proportions and volumes of uninsured/self-pay emergency department visits have also fallen substantially, primarily in Medicaid expansion states.

Analysis of Hospital Cost Reports

Our projection model suggests that uncompensated care costs will continue to fall substantially following major insurance coverage expansions, including coverage expansions through both Medicaid and the Health Insurance Marketplace. Specifically:

- Based on estimated coverage gains in 2014, ASPE estimates that hospital uncompensated care costs were $7.4 billion lower in 2014 than they would have been had coverage remained at its 2013 level, at $27.3 billion versus $34.7 billion (Table 1). This represents a 21 percent reduction in uncompensated care spending.
- $5.0 billion of this reduction comes from the 28 Medicaid expansion states plus Washington DC, representing a 26% reduction in uncompensated care spending and 68% of total savings. $2.4 billion comes from the 22 Medicaid non-expansion states, representing a 16% reduction in uncompensated care spending and 32% of total savings.
- If non-expansion states had proportionately as large increases in Medicaid coverage as did expansion states, their uncompensated care costs would have declined by an additional $1.4 billion.

Table 1: Estimated Reduction in Hospital Uncompensated Care Costs in 2014 as a Result of Marketplace Coverage and Medicaid Expansion (Billions of $)

	Reduction in Uncompensated Care Costs	Reduction in Bad Debt	Reduction in Costs of Charity Care
All States	$7.4 (21%)	$1.9	$5.5
Expansion States	$5.0 (26%)	$1.1	$3.9
Non-expansion States	$2.4 (16%)	$0.8	$1.6

Source: ASPE projections from CMS Hospital Cost Report Data and Census Data from 2011 and 2012 as well as 2014 uninsured estimates from Gallup-Healthways and Medicaid enrollment from CMS. Expansion states are defined to include AR, AZ, CA, CO, CT, DE, DC, HI, IN, IL, IA, KY, MD, MA, MI, MN, NH,NV, NJ, NM, NY, ND, PA, OH, OR, RI, VT, WA, and WV. Non-expansion states are defined as all other states.
See http://aspe.hhs.gov/health/reports/2014/UncompensatedCare/ib_UncompensatedCare.pdf for a detailed description of the methods used in an earlier version of this analysis.

Exhibit A-38

ASPE
ISSUE BRIEF

IMPACT OF INSURANCE EXPANSION ON HOSPITAL UNCOMPENSATED CARE COSTS IN 2014

Thomas DeLeire, Karen Joynt, and Ruth McDonald

This report summarizes research on the effect of the major health insurance coverage expansion under the Affordable Care Act (ACA) on the drivers of uncompensated care (UCC) and on hospital UCC costs.

Key Takeaways:

✓ Early hospital financial reporting and member surveys from hospital associations indicate that, through second quarter 2014, payor mix is shifting in ways that will likely reduce hospital uncompensated care costs. In particular:

- ➢ Volumes of uninsured/self-pay admissions (which comprise a major portion of uncompensated care provided by hospitals) have fallen substantially, particularly in "Medicaid expansion" states (states that have elected to expand the Medicaid program through the Affordable Care Act);
- ➢ Volumes of uninsured/self-pay emergency department visits have fallen substantially, primarily in Medicaid expansion states; and
- ➢ The volume of hospital admissions for patients covered by Medicaid has increased, but only in Medicaid expansion states.

✓ Initial projections suggest that uncompensated care costs will fall substantially following major insurance coverage expansion, including coverage expansion through both Medicaid and the Health Insurance Marketplaces. Specifically:

- ➢ Based on an estimated 10.3 million decrease in the total number of uninsured and an estimated 8 million increase in the number covered by Medicaid, ASPE estimates that hospital uncompensated care costs will be $5.7 billion lower in 2014 than they otherwise

would have been. This represents a 16 percent reduction from baseline uncompensated care spending.

- The projections further suggest that $4.2 billion of this reduction will come from the 25 states plus Washington DC expanding Medicaid as of the beginning of FY2014, representing a 25 percent reduction from baseline uncompensated care spending and 74 percent of total savings. $1.5 billion will come from the 23 Medicaid non-expansion states, representing a 9 percent reduction from baseline uncompensated care spending and 26 percent of total savings. (note NH and PA have decided to expand Medicaid, but had not yet started enrolling individuals at the end of the second quarter of 2014, and therefore they are excluded from these analyses).

I. Introduction: Uncompensated Care Costs, Coverage Expansion, and Hospitals

This report summarizes research on the effect of the major health insurance coverage expansion under the Affordable Care Act (ACA) on the drivers of uncompensated care (UCC) and on hospital UCC costs.

Hospital UCC costs totaled between $46 and $51 billion in 2012, according to the American Hospital Association (AHA)[1] as well as data provided to the Center for Medicare and Medicaid Services (CMS) via Hospital Cost Reports.[2] The Urban Institute reports that each individual uninsured for the full year of 2013 received $1,005 in implicitly subsidized uncompensated care, and that these costs totaled $49 billion nationwide in 2013.[3]

Though specific definitions differ, UCC is generally considered to be the unreimbursed cost of the care provided by hospitals to people who are uninsured, underinsured,[4] or in some cases publicly insured. For the purposes of this report, we define hospital UCC costs as the combined total of bad debt and charity care.[5] Bad debt refers to an amount hospitals anticipated receiving for services but in fact never received. Charity care is the value of services rendered for which hospitals never anticipated receiving payment, because the patient's inability to pay was determined early in the course of care; both of these sources of UCC are in large part generated by medically indigent or uninsured patients, though unrealized co-pays or deductibles for insured patients are also included in this calculation.[6],[7],[8]

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[1] American Hospital Association, Uncompensated Care Cost Fact Sheet, January 2014. Available at http://www.aha.org/content/14/14uncompensatedcare.pdf

[2] ASPE calculations based on 2012 Hospital Cost Report Data. These calculations are described in Part 2 of this report as well as in Appendix B.

[3] Coughlin TA et al, *Uncompensated Care for the Uninsured in 2013: A Detailed Examination*. The Kaiser Commission on Medicaid and the Uninsured, May 2014. Available at http://kff.org/uninsured/report/uncompensated-care-for-the-uninsured-in-2013-a-detailed-examination/

[4] There is variation in how the term "underinsured" is used for the purposes of defining uncompensated care, and likely in how it UCC for these patients is reported on a hospital level. For example, it could include only people who have insurance that doesn't cover a certain service, or if could also include those whose insurance only covers a service partially (either because of copayment / deductible liability or because the payment rate is in adequate).

[5] Medicare collects bad debt, charity care, and governmental payment shortfalls on Worksheet S-10: FORM CMS-2552-10, available at http://www.costreportdata.com/instructions/Instr_S100.pdf. Using bad debt and charity care as the primary measures of UCC is an approach advocated by MedPAC and the AHA. See AHA reference above, as well as the MedPAC comment on the CMS FY2015 proposed inpatient prospective payment system rule, available at http://www.medpac.gov/documents/comment-letters/medpac-comment-on-cms's-acute-and-long-term-care-hospitals-proposed-rule.pdf?sfvrsn=0

[6] Additionally, the AHA makes a distinction between "self-pay" patients, i.e. those who have the means to pay for their care, and "charity care" patients, i.e. those who do not. However, this is not always specified in hospital reporting, particularly in the earnings calls discussed later in this report.

[7] Note that the definition of UCC we use is slightly broader than that used for Medicaid Disproportionate Share Hospital (DSH) purposes, which consider some forms of bad debt to be unallowable for these calculations.

[8] In some settings, including the ACA-strengthened mandatory reporting of community benefit to the Internal Revenue Service for non-profit hospitals, UCC also includes the payment shortfall from Medicaid, the Children's Health Insurance Program (CHIP), and state or local government indigent care programs. The mandatory reporting system is via Schedule H, which is an addendum to hospitals' annual 990 forms, and can be found here: http://www.irs.gov/pub/irs-pdf/f990sh.pdf. This payment shortfall may contribute significantly to hospitals'

Uncompensated care is largely federally funded: through Medicaid, Medicare, the Veterans Health Administration, the Indian Health Service, community health center funding, and Ryan White funding for people with HIV/AIDS, the federal government is estimated to pay for 62 percent of UCC.[9] The largest portion of these federal funds ($13.5 billion in 2013) flows through the Medicaid program in the form of Medicaid disproportionate share hospital (DSH) and upper payment limit (UPL) payments. Additionally, the Medicare program provides significant federal funding to providers for UCC through the Medicare DSH adjustments, payments for Medicare bad debt, and payments for indirect medical education (IME) ($8 billion in 2013).[10] Though neither Medicare DSH nor IME payments are direct payments for UCC, they provide additional funding to recognize the higher cost structure of Medicare services, and may be available to offset provider UCC costs.

Though hospitals are not the only providers of UCC, on a cost basis they provide the majority of such care; 60 percent of all UCC costs are incurred through hospitals, while the other 40 percent of costs are incurred through publicly-supported community providers and office-based physicians. The AHA estimates that 6.1% of hospitals' total expenses in 2012 were related to the provision of uncompensated care.[11]

Most analysts predicted that UCC would decline following the major ACA-driven coverage expansion in 2014 because an increase in the number of insured individuals would reduce the number who could not pay their hospital bills, as well as the need for charity care.[12] The extent of this reduction is an empirical question, however, as it depends on a number of factors, including the extent to which newly-insured individuals are able to meet the cost-sharing obligations imposed by their plans.

Because of this anticipated decline in UCC following coverage expansion, the ACA enacts reductions in the major existing streams of federal Medicaid and Medicare reimbursement that help to offset costs of uncompensated care. For example, federal Medicaid DSH payments, which totaled $11.4 billion in 2012,[13] are scheduled to be cut by just over 10%, or $1.2 billion, in FY2016 and by $17.6 billion in total by FY2020.[14] Base Medicare DSH payments are reduced to 25 percent of previous levels under the ACA, and the remaining amount is distributed based

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uncompensated costs in some settings. A recent study in the *New England Journal of Medicine* reported that non-profit hospitals spent 7.5% of their operating expenses on community benefit, of which 45% was due to public program shortfall, and 25% was for direct charity care provision. (Young et al, N Engl J Med 2013;368:1519-27)

[9] Coughlin et al. (2014).

[10] Coughlin et al. (2014).

[11] AHA, Uncompensated Care Cost Fact Sheet

[12] For example, see Graves JA, Medicaid Expansion Opt-Outs and Uncompensated Care. N Engl J Med 2012; 367:2365-2367; Price and Eibner, For States that Opt Out of Medicaid Expansion: 3.6 Million Fewer Insured and $8.4 Billion Less in Federal Payments. Health Aff (Millwood). 2013 Jun;32(6):1030-6; and Holahan, Buettgens, and Dorn, The Cost of Not Expanding Medicaid. The Kaiser Commission on Medicaid and the Uninsured, July 2013, available at http://kff.org/medicaid/report/the-cost-of-not-expanding-medicaid/.

[13] U.S. Department of Health and Human Services, FY2012 final DSH Allotments, released July 26, 2013. Available at http://www.gpo.gov/fdsys/pkg/FR-2013-07-26/pdf/2013-17965.pdf

[14] Bipartisan Budget Act of 2013 (H.J.Res.59). Available at https://beta.congress.gov/113/bills/hjres59eah3/BILLS-113hjres59eah3.pdf

on hospitals' share of the total amount of uncompensated care provided nationally;[15] these changes are estimated by the Congressional Budget Office to reduce Medicare DSH spending by $22.1 billion between 2010 and 2019.[16] Given the magnitude and timing of these cuts, as well as the uncertainty introduced by whether and how states plan to expand Medicaid, it is critical to determine how UCC is changing following coverage expansion so as to avoid shifting a large financial burden to states, localities, and hospitals.

While this brief focuses primarily on changes in uncompensated care, hospital finances will also be affected by changes in utilization related to the expansion of insurance coverage. Increased volumes from higher utilization will often strengthen hospitals' finances, although this need not be the case if providers agree to treat newly-insured patients with coverage that pays amounts that do not cover their marginal costs. Research examining prior insurance expansions can shed light on the changes in hospital utilization that might be expected. For example, evidence from Oregon's Medicaid expansion showed that Medicaid increased the likelihood of being admitted to the hospital from 6.7 percent to 8.8 percent, a 30 percent relative increase.[17] The Oregon expansion also suggested that Medicaid coverage increased use of emergency services by 40 percent, or 0.41 visits per person per year.[18] Research examining a different abrupt gain of insurance – namely, turning 65 and qualifying for Medicare – similarly suggests a relative increase in admissions of 12-20 percent for those who were previously uninsured, particularly for people with chronic conditions[19] and for admissions including elective procedures.[20]

However, the evidence is not entirely consistent; for example, a study of health care utilization after the creation of a new public insurance plan for low-income uninsured childless adults in Wisconsin found that in the first year of coverage, while outpatient visits increased 29 percent, and emergency department visits increased 46 percent, inpatient hospitalizations actually declined 59 percent as did preventable hospitalizations.[21] Additionally, work from Massachusetts showed that overall hospitalizations in Massachusetts were unchanged relative to other states after the implementation of insurance expansion and that preventable hospitalizations declined.[22] Further, emergency department visits declined to a small degree (6-8 percent), particularly for conditions which were likely treatable in less resource-intense settings.[23]

Given a rapidly changing health insurance landscape, it is clear that close ongoing attention to the impact of coverage expansion on hospital utilization, costs, and UCC at the national level is warranted. This report, which attempts to address these issues using the best available early

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[15] U.S. Department of Health and Human Services, August 2013, Federal Register, 78(160): 50496–51040. See in particular page 50505. Available at http://www.gpo.gov/fdsys/pkg/FR-2013-08-19/pdf/2013-18956.pdf

[16] CBO Director Doug Elmendorf, Letter To Rep. Nancy Pelosi, 3/18/10. See in particular Table 3. Available at http://www.politico.com/static/PPM110_100318_cbo_score.html

[17] Finkelstein et al, Q J Econ. 2012 Aug;127(3):1057-1106

[18] Taubman et al, Science. 2014 Jan 17;343(6168):263-8

[19] McWilliams et al, N Engl J Med. 2007 Jul 12;357(2):143-53

[20] Card et al, Am Econ Rev. 2008 Dec;98(5):2242-2258

[21] DeLeire et al, Health Aff (Millwood). 2013 Jun;32(6):1037-45

[22] Kolstad and Kowalski, J Public Econ. 2012 Dec 1;96(11-12):909-929

[23] Miller S, J Public Econ. 2012 Dec 1;96(11-12):893-908

evidence, is in two sections. The first section, "Changes in Hospital Uncompensated Care in 2014," summarizes evidence available to date on the changes in the drivers of UCC during the first six months of major coverage expansion under the ACA, and allows us to look at initial trends in UCC at a subset of U.S. hospitals. Information in this section is based on quarterly hospital earnings reports, as well as member surveys conducted by hospital associations. The second section, "Projecting the Change in Total Hospital Uncompensated Care Costs," uses estimates of the historical relationship between changes in insurance coverage and changes in UCC costs to project the decline in total U.S. hospital UCC costs as a result of increases in Medicaid coverage and reductions in the number of uninsured.

II. Changes in Hospital Uncompensated Care in 2014

While we know that the number of people without any source of health insurance coverage decreased and the number of people covered by Medicaid increased in the first two quarters of 2014, the impact of these changes on the utilization of hospital services and on hospitals' provision of UCC is as yet unknown. Therefore, the intent of this section is to provide an early picture of changes in Hospital UCC using available data. We first provide a background discussion of what we know about coverage expansion numbers thus far in 2014. We next use data from the financial reporting of five large, for-profit, hospital groups and from member surveys conducted by several hospital associations on how the recent ACA-driven coverage expansion has translated into changes in the volume and payor mix of admitted patients and patients seen in the emergency department in the first two quarters of 2014. Finally, we discuss how these changes likely translate into changes in UCC.

A. Insurance Coverage Expansion Under the Affordable Care Act

For over a decade prior to the ACA, the proportion of the American population that was uninsured had been growing steadily. According to estimates made by the U.S. Bureau of the Census, between 1999 and 2011, the percentage of Americans without any source of health insurance coverage increased from 14 percent to 16 percent (see Appendix A). In 2012, the last year for which Census estimates are available, almost 48 million Americans, or 15 percent, lacked health insurance coverage. This figure was slightly higher among states that have decided (as of the beginning of 2014) to not expand Medicaid (17 percent) than in states that have elected to expand Medicaid (14 percent). Lack of health insurance was more common among adults aged 18 to 64 than among Americans of all ages; in 2012 41 million adults aged 18 to 64, or 21 percent, lacked health insurance.

As a result of implementation of the major coverage provisions in the ACA, the rate of uninsured adults began to drop in the first six months of 2014. The decline was most pronounced in Medicaid expansion states. Data published in the *New England Journal of Medicine,* using the Gallup-Healthways Well-Being Index, suggested that the uninsured rate for Americans ages 18 to 64 fell 4.7 percentage points, from 21.0 percent in September 2013 to 16.3 percent by April 2014 (the end of open enrollment), and stayed stable through June 2014.[24] The study also showed that in Medicaid expansion states, the uninsured rate for those at or below 138 percent of the Department of Health and Human Services Poverty Guidelines declined 6 percent, while in Medicaid non-expansion states it declined by only 3.1 percent.[25] Similarly, the Urban Institute, using the Health Reform Monitoring Survey, reported that the uninsured rate across adults of all ages fell from 17.5 percent in Q1 2013 to 13.9 percent in Q2 2014 (14.8 percent to 10.1 percent in Medicaid expansion states, and 20.8 percent to 18.3 percent in Medicaid non-expansion states).[26]

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[24] Sommers BD et al., N Engl J Med. 2014 Aug 28;371(9):867-74

[25] Sommers 2014.

[26] Long SK et al, Taking Stock at Mid-Year: Health Insurance Coverage under the ACA as of June 2014. Urban Institute Health Policy Center, 2014. Available at http://hrms.urban.org/briefs/taking-stock-at-mid-year.html

Commensurately, Medicaid enrollment data strongly suggest that there has been a large increase in the percentage of adults covered by Medicaid in 2014. As of the end of July 2014, enrollment reports demonstrate 7,935,257 more people enrolled in Medicaid and CHIP than in the comparison baseline period of July to September, 2013. The increases in enrollment were overwhelmingly seen in Medicaid expansion states, with 6,888,391 more enrollees, versus 1,046,866 in non-expansion states.[27]

B. Early Data on Changes in Hospital Volume and Payor Mix: Quarter One and Quarter Two, 2014

The increase in insurance coverage was expected to decrease hospital UCC by decreasing the proportion of hospitals' clinical volume comprised of uninsured patients (although increased volumes of patients covered by Medicaid were expected to have a smaller impact on UCC as a result of lower payment rates). In this subsection, we will use data from the first available sources on volume and payor mix since insurance expansion to examine this issue: hospital earnings data and hospital association surveys. Hospital earnings data are from the Q1 and Q2 2014 earnings reports of five large for-profit hospital operators in the United States: Community Health Systems, Inc. (CHS), Hospital Corporation of America (HCA Holdings, Inc.), Tenet Healthcare Corporation, LifePoint Hospitals, Inc., and Universal Health Services, Inc. (UHS). The surveys come from three hospital associations that are located in Medicaid expansion states: the Arizona Healthcare and Hospital Association, the Colorado Hospital Association, and the Arkansas Hospital Association. The Colorado Hospital Association also released data from its DATABANK of financial and volume data from 465 hospitals across 30 states, 15 of which have expanded Medicaid. While the hospitals represented in these earnings reports and surveys are not necessarily representative of the totality of U.S. hospitals, examining them does allow an early look at the impact of the ACA coverage expansions on the provision of UCC.

Declining Uncompensated Care Volumes

Four of the five for-profit hospital groups – Community Health Systems,[28] HCA,[29] LifePoint,[30] and Tenet[31] – reported how their hospitals' volumes of uninsured and/or self-pay admissions (which we will collectively refer to as UCC) changed in Q1 2014 (relative to Q1 2013). The

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[27] Centers for Medicare and Medicaid Services, Medicaid and CHIP: July 2014 Monthly Applications, Eligibility Determinations and Enrollment Report. Available at http://medicaid.gov/AffordableCareAct/Medicaid-Moving-Forward-2014/Downloads/July-2014-Enrollment-Report.pdf

[28] Community Health Systems earnings presentation, 1st quarter 2014, and Community Health Systems' (CYH) CEO Wayne Smith on Q1 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2200033-community-health-systems-cyh-ceo-wayne-smith-on-q1-2014-results-earnings-call-transcript

[29] HCA Holdings' CEO Discusses Q1 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2174773-hca-holdings-ceo-discusses-q1-2014-results-earnings-call-transcript

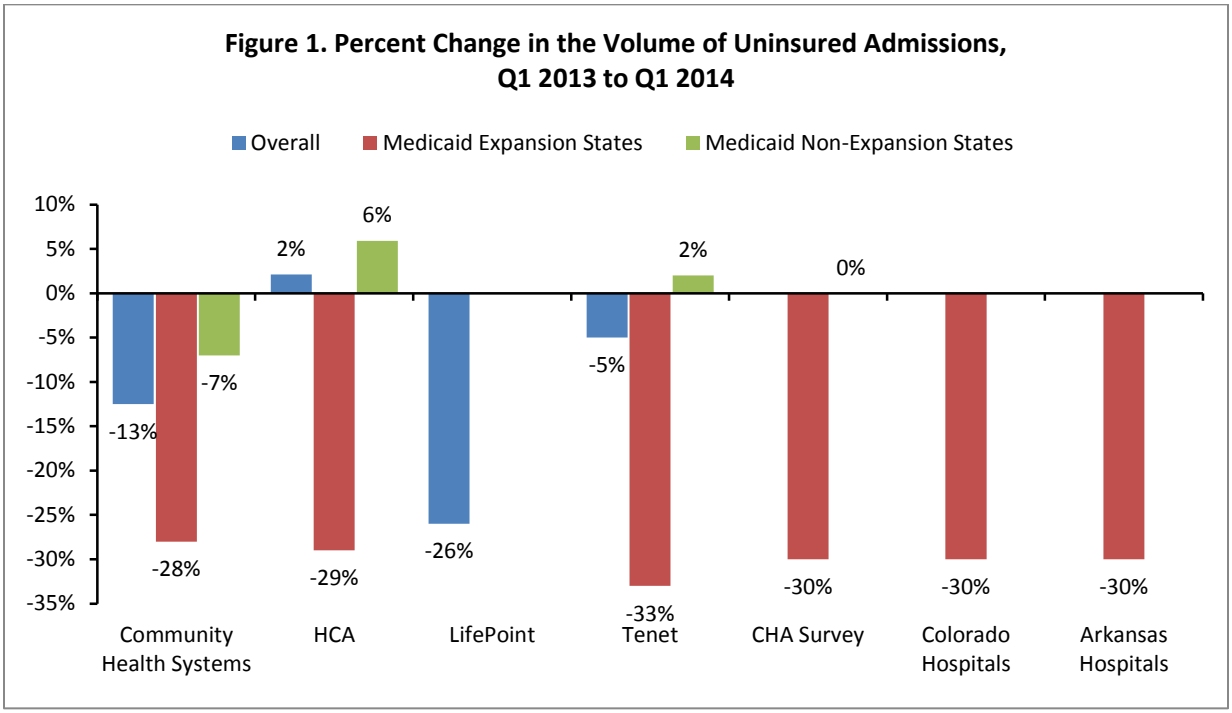
[30] LifePoint Hospitals' CEO Discusses Q1 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2166743-lifepoint-hospitals-ceo-discusses-q1-2014-results-earnings-call-transcript

[31] Tenet Q1 2014 report and Tenet Healthcare's (THC) CEO Trevor Fetter on Q1 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2194873-tenet-healthcares-thc-ceo-trevor-fetter-on-q1-2014-results-earnings-call-transcript

Colorado Hospital Association[32] and Arkansas Center for Health Improvement[33] also reported similar figures for their membership. Please note that the numbers reported here are relative changes, which allow us to compare trends across hospital chains and across states; the absolute proportion of care provided to the uninsured nationwide ranges from roughly 5-10 percent of total admissions.[34]

As shown in Figure 1, hospitals overall tended to see relative reductions in their numbers of admitted patients who were uninsured between Q1 2013 and Q1 2014. Moreover, hospitals in Medicaid expansion states saw substantial declines in their uninsured admissions, ranging from 28 to 33 percent relative reductions compared to one year prior. Hospitals in Medicaid non-expansion states, on the other hand, did not experience declines in their volumes of UCC admissions.

Figure 1. Percent Change in the Volume of Uninsured Admissions, Q1 2013 to Q1 2014



CHA=Colorado Hospital Association. HCA=Hospital Corporation of America.

Though fewer data are available for emergency department (ED) use, among those that reported these figures, hospitals overall saw 0 to 13 percent relative declines in ED visits by uninsured patients between Q1 2013 and Q1 2014. These changes were largely concentrated in Medicaid

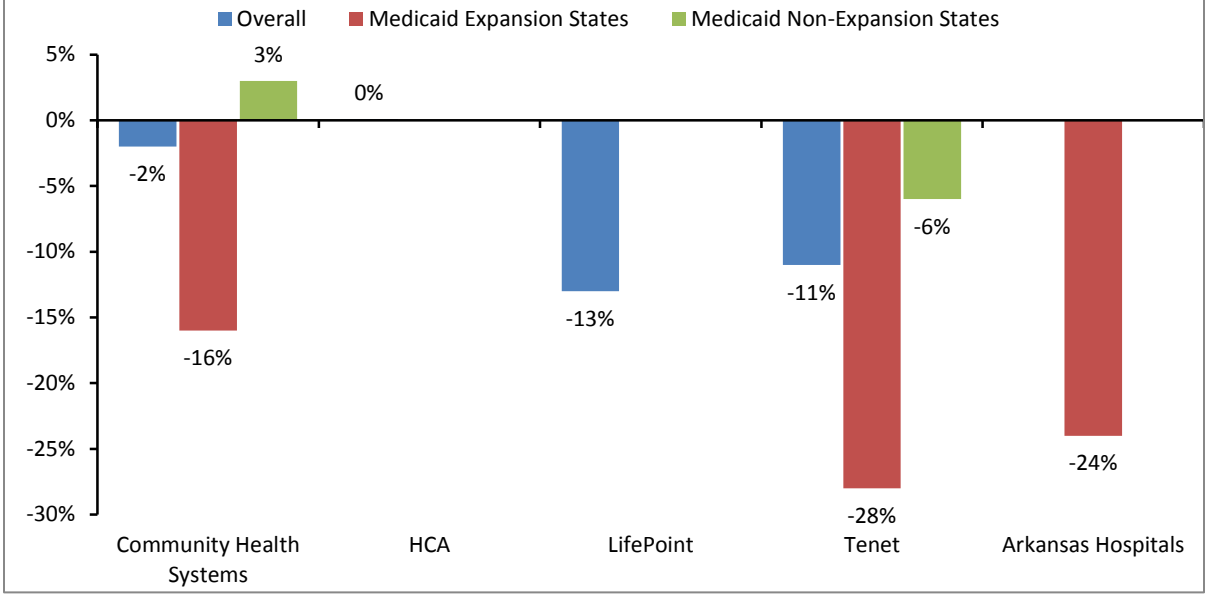
[32] Colorado Hospital Association Center for Health Information and Data Analytics, Impact of Medicaid Expansion on Hospital Volumes, June 2014. Available at http://www.cha.com/Documents/Press-Releases/CHA-Medicaid-Expansion-Study-June-2014.aspx

[33] Arkansas Center for Health Improvement, Arkansas Hospitals Show Reduction in Emergency Room Use and Uninsured Admissions Three Months Into Private Option, May 2014. Available at http://www.achi.net/pages/news/article.aspx?ID=33

[34] Hempstead K., Hospitals and Health Reform: What's at Stake? Robert Wood Johnson Foundation, August 2014. Available at http://www.rwjf.org/en/about-rwjf/newsroom/newsroom-content/2014/08/hamp-8-22.html

expansion states, ranging from 16 percent to 28 percent in these states (Figure 2), with small to no changes among hospitals in Medicaid non-expansion states.

Figure 2. Percent Change in the Volume of Uninsured ED Visits, Q1 2013 to Q1 2014



HCA=Hospital Corporation of America. NA=not applicable. NR=not reported.

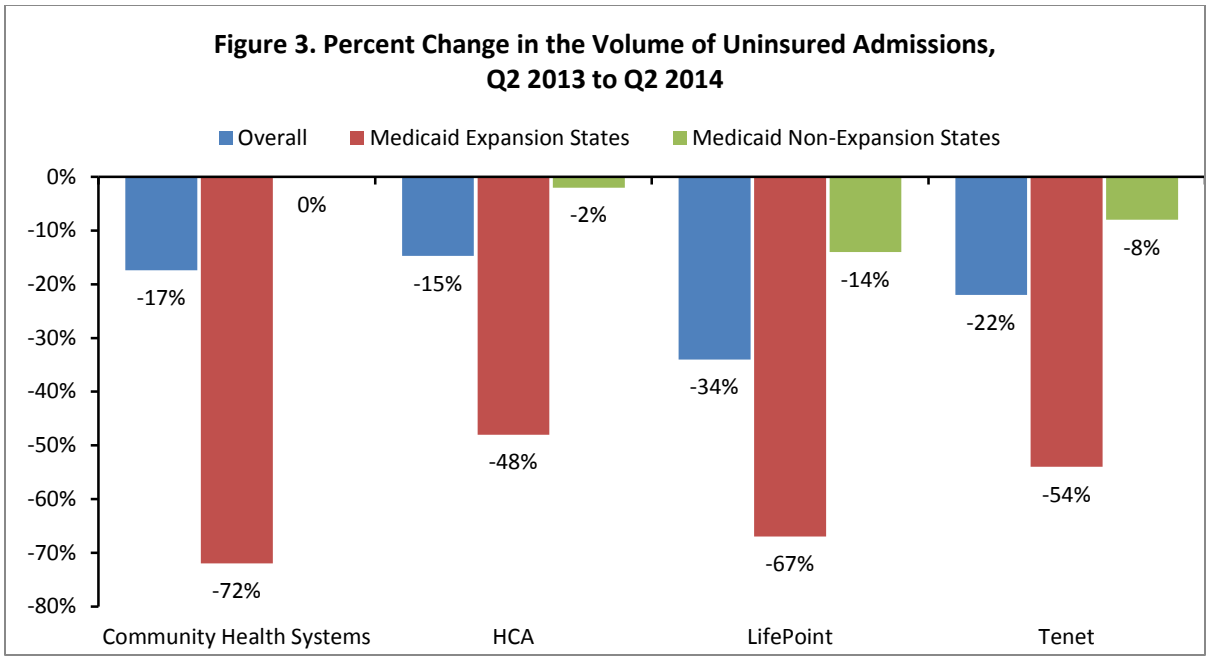
The declines in volumes of uninsured admissions were even greater between Q2 2013 and Q2 2014. Overall, hospitals saw relative declines in their volumes of uninsured admissions that ranged from 15 to 34 percent. Among hospitals in states that expanded Medicaid, the number of uninsured patients admitted declined between 48 percent and 72 percent between Q2 2013 and Q2 2014 (Figure 3). By contrast, in states that did not expand Medicaid, the decrease in volume of uninsured patients admitted to hospitals ranged between 0 and 14 percent.[35] [36] [37] [38]

[35] Community Health Systems earnings presentation, 2nd quarter 2014, and Community Health Systems' (CYH) CEO Wayne Smith on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2372765-community-health-systems-cyh-ceo-wayne-smith-on-q2-2014-results-earnings-call-transcript

[36] HCA Holdings' (HCA) CEO Milton Johnson on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2353325-hca-holdings-hca-ceo-milton-johnson-on-q2-2014-results-earnings-call-transcript

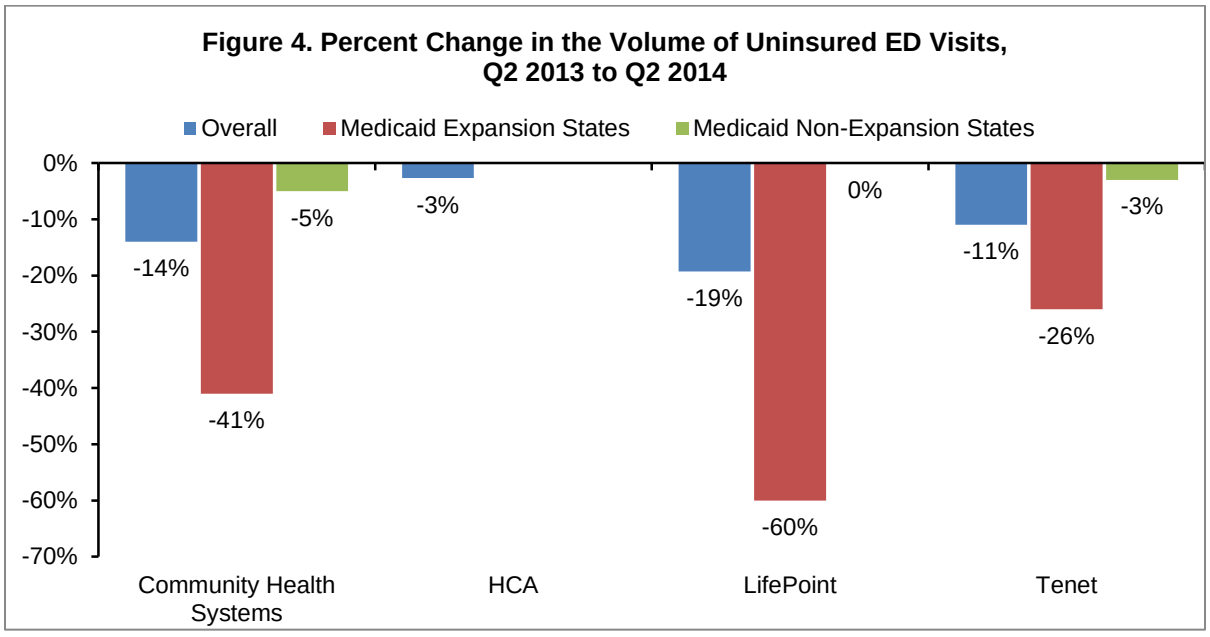
[37] LifePoint Hospitals' (LPNT) CEO Bill Carpenter on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2343785-lifepoint-hospitals-lpnt-ceo-bill-carpenter-on-q2-2014-results-earnings-call-transcript

[38] Tenet Q2 2014 report and Tenet's (THC) CEO Trevor Fetter on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2384715-tenets-thc-ceo-trevor-fetter-on-q2-2014-results-earnings-call-transcript



HCA=Hospital Corporation of America.

Again, though less evidence is available, relative reductions in UCC in the ED appeared to continue to grow when comparing Q2 2013 and Q2 2014, ranging from 26 percent to 60 percent in Medicaid expansion states (Figure 4).



HCA=Hospital Corporation of America.

It is also important to note that the decreases in the volume of uninsured patients that we report above are being seen in both urban and rural hospitals. The two non-urban hospital operators

observed, Community Health Systems[39] and LifePoint,[40] saw a decrease of roughly 70 percent in uninsured admissions in Q2 2004, and a significant drop in uninsured ED volume; the two more urban hospital providers, HCA[41] and Tenet,[42] saw an average decrease of around 50 percent. Arkansas, a primarily rural state, saw the volume of uninsured patients in inpatient and ED settings decline up to 30 percent[43] – on par with other states and hospitals with more urban geography.

Overall, there is thus strong evidence that the volume of uninsured patients is dropping in both the inpatient and ED settings and across a variety of geographical areas, indicating a likely drop in hospital UCC costs.

Increasing Overall Patient Volumes

Despite the observed reductions in the volume of uninsured patients, hospitals have experienced positive trends in their overall volumes of admissions compared to prior years.[44] [45] [46] [47] The same-quarter to same-quarter comparisons have improved each of the last three quarters, which is in contrast to prior trends in hospital admission volumes. For example, comparing Q4 2012 to Q4 2013, total hospital admissions declined from 1.8 percent to 10.5 percent across four large for-profit hospital groups. However, when comparing Q1 2013 to Q1 2014, declines were smaller (Figure 5), and when comparing Q2 2013 to Q2 2014, two of the four chains moved into positive comparisons in admission volumes.

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[39] Community Health Systems earnings presentation, 2nd quarter 2014, and Community Health Systems' (CYH) CEO Wayne Smith on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2372765-community-health-systems-cyh-ceo-wayne-smith-on-q2-2014-results-earnings-call-transcript

[40] LifePoint Hospitals' (LPNT) CEO Bill Carpenter on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2343785-lifepoint-hospitals-lpnt-ceo-bill-carpenter-on-q2-2014-results-earnings-call-transcript

[41] HCA Holdings' (HCA) CEO Milton Johnson on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2353325-hca-holdings-hca-ceo-milton-johnson-on-q2-2014-results-earnings-call-transcript

[42] Tenet Q2 2014 report and Tenet's (THC) CEO Trevor Fetter on Q2 2014 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2384715-tenets-thc-ceo-trevor-fetter-on-q2-2014-results-earnings-call-transcript

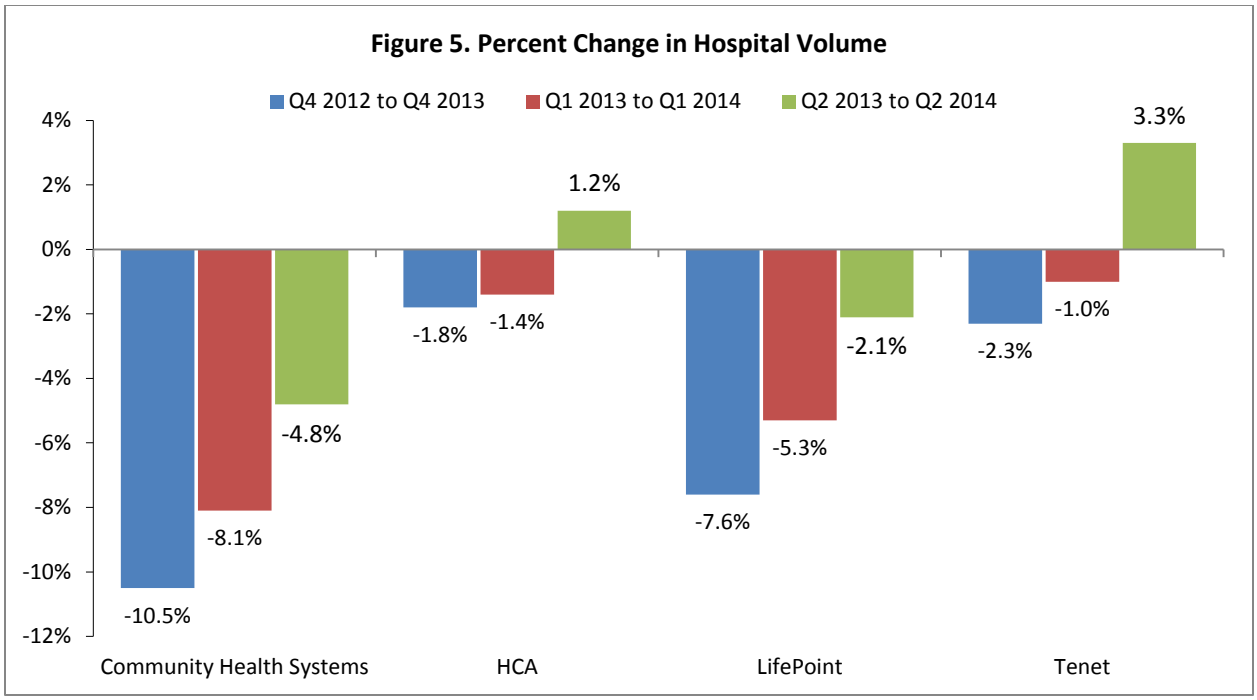
[43] Arkansas Center for Health Improvement, Arkansas Hospitals Show Reduction in Emergency Room Use and Uninsured Admissions Three Months Into Private Option, May 2014. Available at http://www.achi.net/pages/news/article.aspx?ID=33

[44] Community Health Systems Management Discusses Q4 2013 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2032761-community-health-systems-management-discusses-q4-2013-results-earnings-call-transcript

[45] HCA Holdings Management Discusses Q4 2013 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/1992601-hca-holdings-management-discusses-q4-2013-results-earnings-call-transcript

[46] LifePoint Hospitals' CEO Discusses Q4 2013 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2023301-lifepoint-hospitals-ceo-discusses-q4-2013-results-earnings-call-transcript

[47] Tenet Healthcare Management Discusses Q4 2013 Results - Earnings Call Transcript. Available at http://seekingalpha.com/article/2047653-tenet-healthcare-management-discusses-q4-2013-results-earnings-call-transcript



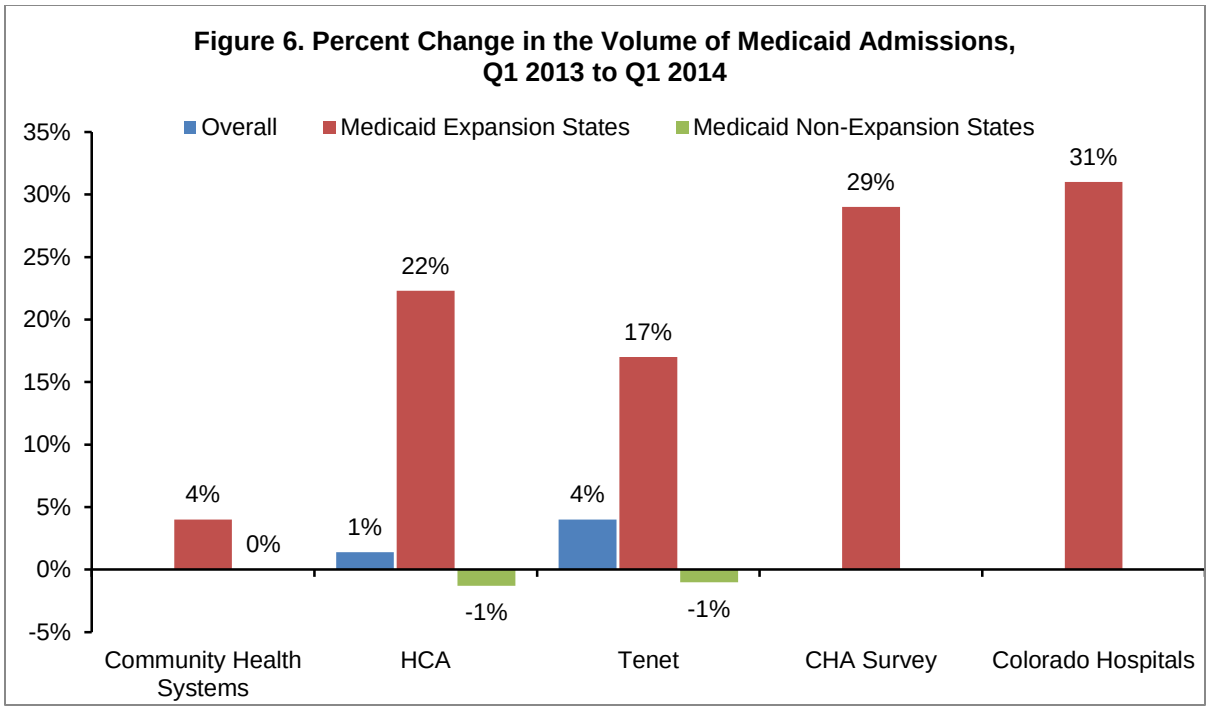
HCA=Hospital Corporation of America

Increases in the Volume of Medicaid Admissions

One group that seems to be driving these volume increases is those patients who are newly insured by Medicaid. Initial data from hospitals and hospital associations suggest that the volume of admissions represented by patients covered by Medicaid has increased, but only in Medicaid expansion states. Between Q1 2013 and Q1 2014, hospitals in Medicaid expansion states experienced relative increases in their volume of Medicaid patients that ranged between 4 percent and 31 percent, while there is no evidence that Medicaid admissions increased among hospitals in Medicaid non-expansion states (Figure 6).[48] Please note that the proportion of admitted patients who are insured by Medicaid at baseline ranges significantly across these hospital chains, but Medicaid patients comprise up to 21 percent of total hospital admissions nationwide.[49]

[48] Community Health Systems Presentation and Earnings Call Transcript Q1 2014, HCA Earnings Call Transcript Q1 2014, Tenet Presentation and Earnings Call Transcript Q1 2014, Colorado Hospital Association 2014

[49] Pfuntner A et al., Costs for Hospital Stays in the United States, 2010. HCUP Statistical Brief #146, Agency for Healthcare Research and Quality, January 2013. Available at http://www.hcup-us.ahrq.gov/reports/statbriefs/sb146.pdf

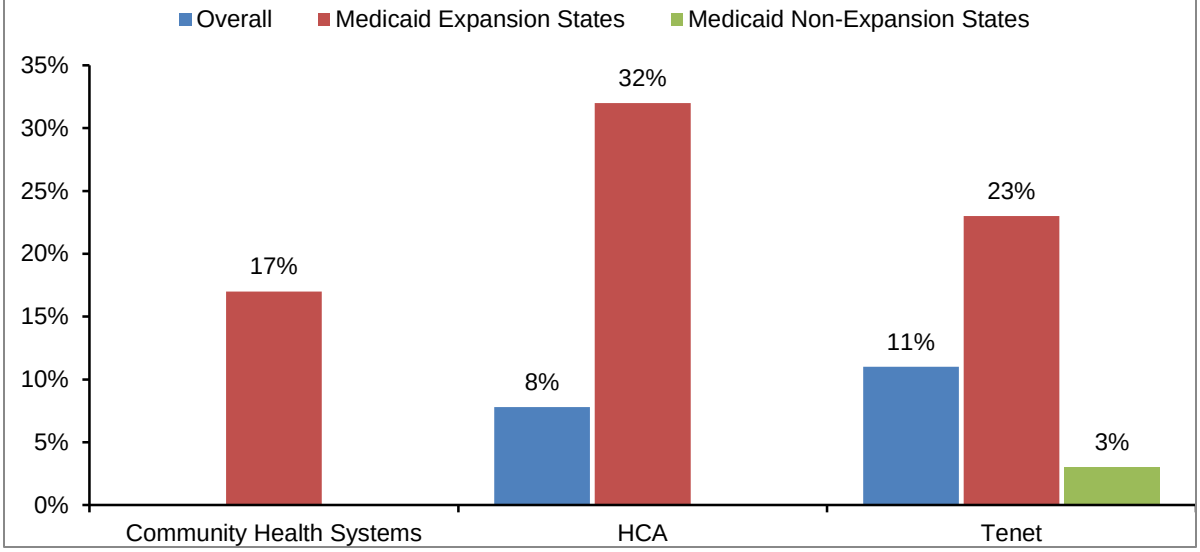


CHA=Colorado Hospital Association; HCA=Hospital Corporation of America.

Growth has continued in the second quarter. Comparing Q2 2013 and Q2 2014, it appears that hospitals in states that expanded Medicaid experienced further relative increases in their volumes of Medicaid admissions that ranged between 17 percent and 32 percent, with again no evidence of increases among hospitals in non-expansion states (Figure 7).[50] These large percent increases in the volumes of Medicaid admissions are most likely the result of a shift in admissions of uninsured patients to admissions of patients covered by Medicaid, although some of the increase in Medicaid admissions could be the result of pent-up demand among the formerly uninsured.

[50] Community Health Systems Presentation and Earnings Call Transcript Q1 2014, HCA Earnings Call Transcript Q1 2014, Tenet Presentation and Earnings Call Transcript Q1 2014

Figure 7. Percent Change in the Volume of Medicaid Admissions, Q2 2013 to Q2 2014



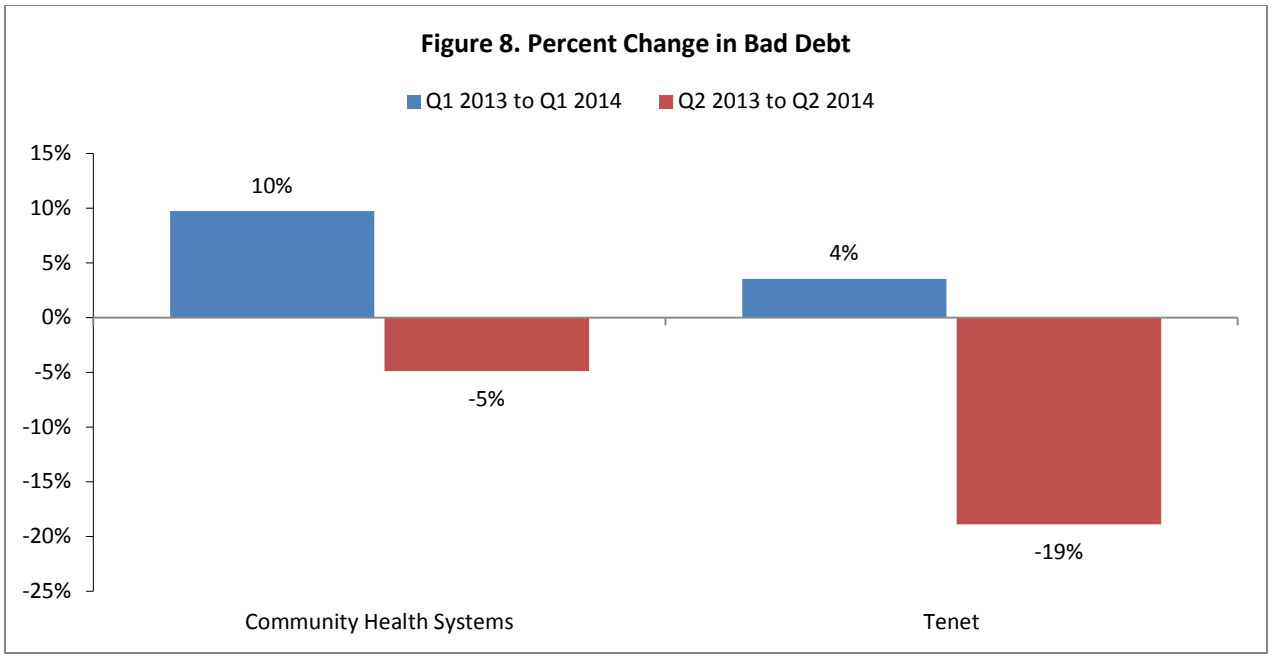
HCA=Hospital Corporation of America.

Evidence suggests that Medicaid admissions are increasing outside these health systems as well, and that the expansions are in both urban and rural areas. For example, in Kentucky, 46 percent of urban hospitals and 36 percent of rural hospitals are receiving more in Medicaid reimbursements than they did a year ago, according to the state's Cabinet for Health and Family Services, which administers Kentucky Medicaid.[51]

Changes in UCC and Bad Debt Costs

Very little direct evidence on changes in UCC and bad debt costs as a result of insurance expansion is available to date, as bad debt is not always split out in the surveys and earnings reports, and formal 2013 Cost Report filings (which do require separate reporting of bad debt) are not yet available. However, two of the large hospital groups – Community Health Systems and Tenet – did report on their changes in bad debt in the first two quarters of 2014. When comparing Q1 2013 and Q1 2014, bad debt was higher in 2014 in these two hospital groups, with the increase ranging from 4 to 10 percent. In contrast, these groups experienced large declines in bad debt when comparing Q2 2013 and Q2 2014 that range from 5 to 19 percent (Figure 8).

[51] Kentucky Cabinet for Health and Family Services, Preliminary Data Regarding Medicaid Expansion, Enrollment, and Reimbursement in Kentucky. July 14, 2014. Available at http://www.new-kyha.com/Portals/5/NewsDocs/MedicaidExpansionReport.pdf.



Additionally, reports from the Arizona Hospital and Healthcare Association[52] suggest a 31 percent drop in total UCC costs between Q1 2013 and Q1 2014, though again this is not split out into charity care versus bad debt. Similarly, Colorado's urban hospitals reported providing $3.6 million less in UCC in Q1 2014 than in Q1 2013, while its rural hospitals also experienced a drop in UCC during Q1 2014.[53]

Finally, though in this brief we focus on hospital uncompensated care, there is also evidence from other sources that uncompensated care in the outpatient setting may be decreasing as well. A recent report from the Robert Wood Johnson Foundation and athenaResearch suggested that the proportion of outpatient visits accounted for by uninsured patients has decreased, particularly in Medicaid expansion states, while the proportion accounted for by Medicaid patients has increased.[54] Further study is necessary to understand the consequences and stability of these trends in the outpatient setting.

Summary and Implications

Based on the available data, hospitals in Medicaid expansion states have seen substantial declines in their admission volumes of uninsured patients, declines in their volumes of uninsured patients visiting the ED, and increases in admissions that are covered by Medicaid. Hospitals in non-expansion states, by contrast, report relatively little change in these volumes.

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[52] Jim Haynes, Arizona Hospital and Healthcare Association, Memorandum June 13, 2014

[53] Colorado Hospital Association Center for Health Information and Data Analytics, Impact of Medicaid Expansion on Hospital Volumes, June 2014. Available at http://www.cha.com/Documents/Press-Releases/CHA-Medicaid-Expansion-Study-June-2014.aspx

[54] Sung I and Gray J, ACA View: First Observations Around the Affordable Care Act. Robert Wood Johnson Foundation and athenaResearch, 2014. See in particular page 8, Figure 8. Available at http://www.athenahealth.com/_doc/pdf/ACAView_Final_Comprehensive_Report.pdf

Thus, UCC costs are likely declining among hospitals, particularly among hospitals in Medicaid-expansion states. This has important implications for future financial performance in the hospital industry, as well as for hospitals' ability to remain clinically excellent and financially solvent in the setting of impending decreases in federal reimbursement for uncompensated care in coming years, as well as implications for state and federal governments.

III. Projecting the Change in Total Hospital Uncompensated Care Costs

In this section, we use existing data from Hospital Cost Reports to project how much lower hospital UCC costs likely will be in 2014 nationally compared to what they would have been without the coverage expansion, based on assumptions about the reduction in uninsured individuals and the growth in Medicaid coverage. It is necessary to project UCC because the Cost Reports are submitted to CMS with a substantial lag: though some hospitals have submitted reports for 2013, the latest comprehensive set of filings available are for fiscal year 2012. As a result, data reported via Hospital Cost Reports will not be available to directly measure any changes in UCC following the 2014 coverage expansion for at least one to two years.

A. Methods

We used data as reported in Hospital Cost Reports for 2011 and 2012 for our analysis. These reports are submitted to CMS annually by all acute-care and critical access hospitals (CAHs). Data on UCC are reported in Worksheet S-10 of Form CMS-2552-10, which was first used beginning in May 2010.[55] We defined UCC as the sum of two reported items: (1) the cost of charity care provided to uninsured patients (line 23 column 1); and (2) the cost of non-Medicare bad-debt expense (line 29).[56]

Table 1 reports the sum of UCC over all reporting hospitals as well as its two components (charity care and bad debt) for the years 2011 and 2012 for the 25 states plus Washington DC that have expanded Medicaid and initiated enrollment as of July 2014, the 2 states that have expanded Medicaid and are now initiating enrollment (PA and NH), and the 23 non-expansion states (note that PA and NH are listed separately because, though they are expanding Medicaid, their enrollment will begin during or after the time period covered in our savings projections; CMS similarly separates out these two states on their most recent Medicaid enrollment report).[57] Also note that hospital UCC in expansion states was slightly higher than in non-expansion states in 2011 and 2012:

[55] Please note: the Department has raised concerns regarding the accuracy of the information reported on Worksheet S-10, including that it is not yet subject to audit. These concerns have led the agency not to rely on these data for the purposes of making Medicare uncompensated care payments under section 3133 of the Affordable Care Act. We use them for the purposes of this analysis acknowledging these limitations.

[56] As outlined in FORM CMS-2552-10, available at http://www.costreportdata.com/instructions/Instr_S100.pdf

[57] Centers for Medicare and Medicaid Services, Medicaid and CHIP: July 2014 Monthly Applications, Eligibility Determinations and Enrollment Report. Available at http://medicaid.gov/AffordableCareAct/Medicaid-Moving-Forward-2014/Downloads/July-2014-Enrollment-Report.pdf

Table 1: Amounts and Sources of Hospital Uncompensated Care as Reported in CMS Hospital Cost Reports, 2011-2012 (billions of current $)

	Uncompensated Care (Total)	Non-Medicare Bad Debt	Charity Care to Uninsured Patients
2011			
All States	34.1	14.7	19.4
Medicaid Expansion States	18.2	7.1	11.0
States Implementing Medicaid Expansion after Q2 2014 (NH and PA)*	0.8	0.5	0.3
Non-expansion States	15.0	7.0	8.0
2012			
All States	34.7	15.2	19.5
Medicaid Expansion States	17.6	6.8	10.8
States Implementing Medicaid Expansion after Q2 2014 (NH and PA)*	0.9	0.5	0.3
Non-expansion States	16.3	7.9	8.4

Source: ASPE calculations from CMS Hospital Cost Reports available publicly from CMS.gov. Figures are summed over all reporting hospitals. Expansion states are defined to include AR, AZ, CA, CO, CT, DE, DC, HI, IL, IA, KY, MD, MA, MI, MN, NV, NJ, NM, NY, ND, OH, OR, RI, VT, WA, and WV. Non-expansion states are defined as all other states, with the exception of NH and PA (see next).

*: Note that NH and PA are implementing the Medicaid expansion, but were not included among actively enrolling states for this analysis because enrollment in these states is scheduled to begin either in mid-2014 or at the beginning of 2015, and thus coverage gains would not be expected to fully accrue during the time frame included in our projection (FY 2014). These states were therefore excluded from the analyses.

The numbers of individuals who were uninsured and who were covered by Medicaid in each state and in each year in 2011 and 2012 were obtained from estimates made by the U.S. Bureau of the Census.[58] These estimates are based on survey data from the Current Population Survey's Annual Social and Economic Supplement. These numbers were used to model the association between numbers of uninsured and Medicaid-covered individuals in each state and the amount of UCC provided in 2011 and 2012 (see Appendix B for detailed methodology and model outputs).

We then used this model to project 2014 UCC by using projected numbers of individuals who are uninsured and covered by Medicaid at the state-level. The most recent estimate of the reduction in uninsured was published in the *New England Journal of Medicine*, using ASPE analyses based on the Gallup-Healthways WBI poll, and suggests that 10.3 million fewer people were uninsured as of June 2014.[59] Based on Medicaid enrollment reports,[60] we assumed that the

[58] United States Census Bureau, online Health Insurance data. Available at http://www.census.gov/hhes/www/hlthins/.
[59] Sommers 2014

number of individuals covered by Medicaid would be 7.9 million higher than it otherwise would have been as a result of coverage expansion, of which 6.9 million is in expansion states, and 1.0 million in non-expansion states. We also estimated that roughly two-thirds of the decline in the number of uninsured persons (which is composed of both new enrollment in Medicaid and new enrollment in private insurance programs, through the Marketplace or through employers) would come from states that expanded Medicaid.

There are limitations to these projections; for example, if consumers cannot pay the cost-sharing amounts required under their coverage, it is possible that hospitals will still be left with a degree of uncompensated care for these individuals. The mix of rates and plans offered and selected in any given state will impact hospital reimbursement; our models reflect overall patterns. Additionally, there is concern that the Cost Report data, because it is self-reported by hospitals, may not be of high enough fidelity to use in estimating hospital UCC. For this reason, Medicare has continued to use each hospital's number of Medicaid days and Medicare Supplemental Security Income days as their proxy for uncompensated care rather than the Cost Report information. However, MedPAC and others have recommended that the Cost Report data be used because they believe it provides a better estimate of uncompensated care.[61] We chose to use Cost Report data because it allows us to examine multiple components of uncompensated care, but we recognize the limitations inherent in hospital-reported data.

B. Projected Reduction in Uncompensated Care Costs in 2014 as a Result of Increased Rates of Medicaid Coverage and Decreased Rates of Uninsurance

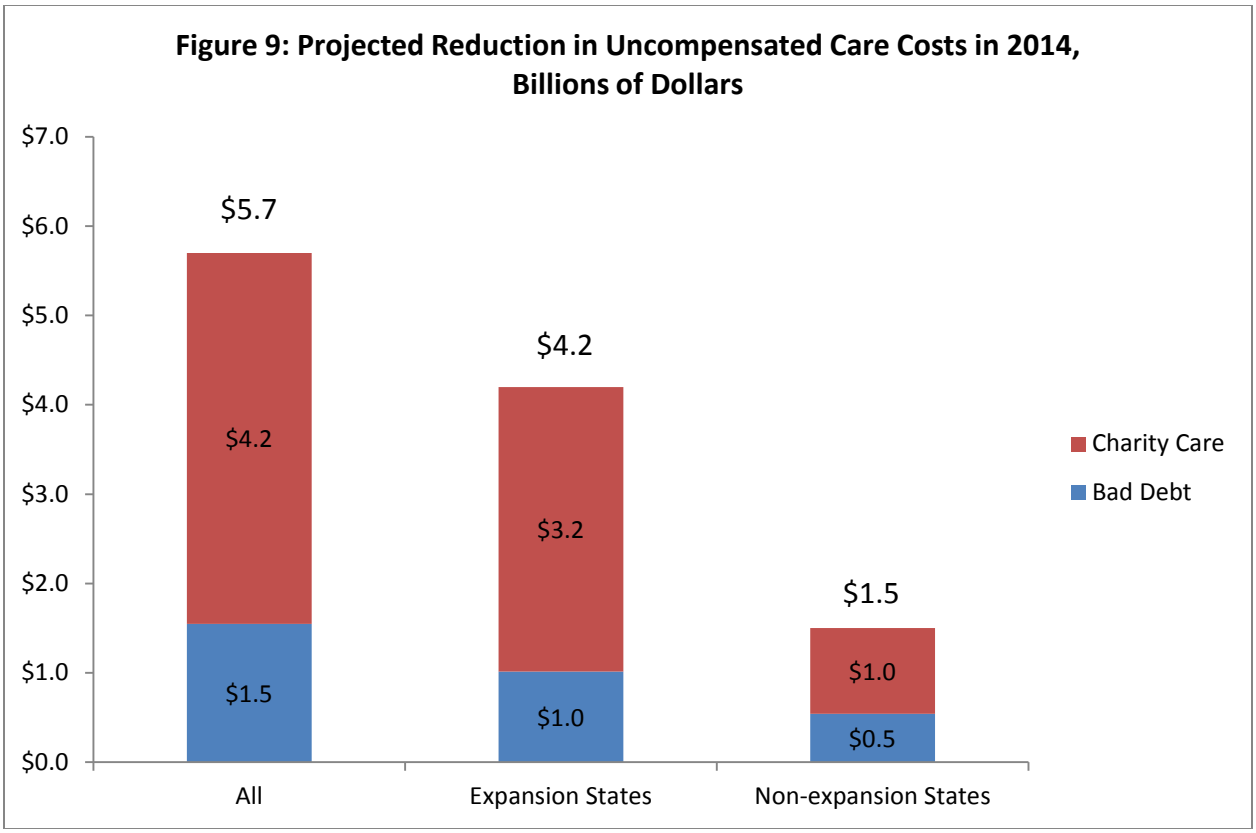
Based on the model outlined above, we found that, in 2011-2012, a one-million person increase in the number of individuals covered by Medicaid in a state was associated with a $0.292 billion decrease in hospital UCC in that state. Similarly, a one-million person increase in the number of uninsured in a state was associated with a $0.344 billion increase in hospital UCC in that state.

Therefore, a 7.9 million person increase in the number of uninsured individuals covered by Medicaid and an 10.3 million person decrease in the number of individuals who are uninsured overall, as we see in 2014 thus far, should lead to a net $5.7 billion reduction in hospital UCC costs in FY 2014 relative to what these costs would have been in the absence of coverage expansion, or a 16 percent reduction overall.

Most of this projected reduction ($4.2 billion of the $5.7 billion) is projected to come from reductions in charity care, with the remainder coming from reductions in bad debt. $4.2 billion of the reduction in UCC is projected to accrue in Medicaid expansion states, and $1.5 billion in Medicaid non-expansion states (Figure 9).

[60] Centers for Medicare and Medicaid Services, Medicaid and CHIP: July 2014 Monthly Applications, Eligibility Determinations and Enrollment Report. Available at http://medicaid.gov/AffordableCareAct/Medicaid-Moving-Forward-2014/Downloads/July-2014-Enrollment-Report.pdf

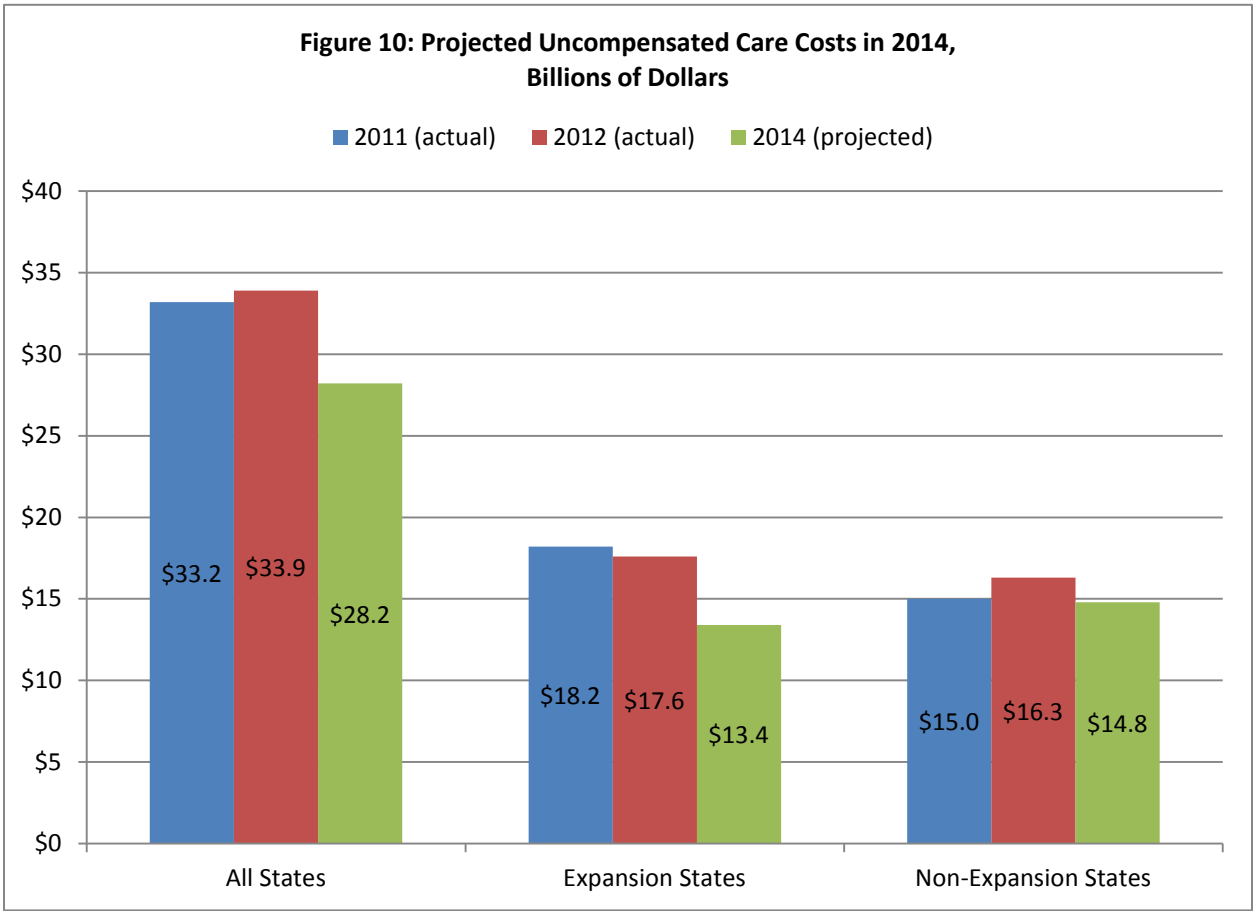
[61] AHA, Uncompensated Care Cost Fact Sheet and http://www.medpac.gov/documents/comment-letters/medpac-comment-on-cms's-acute-and-long-term-care-hospitals-proposed-rule.pdf?sfvrsn=0



Reassuringly, this estimated reduction is similar to the reduction that would be obtained by multiplying estimates of per capita uncompensated care costs in the literature by the total change in insurance coverage. For example, Coughlin et al.[62] estimate that each full-year uninsured person incurred $1,005 in implicitly subsidized uninsured costs (the concept of uncompensated care most closely comparable to the estimate in this brief) in 2013. If 60 percent of that care is hospital-based, then a 10.3 million person reduction in the uninsured might be expected to lead to a 10.3 million * $1,005 * 60 percent, or $6.2 billion reduction in hospital uncompensated care costs, very similar to the $5.7 billion estimate arrived at above.

Applying our estimated reductions from the model, and assuming an otherwise stable level of anticipated spending in 2014 of $33.2 billion, we calculate that hospital UCC in 2014 under insurance expansion would therefore project to around $28 billion overall. We project that $13 billion of spending on UCC at hospitals would take place in Medicaid expansion states and $15 billion in Medicaid non-expansion states (Figure 10).

[62] Coughlin et al, 2014



In sum, we find that insurance expansion under the ACA, via both Medicaid and Marketplace insurance expansion, can be anticipated to be associated with a sizeable reduction in hospital UCC costs. Though baseline UCC spending was similar between expansion and non-expansion states, projected UCC costs drop significantly more in expansion states under this projection. Hospitals in expansion states are projected to save $4.2 billion, which represents about 25 percent of these states' baseline spending or 74 percent of the total savings nationally. Hospitals in non-expansion states are projected to save $1.5 billion, representing 9 percent of these states' baseline spending, or 26 percent of the total savings nationally.

Summary

Early hospital financial reporting and member surveys from hospital associations indicate that payor mix is shifting and uncompensated care is declining through second quarter 2014. Volumes of uninsured/self-pay admissions and ED visits (which are major drivers of uncompensated care) have fallen substantially, but particularly in Medicaid expansion states. Overall volumes of admissions from patients covered by Medicaid have increased, but predominantly in Medicaid expansion states. Projections suggest that UCC costs will be substantially lower in 2014 as a result of coverage expansion than they otherwise would have

been: projections estimate a $5.7 billion reduction in hospital UCC costs in 2014 (16 percent of baseline uncompensated care spending). In Medicaid expansion states, hospitals are projected to experience reductions of $4.2 billion, representing 25 percent of these states' baseline spending or 74 percent of the total savings nationally. In Medicaid non-expansion states, hospitals are projected to experience reductions of $1.5 billion, representing 9 percent of these states' baseline spending, or 26 percent of the total savings nationally. This has important implications for hospitals' future financial performance as public and private insurance continue to expand and as levels of federal reimbursement for UCC are reduced through cuts in DSH payments.

APPENDICES:

Appendix A: Individuals Uninsured and Covered by Medicaid, by Year (all ages, millions of individuals)

	Uninsured						Medicaid					
	All States		Non-Expansion States		Expansion States		All States		Non-Expansion States		Expansion States	
Year	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
1999	37,702	14%	19,230	13%	18,471	14%	27,353	10%	13,389	9%	13,964	11%
2000	36,586	13%	18,880	13%	17,706	13%	28,062	10%	13,721	9%	14,341	11%
2001	38,023	13%	19,936	13%	18,087	14%	30,166	11%	15,260	10%	14,906	11%
2002	39,776	14%	21,264	14%	18,512	14%	31,934	11%	16,054	11%	15,880	12%
2003	41,949	15%	22,229	15%	19,719	14%	34,326	12%	17,406	11%	16,920	12%
2004	41,752	14%	22,707	15%	19,045	14%	38,055	13%	19,170	12%	18,885	14%
2005	43,035	15%	23,354	15%	19,681	14%	38,191	13%	19,514	13%	18,677	14%
2006	45,214	15%	24,587	16%	20,627	15%	38,370	13%	19,061	12%	19,309	14%
2007	44,088	15%	24,691	16%	19,397	14%	39,685	13%	19,639	12%	20,046	14%
2008	44,780	15%	24,684	15%	20,097	14%	42,831	14%	21,455	13%	21,376	15%
2009	48,985	16%	27,503	17%	21,482	15%	47,847	16%	23,702	15%	24,145	17%
2010	49,951	16%	27,816	17%	22,134	15%	48,533	16%	24,300	15%	24,233	17%
2011	48,613	16%	27,172	16%	21,442	15%	50,835	16%	25,438	15%	25,397	18%
2012	47,951	15%	27,474	17%	20,476	14%	50,903	16%	25,012	15%	25,891	18%

Source: U.S. Census Bureau

Appendix B: Projected Effects of Increased Medicaid Coverage and Decreases in Uninsurance on Hospital Uncompensated Care: Detailed Methods

APSE conducted a statistical analysis to assess, at the state level, the association between the amount of uncompensated care (UCC) provided by hospitals in a state in a year and the number of individuals covered by Medicaid and the number of individuals who are uninsured. It then used the results of this analysis along with state-level projections of the numbers of uninsured and Medicaid-covered individuals to project how much lower UCC would be.

Hospital UCC in 2011 and 2012 was calculated from Hospital Cost Reports, as described in the main body of this report. These data were then aggregated to the state level in each year for use in the state-level analysis.

The numbers of individuals who were uninsured and who were covered by Medicaid in each state and in each year were obtained from estimates made by the U.S. Bureau of the Census.[63] These estimates are based on survey data from the Current Population Survey.

To assess the association between UCC and the numbers of uninsured and Medicaid-covered individuals, we used the following panel-data model:

$$UCC_{s,t} = \beta + \gamma Medicaid_{s,t} + \delta Uninsured_{s,t} + \phi_s + \theta_t + \varepsilon_{s,t}$$

where:

$UCC_{s,t}$ is the dollar amount of UCC provided by hospitals in state *s* and in year *t* (in billions of current dollars);

$Medicaid_{s,t}$ is the number of individuals covered by the Medicaid program in state *s* and in year *t* (in millions);

$Uninsured_{s,t}$ is the number of individuals who were uninsured for the entire year in state s and in year t (in millions);

ϕ_s is a set of state fixed effects; and

θ_t is a set of year fixed effects.

The use of panel data and the inclusion of a set of state and year fixed effects is preferred over a simpler model assessing the cross-sectional association between UCC, Medicaid, and Uninsured because the latter model is more likely to be affected by omitted variable bias.

The results of this statistical model are reported in the Table below. The results indicate that a one-million increase in the number of people uninsured in a state is associated with a $0.344 billion increase in hospital UCC in that state. Similarly, a one-million increase in the number of

[63] United States Census Bureau, online Health Insurance data. Available at http://www.census.gov/hhes/www/hlthins/

people covered by Medicaid in a state is associated with a $0.292 billion decrease in hospital UCC in that state.

Appendix B Table: The Association Between Hospital Uncompensated Care and the Numbers of Uninsured and Medicaid-Covered Individuals, 2011-2012

	Uncompensated Care (Total)	Bad Debt	Charity Care
Uninsured	0.344***	0.128**	0.216***
	(0.0837)	(0.0537)	(0.0699)
Medicaid	-0.292**	-0.0249	-0.267*
	(0.138)	(0.0744)	(0.136)
Observations	102	102	102
R-squared	0.998	0.993	0.999

Robust standard errors are reported in parentheses.

***** p-value<0.01; ** p-value<0.05; * p-value<0.10.**

Source: ASPE calculations from CMS Hospital Cost Reports and U.S. Census Bureau data available publicly from CMS.gov and from Census.gov.

Exhibit A-39

Emergency Declaration Press Call Remarks by CMS Administrator Seema Verma

Mar 13, 2020 Nursing facilities, Safety, Medicaid & CHIP, Medicare Parts A & B

Share

Emergency Declaration Press Call Remarks by CMS Administrator Seema Verma

(As prepared for delivery – March 13, 2020)

As you know, earlier today, President Trump declared the rapidly evolving COVID-19 situation a national emergency. This bold move empowers CMS to waive certain federal requirements in Medicare, Medicaid, and CHIP to rapidly expand the Administration's aggressive efforts against COVID-19 led by the White House Coronavirus Taskforce.

As more communities around the nation begin experiencing community spread, America faces a hard reality: more cases of this virus are coming. This Administration's travel restrictions – adopted on the urgent recommendation of numerous public health experts – will help slow the rate of growth in the virus and minimize undue burden on the system at any one time. However, it remains vital that our healthcare system be equipped to respond effectively to the additional cases that do arise, that federal requirements designed for periods of relative calm do not hinder measures needed in an emergency.

These temporary blanket waivers – offered to providers, and clinicians across the country – are reserved for the rarest of situations. They represent a massive mobilization of our country's resources to combat this terrible virus. In a time of emergency, the health system needs maximum flexibility to respond appropriately. That's exactly what this will accomplish.

Today's relief measures take effect retroactively to March 1. They have implications across the entire healthcare system. I'd like to walk you through some of them. Our actions allow hospitals to reserve beds for the most severely ill patients by discharging those who are less severely ill to skilled nursing facilities; they bolster hospital capacity in rural areas by removing restrictions on critical access hospitals; and – crucially – they allow healthcare professionals to provide care across state lines more easily. I'll also flag the expanded use of telehealth, allowing people to communicate with their providers from home and limit the spread of the virus. And this is just the beginning of our work on telehealth – we will have more flexibility coming in the coming days.

In addition, CMS will temporarily suspend certain Medicare enrollment screening requirements including site visits and finger-printing for non-certified Part B suppliers, physicians and non-physician practitioners.

We will also temporarily suspend non-emergency survey inspections, allowing providers to focus on the most current health and safety threats like infectious diseases and abuse.

Under the emergency, states can also seek waivers for Medicaid that allow providers to provide care to other coronavirus patients from other states, streamline provider enrollment requirements, and ease licensing requirements to maximize the medical workforce treating ill patients. We strongly encourage states to take advantage of the broad range of options potentially available through these waivers. Just yesterday, CMS put out FAQ guidance to states that explain more about authorities they will have under an emergency.

The flexibilities we are offering will be a godsend to the providers, clinicians, plans, facilities, on the front lines of this fight. We encourage them to carefully review the broad range of options available to them.

I'd like to pause to say a word about nursing homes, which have been top of mind for the Task Force from the beginning. Later today, CMS will be issuing new guidance, directing nursing homes to temporarily restrict all visitors and nonessential personnel with a few exceptions such as end-of-life situations. We fully appreciate that this measure represents a severe trial for residents of nursing homes and those who love them, but we are doing what we must to protect our vulnerable elderly. Needless to say, the moment we believe these restrictions can be relaxed, we will do so.

This emergency declaration is another bold move from a bold President. His leadership is empowering the White House Coronavirus

task force to kick its response into another gear. We are not waiting for this virus to get worse; we are acting today – quickly, decisively, and effectively – to protect the American people

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Exhibit A-40

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

MEDICARE ENROLLMENT & APPEALS GROUP

DATE: May 5, 2020

TO: All Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans

FROM: Jerry Mulcahy
Director

SUBJECT: Special Enrollment Period (SEP) for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Other Major Disaster: Applicable for COVID-19

As the Centers for Medicare & Medicaid Services (CMS) is working to identify policies and procedures we can put in place to help partners who are responding to the COVID-19 pandemic, we would like to clarify for Medicare Advantage (MA) and Part D plan sponsors that the exceptional conditions Special Enrollment Period (SEP) adopted under 42 CFR 422.62(b)(4) and 423.38(c)(8)(ii) for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster is applicable and is available for beneficiaries who were eligible for -- but unable to make -- an election because they were affected by the COVID-19 pandemic and meet the terms of the SEP listed below. Consistent with the President's emergency declaration pursuant to section 501 (b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act") on March 13, 2020[1], and the President's subsequent approval of major disaster declarations in all 50 states and the District of Columbia, this SEP is available nationwide to residents of all states, tribes, territories, and the District of Columbia effective March 1, 2020, as these entities are eligible to apply for Public Assistance.

An SEP exists for individuals affected by a weather-related emergency or major disaster who were unable to and did not make an election during another valid election period as a result of the emergency or major disaster. This includes both enrollment and disenrollment elections. Individuals will be considered "affected" and eligible for this SEP if they:

- Reside, or resided at the start of the incident period, in an area for which FEMA has declared an emergency or a major disaster[2][3] and has designated affected counties as being eligible to apply for individual or public level assistance;
- Had another valid election period at the time of the incident period; and
- Did not make an election during that other valid election period.

In addition, the SEP is available to those individuals who do not live in the affected areas but rely on help making healthcare decisions from friends or family members who live in the affected areas. The SEP is available from the start of the incident period and for four full

[1] https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/
[2] https://www.fema.gov/disasters
[3] https://www.fema.gov/news-release/2020/03/13/covid-19-emergency-declaration

calendar months after the start of the incident period. Further, an eligible beneficiary would be given one opportunity to make that missed election as a result of this SEP. Beneficiaries will not be expected to provide proof that they were affected by the pandemic-related emergency.

Beneficiaries can contact 1-800-MEDICARE (1-800-633-4227) anytime, 24 hours a day, 7 days a week with any questions. TTY users should call 1-877-486-2048. They can submit their enrollment request through 1-800-MEDICARE, their agent/broker, or by contacting the Medicare health or prescription drug plan directly.
Plans should refer to the following sections in posted manual guidance for details on the SEP:

- Section 30.4.4.18 of Chapter 2 (Medicare Advantage Enrollment and Disenrollment) of the Medicare Managed Care Manual.
- Section 30.3.8.17 of Chapter 3 (Eligibility, Enrollment and Disenrollment) of the Medicare Prescription Drug Benefit Manual.

Beneficiary-directed questions and answers for this SEP are available at any of the following links on CMS.gov and address issues such as eligibility for the SEP and how to enroll:

- Questions and Answers on the Medicare Managed Care Eligibility and Enrollment webpage: https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/Disaster_SEP_QAs_for_Beneficiaries.pdf
- Questions and Answers on the Medicare Prescription Drug Eligibility and Enrollment webpage: https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/index

Exhibit A-41

Enrollment Issues for COVID-19 Pandemic-Related National Emergency Questions and Answers for Medicare Beneficiaries

Q1. I missed my opportunity to enroll because Social Security Administration (SSA) offices were closed and I didn't know how to submit an application or was not able to get my questions answered through other governmental communication channels during the public health emergency caused by the Coronavirus Disease (COVID-19) Outbreak. Can I have more time to enroll in Medicare Part A or B?

YES. Retroactively effective March 17, 2020, equitable relief is available to eligible individuals who could not submit a timely enrollment due to the impact COVID-19 pandemic-related national emergency had on SSA's processing.

To be eligible for this equitable relief, the following conditions must be met:

(1) The individual must have been in their Initial Enrollment Period (IEP), General Enrollment Period (GEP), or Special Enrollment Period (SEP) between March 17, 2020 and June 17, 2020; and
(2) The individual did not submit an enrollment request to SSA.

Individuals who already used their IEP, GEP, or SEP to make an enrollment election are not eligible for this equitable relief to change that election. Eligible individuals will be given an extension of their IEP, GEP or SEP in order to have extra time to enroll in Part B or premium-Part A without penalty, or refuse automatic Part B enrollment. This assistance is available starting March 17, 2020 and will continue until June 17, 2020.

Q2. Does an individual need to show proof that they were not able to apply or submit an enrollment request because of the impact the COVID-19 pandemic-related national emergency had on SSA's processing?

No. They will not need to show proof they were impacted. They will need to meet the eligibility criteria for equitable relief and submit an enrollment request between March 17, 2020 and June 17, 2020.

Q3. What should people do to take advantage of this equitable relief?

Individuals who believe they are eligible for the equitable relief should contact SSA to apply for or enroll in Medicare as follows:

Individuals can apply for Medicare Part A and Part B online at https://www.ssa.gov/benefits/medicare/.

Individuals who already have Medicare Part A and wish to sign up for Medicare Part B cannot sign up online. Individuals interested in enrolling in Medicare Part B coverage who are eligible

to apply under the IEP or GEP should complete form CMS-40B and mail the request to their local SSA field office.

Individuals interested in enrolling in Medicare Part B coverage who are eligible to apply under the SEP, should complete forms CMS-40B and CMS-L564; both forms are available in English and Spanish versions. The CMS-40B application is completed entirely by the individual enrolling in Part B. For the CMS-L564 enrollment form:

- Section A:
  - Must be completed by individuals enrolling in Part B
- Section B:
  - Can be completed by the employer; OR
  - If it isn't feasible for your employer to complete the form, leave section B (the rest of the form) blank and provide at least one of the items listed below. Acceptable proof of employment, Group Health Coverage Plan (GHP), or large Group Health Plan (LGHP) include but are not limited to:

    - income tax returns that show health insurance premiums paid;
    - W-2s reflecting pre-tax medical contributions;
    - pay stubs that reflect health insurance premium deductions;
    - health insurance cards with a policy effective date;
    - explanations of benefits paid by the GHP or LGHP; and
    - statements or receipts that reflect payment of health insurance premiums

Individuals can fax their completed enrollment forms to SSA toll free at 1-833-914-2016, or mail the request to their local SSA field office. Although SSA offices are closed for in-person service, requests received by mail are still being processed. Individuals can find the address and phone number for their local field office using the Social Security Office Locator https://secure.ssa.gov/ICON/main.jsp.

Q4. If I enroll in Part B or Part A under this offer of equitable relief, when would my Part B or Part A enrollment take effect?

The effective date would be the month that would have been granted had the application been filed at the time of the individual's original (but missed) IEP, GEP, or SEP.

Q5. If I missed my opportunity to enroll and take the extra time under this offer of assistance to enroll in Part B or Part A, will I be subject to a Part A or Part B late enrollment penalty?

No. Individuals who use this equitable relief to enroll in Medicare will not be subject to a late enrollment penalty for the period between when their IEP, GEP or SEP would have ended and their effective date of coverage. Individuals who would have had a late enrollment penalty if they timely enrolled during the GEP occurring from January through March 2020 will have that late enrollment penalty applied.

Exhibit A-42

COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers

The Trump Administration is taking aggressive actions and exercising regulatory flexibilities to help healthcare providers contain the spread of 2019 Novel Coronavirus Disease (COVID-19). CMS is empowered to take proactive steps through 1135 waivers as well as, where applicable, authority granted under section 1812(f) of the Social Security Act (the Act) and rapidly expand the Administration's aggressive efforts against COVID-19. As a result, the following blanket waivers are in effect, with a retroactive effective date of March 1, 2020 through the end of the emergency declaration. For general information about waivers, see Attachment A to this document. **These waivers DO NOT require a request to be sent to the 1135waiver@cms.hhs.gov mailbox or that notification be made to any of CMS's regional offices.**

Flexibility for Medicare Telehealth Services

- **Eligible Practitioners.** Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.

- **Audio-Only Telehealth for Certain Services.** Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Hospitals, Psychiatric Hospitals, and Critical Access Hospitals (CAHs), including Cancer Centers and Long-Term Care Hospitals (LTCHs)

- **Emergency Medical Treatment & Labor Act (EMTALA).** CMS is waiving the enforcement of section 1867(a) of the Act. This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.

- **Verbal Orders.** CMS is waiving the requirements of 42 CFR §482.23, §482.24 and §485.635(d)(3) to provide additional flexibility related to verbal orders where read- back verification is required, but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations. Specifically, the following requirements are waived:
    - §482.23(c)(3)(i) - If verbal orders are used for the use of drugs and biologicals (except immunizations), they are to be used infrequently.
    - §482.24(c)(2) - All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient.
    - §482.24(c)(3) - Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders. This would include all subparts at §482.24(c)(3).
    - §485.635(d)(3) - Although the regulation requires that medication administration be based on a written, signed order, this does not preclude the CAH from using verbal orders. A practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact.

- **Reporting Requirements**. CMS is waiving the requirements at 42 CFR §482.13(g) (1)(i)-(ii), which require that hospitals report patients in an intensive care unit whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs, no later than the close of business on the next business day. Due to current hospital surge, CMS is waiving this requirement to ensure that hospitals are focusing on increased patient care demands and increased patient census, provided any death where the restraint may have contributed is still reported within standard time limits (i.e., close of business on the next business day following knowledge of the patient's death).

- **Patient Rights.** CMS is waiving requirements under 42 CFR §482.13 **only for hospitals that are considered to be impacted by a widespread outbreak of COVID-19**. Hospitals that are located in a state which has widespread confirmed cases (i.e., 51 or more confirmed cases*) as updated on the CDC website, CDC States Reporting Cases of COVID-19, at **https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html**, would not be required to meet the following requirements:

- §482.13(d)(2) - With respect to timeframes in providing a copy of a medical record.
- §482.13(h) - Related to patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.
- §482.13(e)(1)(ii) - Regarding seclusion.

*The waiver flexibility is based on the number of confirmed cases as reported by CDC and will be assessed accordingly when COVID-19 confirmed cases decrease.

- **Sterile Compounding.** CMS is waiving requirements (also outlined in USP797) at 42 CFR §482.25(b)(1) and §485.635(a)(3) in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies. CMS will not review the use and storage of face masks under these requirements.

- **Detailed Information Sharing for Discharge Planning for Hospitals and CAHs.** CMS is waiving the requirement 42 CFR §482.43(a)(8), §482.61(e), and §485.642(a)(8) to provide detailed information regarding discharge planning, described below:
  - The hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. The hospital must ensure that the post-acute care data on quality measures and resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.
  - CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b).

- **Limiting Detailed Discharge Planning for Hospitals.** CMS is waiving all the requirements and subparts at 42 CFR §482.43(c) related to post-acute care services so as to expedite the safe discharge and movement of patients among care settings, and to be responsive to fluid situations in various areas of the country. CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care as described in 42 CFR §482.43(a)(1)-(7) and (b). CMS is waiving the more detailed requirement that hospitals ensure those patients discharged home and referred for HHA services, or transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, must:
  - §482.43(c)(1): Include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient.
  - §482.43(c)(2): Inform the patient or the patient's representative of their freedom to

choose among participating Medicare providers and suppliers of post-discharge services.

- §482.43(c)(3): Identify in the discharge plan any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare.

- **Medical Staff.** CMS is waiving requirements under 42 CFR §482.22(a)(1)-(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID-19. CMS is waiving §482.22(a) (1)-(4) regarding details of the credentialing and privileging process. **(Please also refer to Practitioner Locations Blanket Waiver listed below.)**

- **Medical Records.** CMS is waiving requirements under 42 CFR §482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements, and these flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. CMS is waiving §482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.

- **Flexibility in Patient Self Determination Act Requirements (Advance Directives).** CMS is waiving the requirements at sections 1902(a)(58) and 1902(w)(1)(A) of the Act (for Medicaid); 1852(i) of the Act (for Medicare Advantage); and 1866(f) of the Act and 42 CFR §489.102 (for Medicare), which require hospitals and CAHs to provide information about their advance directive policies to patients. CMS is waiving this requirement to allow staff to more efficiently deliver care to a larger number of patients.

- **Physical Environment.** ***(Modified since 5/11 Release)*** CMS is waiving certain physical environment requirements under the Medicare conditions of participation at 42 CFR §482.41 and 42 CFR §485.623 to allow for increased flexibilities for surge capacity and patient quarantine at hospitals, psychiatric hospitals, and critical access hospitals (CAHs) as a result of COVID-19. CMS will permit facility and non-facility space that is not normally used for patient care to be utilized for patient care or quarantine, provided the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and is consistent with the state's emergency preparedness or pandemic plan. This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients. States are still

subject to obligations under the integration mandate of the Americans with Disabilities Act, to avoid subjecting persons with disabilities to unjustified institutionalization or segregation [1].

- **Telemedicine.** CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a) (8)–(9) for hospitals and §485.616(c) for CAHs, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care.

- **Physician Services.** CMS is waiving requirements under 42 CFR §482.12(c)(1)–(2) and §482.12(c)(4), which requires that Medicare patients be under the care of a physician. This waiver may be implemented so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible.

- **Anesthesia Services.** CMS is waiving requirements under 42 CFR §482.52(a)(5), §485.639(c) (2), and §416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs §482.52(a)(5) and §485.639(c)(2). CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **Utilization Review.** CMS is waiving certain requirements under 42 CFR §482.1(a)(3) and 42 CFR §482.30 which address the statutory basis for hospitals and includes the requirement that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.
    - CMS is waiving the entire utilization review condition of participation Utilization Review (UR) at §482.30, which requires that a hospital must have a UR plan with a UR committee that provides for a review of services furnished to Medicare and Medicaid beneficiaries to evaluate the medical necessity of the admission, duration of stay, and services provided. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

[1]Please note that consistent with the integration mandate of Title II of the ADA and the *Olmstead vs LC* decision, States are obligated to offer/ provide discharge planning and/or case management/ transition services, as appropriate, to individuals who are removed from their Medicaid home and community based services under these authorities during the course of the public health emergency as well as to individuals with disabilities who may require these services in order to avoid unjustified institutionalization or segregation. Transition services/ case management and/or discharge planning would be provided to facilitate these individuals in their return to the community when their condition and public health circumstances permit.

- **Written Policies and Procedures for Appraisal of Emergencies at Off Campus Hospital Departments**. CMS is waiving 42 CFR §482.12(f)(3), emergency services, with respect to surge facilities **only**, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities. This removes the burden on facilities to develop and establish additional policies and procedures at their surge facilities or surge sites related to the assessment, initial treatment, and referral of patients. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **Emergency Preparedness Policies and Procedures.** CMS is waiving 42 CFR §482.15(b) and §485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and §482.15(c)(1)–(5) and §485.625(c)(1)–(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the surge site. This waiver applies to both hospitals and CAHs, and removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.

- **Quality Assessment and Performance Improvement Program.** CMS is waiving 42 CFR §482.21(a)–(d) and (f), and §485.641(a), (b), and (d), which provide details on the scope of the program, the incorporation, and setting priorities for the program's performance improvement activities, and integrated Quality Assurance & Performance Improvement programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (PHE). While this waiver decreases burden associated with the development of a hospital or CAH QAPI program, the requirement that hospitals and CAHs maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program will remain. This waiver applies to both hospitals and CAHs.

- **Nursing Services.** CMS is waiving the requirements at 42 CFR §482.23(b)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and §482.23(b)(7), which requires the hospital to have policies and procedures in place establishing which outpatient departments are not required to have a registered nurse present. These waivers allow nurses increased time to meet the clinical care needs of each patient and allow for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs §485.635(d)(4), and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **Food and Dietetic Services.** CMS is waiving the requirement at paragraph 42 CFR §482.28(b) (3), which requires providers to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

- **Respiratory Care Services.** CMS is waiving the requirements at 42 CFR §482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Not being required to designate these professionals in writing will allow qualified professionals to operate to the fullest extent of their licensure and training in providing patient care.

- **Expanded Ability for Hospitals to Offer Long-term Care Services ("Swing-Beds") for Patients Who do not Require Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31.** Under section 1135(b)(1) of the Act, CMS is waiving the requirements at 42 CFR 482.58, "*Special Requirements for hospital providers of long-term care services ("swing-beds")"* subsections (a)(1)-(4) *"Eligibility"*, to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system (PPS) to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF.

  In order to qualify for this waiver, hospitals must:

  - Not use SNF swing beds for acute level care.
  - Comply with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived.
  - Be consistent with the state's emergency preparedness or pandemic plan.

  Hospitals must call the CMS Medicare Administrative Contractor (MAC) enrollment hotline to add swing bed services. The hospital must attest to CMS that:

  - They have made a good faith effort to exhaust all other options;
  - There are no skilled nursing facilities within the hospital's catchment area that under normal circumstances would have accepted SNF transfers, but are currently not willing to accept or able to take patients because of the COVID-19 public health emergency (PHE);

- The hospital meets all waiver eligibility requirements; and
- They have a plan to discharge patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.

This waiver applies to all Medicare enrolled hospitals, except psychiatric and long term care hospitals that need to provide post-hospital SNF level swing-bed services for non-acute care patients in hospitals, so long as the waiver is not inconsistent with the state's emergency preparedness or pandemic plan. The hospital shall not bill for SNF PPS payment using swing beds when patients require acute level care or continued acute care at any time while this waiver is in effect. This waiver is permissible for swing bed admissions during the COVID-19 PHE with an understanding that the hospital must have a plan to discharge swing bed patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.

- **CAH Personnel Qualifications.** CMS is waiving the minimum personnel qualifications for clinical nurse specialists at paragraph 42 CFR §485.604(a)(2), nurse practitioners at paragraph §485.604(b)(1)–(3), and physician assistants at paragraph §485.604(c)(1)–(3). Removing these Federal personnel requirements will allow CAHs to employ individuals in these roles who meet state licensure requirements and provide maximum staffing flexibility. These flexibilities should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **CAH Staff Licensure.** CMS is deferring to staff licensure, certification, or registration to state law by waiving 42 CFR §485.608(d) regarding the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations. This waiver will provide maximum flexibility for CAHs to use all available clinicians. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **CAH Status and Location.** CMS is waiving the requirement at 42 CFR §485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of surge site locations. CMS is also waiving the requirement at §485.610(e) regarding the CAH's off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will suspend restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

- **CAH Length of Stay.** CMS is waiving the requirements that CAHs limit the number of beds to 25, and that the length of stay be limited to 96 hours under the Medicare conditions of participation for number of beds and length of stay at 42 CFR §485.620.

- **Temporary Expansion Locations:** For the duration of the PHE related to COVID-19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 (as noted elsewhere in this waiver document) and the provider- based department requirements at §413.65 to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation for hospitals that continue to apply during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an Ambulatory Surgical Center (ASC) enrolling as a hospital during the PHE pursuant to a streamlined enrollment and survey and certification process) so long as the relevant location meets the conditions of participation and other requirements not waived by CMS. This waiver will enable hospitals to meet the needs of Medicare beneficiaries.

- **Responsibilities of Physicians in Critical Access Hospitals (CAHs).** 42 CFR § 485.631(b)(2). CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available "through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral." Retaining this longstanding CMS policy and related longstanding subregulatory guidance that further described communication between CAHs and physicians will assure an appropriate level of physician direction and supervision for the services provided by the CAH. This will allow the physician to perform responsibilities remotely, as appropriate. This also allows CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.

- **Long Term Care Hospitals - Site Neutral Payment Rate Provisions.** Also as required by section 3711(b) of the CARES Act, during the Public Health Emergency (PHE) due to COVID-19, the Secretary has waived section 1886(m)(6) of the Social Security Act relating to certain site neutral payment rate provisions for long-term care hospitals (LTCHs).
    - Section 3711(b)(1) of the CARES Act waives the payment adjustment under section 1886(m)(6)(C)(ii) of the Act for LTCHs that do not have a discharge payment percentage (DPP) for the period that is at least 50 percent during the COVID-19 public health emergency period. Under this provision, for the purposes of calculating an LTCH's DPP, all admissions during the COVID-19 public health emergency period will be counted in the numerator of the calculation, that is, LTCH cases that were admitted during the COVID-19 public health emergency period will be counted as discharges paid the LTCH PPS standard Federal payment rate.
    - Section 3711(b)(2) of the CARES Act provides a waiver of the application of the site neutral payment rate under section 1886(m)(6)(A)(i) of the Act for those LTCH admissions that are in response to the public health emergency and occur during the

COVID-19 public health emergency period. Under this provision, all LTCH cases admitted during the COVID-19 public health emergency period will be paid the relatively higher LTCH PPS standard Federal rate. A new LTCH PPS Pricer software package will be released in April 2020 to include this temporary payment policy effective for claims with an admission date occurring on or after January 27, 2020 and continuing through the duration of the COVID-19 public health emergency period. Claims received on or after April 21, 2020, will be processed in accordance with this waiver. Claims received April 20, 2020, and earlier will be reprocessed. LTCHs should add the "DR" condition code to applicable claims.

Hospitals Classified as Sole Community Hospitals (SCHs)

- CMS is waiving certain eligibility requirements at 42 CFR § 412.92(a) for hospitals classified as SCHs prior to the PHE. Specifically, CMS is waiving the distance requirements at paragraphs (a), (a)(1), (a)(2), and (a)(3) of 42 CFR § 412.92, and is also waiving the "market share" and bed requirements (as applicable) at 42 CFR § 412.92(a)(1)(i) and (ii). CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.

Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDHs)

- For hospitals classified as MDHs prior to the PHE, CMS is waiving the eligibility requirement at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID-19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

- **Certain Staffing Requirements.** 42 CFR 491.8(a)(6). CMS is waiving the requirement in the second sentence of § 491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50 percent of the time the RHC operates. CMS is not waiving the first sentence of § 491.8(a)(6) that requires a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist to be available to furnish patient care services at all times the clinic or center

operates. This will assist in addressing potential staffing shortages by increasing flexibility regarding staffing mixes during the PHE.

- **Physician Supervision of NPs in RHCs and FQHCs.** 42 CFR 491.8(b)(1). We are modifying the requirement that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.

- **Temporary Expansion Locations.** CMS is waiving the requirements at 42 CFR §491.5(a)(3)(iii) which require RHCs and FQHCs be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS is temporarily waiving this requirement removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand services locations to meet the needs of Medicare beneficiaries. This flexibility includes areas which may be outside of the location requirements 42 CFR §491.5(a)(1) and (2) but will end when the HHS Secretary determines there is no longer a PHE due to COVID-19.

Housing Acute Care Patients in the IRF or Inpatient Psychiatric Facility (IPF) Excluded Distinct Part Units

- CMS is waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit's beds are appropriate for acute care inpatients. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.

Care for Excluded Inpatient Psychiatric Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing acute care hospitals with excluded distinct part inpatient psychiatric units to relocate inpatients from the excluded distinct part psychiatric unit to an acute care bed and unit as a result of a disaster or emergency. The hospital should continue to bill for inpatient psychiatric services under the Inpatient Psychiatric Facility Prospective Payment System for these patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID-19 emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients and the staff and environment are conducive to safe

care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.

Care for Excluded Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital

- CMS is allowing acute care hospitals with excluded distinct part inpatient rehabilitation units that, as a result of a disaster or emergency, need to relocate inpatients from the excluded distinct part rehabilitation unit to an acute care bed and unit as a result of this PHE. The hospital should continue to bill for inpatient rehabilitation services under the inpatient rehabilitation facility prospective payment system for these patients and annotate the medical record to indicate the patient is a rehabilitation inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the disaster or emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for providing care to rehabilitation patients and such patients continue to receive intensive rehabilitation services.

Flexibility for Inpatient Rehabilitation Facilities Regarding the "60 Percent Rule"

- CMS is allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60 percent rule") if an IRF admits a patient solely to respond to the emergencyand the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.

Inpatient Rehabilitation Facility – Intensity of Therapy Requirement ("3-Hour Rule")

- As required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, during the COVID-19 public health emergency, the Secretary has waived 42 CFR § 412.622(a)(3)(ii) which provides that payment generally requires that patients of an inpatient rehabilitation facility receive at least 15 hours of therapy per week. This waiver clarifies information provided in "Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (CMS-1744-IFC). (85 Federal Register 19252, 19287, April 6, 2020). The information in that rulemaking (CMS-1744-IFC) about Inpatient Rehabilitation Facilities was contemplated prior to the passage of the CARES Act.

Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission

- CMS collects data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. Completed 2019 Occupational Mix Surveys, Hospital Reporting Form CMS-10079, for the Wage Index Beginning FY 2022, are due to the Medicare Administrative Contractors (MACs) on the Excel hospital reporting form available at **https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html** by July 1, 2020. CMS is currently granting an extension for hospitals nationwide affected by COVID-19 until August 3, 2020. If hospitals encounter difficulty meeting this extended deadline date, hospitals should communicate their concerns to CMS via their MAC, and CMS may consider an additional extension if CMS determines it is warranted.

Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs)

- CMS has determined it is appropriate to issue a blanket waiver to long-term care hospitals (LTCHs) to exclude patient stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement, which allows these facilities to be paid as LTCHs. In addition, during the applicable waiver time period, we would also apply this waiver to facilities not yet classified as LTCHs, but seeking classification as an LTCH.

Care for Patients in Extended Neoplastic Disease Care Hospitals

- CMS is allowing extended neoplastic disease care hospitals to exclude inpatient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the greater than 20-day average length of stay requirement, which allows these facilities to be excluded from the hospital inpatient prospective payment system and paid an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules as authorized under Section 1886(d)(1)(B)(vi) of the Act and §42 CFR 412.22(i).

Long-Term Care Facilities and Skilled Nursing Facilities (SNFs) and/or Nursing Facilities (NFs)

- **3-Day Prior Hospitalization.** Using the authority under Section 1812(f) of the Act, CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID-19. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes renewed SNF coverage without first having to start a new benefit period (this waiver will apply only for those

beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances).

- **Reporting Minimum Data Set.** CMS is waiving 42 CFR 483.20 to provide relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.

- **Staffing Data Submission.** CMS is waiving 42 CFR 483.70(q) to provide relief to long-term care facilities on the requirements for submitting staffing data through the Payroll-Based Journal system.

- **Waive Pre-Admission Screening and Annual Resident Review (PASARR).** CMS is waiving 42 CFR 483.20(k), allowing nursing homes to admit new residents who have not received Level 1 or Level 2 Preadmission Screening. Level 1 assessments may be performed post-admission. On or before the 30th day of admission, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should be referred promptly by the nursing home to State PASARR program for Level 2 Resident Review.

- **Physical Environment.** CMS is waiving requirements related at 42 CFR 483.90, specifically the following:
    - Provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under § 483.90 to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there are needs for isolation processes for COVID-19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID-19 are available while protecting other vulnerable adults.
    - CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will waive certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID-19 isolation and treatment location.
    - CMS is also waiving requirements under 42 CFR 483.90 to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met. This can be done so long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department.

- **Resident Groups.** CMS is waiving the requirements at 42 CFR 483.10(f)(5), which ensure residents can participate in-person in resident groups. This waiver would only permit the facility to restrict in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID-19.

- **Training and Certification of Nurse Aides.** CMS is waiving the requirements at 42 CFR 483.35(d) (with the exception of 42 CFR 483.35(d)(1)(i)), which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under § 483.35(d). CMS is waiving these requirements to assist in potential staffing shortages seen with the COVID-19 pandemic. To ensure the health and safety of nursing home residents, CMS is not waiving 42 CFR § 483.35(d)(1)(i), which requires facilities to not use any individual working as a nurse aide for more than four months, on a full-time basis, unless that individual is competent to provide nursing and nursing related services. We further note that we are not waiving § 483.35(c), which requires facilities to ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

- **Physician Visits in Skilled Nursing Facilities/Nursing Facilities.** CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in- person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.

- **Resident Roommates and Grouping.** CMS is waiving the requirements in 42 CFR 483.10(e) (5), (6), and (7) solely for the purposes of grouping or cohorting residents with respiratory illness symptoms and/or residents with a confirmed diagnosis of COVID-19, and separating them from residents who are asymptomatic or tested negative for COVID-19. This action waives a facility's requirements, under 42 CFR 483.10, to provide for a resident to share a room with his or her roommate of choice in certain circumstances, to provide notice and rationale for changing a resident's room, and to provide for a resident's refusal a transfer to another room in the facility. This aligns with CDC guidance to preferably place residents in locations designed to care for COVID-19 residents, to prevent the transmission of COVID-19 to other residents.

- **Resident Transfer and Discharge.** CMS is waiving requirements in 42 CFR 483.10(c)(5); 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), (c)(9), and (d); and § 483.21(a)(1)(i), (a)(2)(i), and (b)(2)(i) (with some exceptions) to allow a long term care (LTC) facility to transfer or discharge residents to another LTC facility solely for the following cohorting purposes:

    1. Transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID-19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents;

    2. Transferring residents without symptoms of a respiratory infection or confirmed to not have COVID-19 to another facility that agrees to accept each specific resident, and is

dedicated to the care of such residents to prevent them from acquiring COVID-19; or

3. Transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days.

Exceptions:

- These requirements are **only** waived in cases where the transferring facility receives confirmation that the receiving facility agrees to accept the resident to be transferred or discharged. Confirmation may be in writing or verbal. If verbal, the transferring facility needs to document the date, time, and person that the receiving facility communicated agreement.

- In § 483.10, we are only waiving the requirement, under § 483.10(c)(5), that a facility provide advance notification of options relating to the transfer or discharge to another facility. Otherwise, all requirements related to § 483.10 are not waived. Similarly, in § 483.15, we are only waiving the requirement, under § 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), and (d), for the written notice of transfer or discharge to be provided before the transfer or discharge. This notice must be provided as soon as practicable.

- In § 483.21, we are only waiving the timeframes for certain care planning requirements for residents who are transferred or discharged for the purposes explained in 1–3 above. Receiving facilities should complete the required care plans as soon as practicable, and we expect receiving facilities to review and use the care plans for residents from the transferring facility, and adjust as necessary to protect the health and safety of the residents the apply to.

- These requirements are also waived when the transferring residents to another facility, such as a COVID-19 isolation and treatment location, with the provision of services "under arrangements," as long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department. In these cases, the transferring LTC facility need not issue a formal discharge, as it is still considered the provider and should bill Medicare normally for each day of care. The transferring LTC facility is then responsible for reimbursing the other provider that accepted its resident(s) during the emergency period.
    - If the LTC facility does not intend to provide services under arrangement, the COVID-19 isolation and treatment facility is the responsible entity for Medicare billing purposes. The LTC facility should follow the procedures described in 40.3.4 of the Medicare Claims Processing Manual (**https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf**) to submit a discharge bill to Medicare. The COVID-19 isolation and treatment facility should

then bill Medicare appropriately for the type of care it is providing for the beneficiary. If the COVID-19 isolation and treatment facility is not yet an enrolled provider, the facility should enroll through the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area to establish temporary Medicare billing privileges.

We remind LTC facilities that they are responsible for ensuring that any transfers (either within a facility, or to another facility) are conducted in a safe and orderly manner, and that each resident's health and safety is protected.

We also remind states that under 42 CFR 488.426(a)(1), in an emergency, the State has the authority to transfer Medicaid and Medicare residents to another facility.

- **Physician Services.** CMS is providing relief to long-term care facilities related to provision of physician services through the following actions:
    - **Physician Delegation of Tasks in SNFs.** 42 CFR 483.30(e)(4). CMS is waiving the requirement in § 483.30(e)(4) that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gives physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who meets the applicable definition in 42 CFR 491.2 or, in the case of a clinical nurse specialist, is licensed as such by the State and is acting within the scope of practice laws as defined by State law. We are temporarily modifying this regulation to specify that any task delegated under this waiver must continue to be under the supervision of the physician. This waiver does not include the provision of § 483.30(e)(4) that prohibits a physician from delegating a task when the delegation is prohibited under State law or by the facility's own policy.
    - **Physician Visits.** 42 CFR 483.30(c)(3). CMS is waiving the requirement at § 483.30(c)(3) that all required physician visits (not already exempted in § 483.30(c)(4) and (f)) must be made by the physician personally. We are modifying this provision to permit physicians to delegate any required physician visit to a nurse practitioner (NPs), physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope of practice laws.
    - **Note to Facilities.** These actions will assist in potential staffing shortages, maximize the use of medical personnel, and protect the health and safety of residents during the PHE. We note that we are not waiving the requirements for the frequency of required physician visits at § 483.30(c)(1). As set out above, we have only modified the requirement to allow for the requirement to be met by an NP, physician assistant, or clinical nurse specialist, and via telehealth or other remote communication options, as appropriate. In addition, we note that we are not waiving our requirements for physician supervision in § 483.30(a)(1), and the requirement at § 483.30(d)(3) for the facility to provide or arrange for the provision of physician services 24 hours a day, in

case of an emergency. It is important that the physician be available for consultation regarding a resident's care.

- **Quality Assurance and Performance Improvement (QAPI).** CMS is modifying certain requirements in 42 CFR §483.75, which require long-term care facilities to develop, implement, evaluate, and maintain an effective, comprehensive, data-driven QAPI program. Specifically, CMS is modifying §483.75(b)–(d) and (e)(3) to the extent necessary to narrow the scope of the QAPI program to focus on adverse events and infection control. This will help ensure facilities focus on aspects of care delivery most closely associated with COVID-19 during the PHE.
- **In-Service Training:** CMS is modifying the nurse aide training requirements at §483.95(g)(1) for SNFs and NFs, which requires the nursing assistant to receive at least 12 hours of in-service training annually. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes.
- **Detailed Information Sharing for Discharge Planning for Long-Term Care (LTC) Facilities.** CMS is waiving the discharge planning requirement in §483.21(c)(1)(viii), which requires LTC facilities to assist residents and their representatives in selecting a post-acute care provider using data, such as standardized patient assessment data, quality measures and resource use. This temporary waiver is to provide facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements, such as but not limited to, ensuring that the discharge needs of each resident are identified and result in the development of a discharge plan for each resident; involving the interdisciplinary team, as defined at 42 CFR §483.21(b)(2)(ii), in the ongoing process of developing the discharge plan address the resident's goals of care and treatment preferences.
- **Clinical Records.** Pursuant to section 1135(b)(5) of the Act, CMS is modifying the requirement at 42 CFR §483.10(g)(2)(ii) which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident). Specifically, CMS is modifying the timeframe requirements to allow LTC facilities ten working days to provide a resident's record rather than two working days.
- **Paid Feeding Assistants.** CMS is modifying the requirements at 42 CFR §§ 483.60(h)(1)(i) and 483.160(a) regarding required training of paid feeding assistants. Specifically, CMS is modifying the minimum timeframe requirements in these sections, which require this training to be a minimum of 8 hours. CMS is modifying to allow that the training can be a minimum of 1 hour in length. CMS is not waiving any other requirements under 42 CFR §483.60(h) related to paid feeding assistants or the required training content at 42 CFR §483.160(a)(1)-(8), which contains infection control training and other elements. Additionally, CMS is also not waiving or modifying the requirements at 42 CFR §483.60(h)(2)(i), which requires that a feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

Home Health Agencies (HHAs)

- **Requests for Anticipated Payment (RAPs).** CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.

- **Reporting.** CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below:
    - Extending the 5-day completion requirement for the comprehensive assessment to 30 days.
    - Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.

- **Initial Assessments.** CMS is waiving the requirements at 42 CFR §484.55(a) to allow HHAs to perform Medicare-covered initial assessments and determine patients' homebound status remotely or by record review. This will allow patients to be cared for in the best environment for them while supporting infection control and reducing impact on acute care and long- term care facilities. This will allow for maximizing coverage by already scarce physician, and advanced practice clinicians, and allow those clinicians to focus on caring for patients with the greatest acuity.

- **Waive Onsite Visits for HHA Aide Supervision.** CMS is waiving the requirements at 42 CFR §484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. This waiver is also temporarily suspending the 2-week aide supervision by a registered nurse for home health agencies requirement at §484.80(h)(1), but virtual supervision is encouraged during the period of the waiver.

- **Allow Occupational Therapists (OTs), Physical Therapists (PTs), and Speech Language Pathologists (SLPs) to Perform Initial and Comprehensive Assessment for all Patients.** CMS is waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered. This temporary blanket modification allows any rehabilitation professional (OT, PT, or SLP) to perform the initial and comprehensive assessment for all patients receiving therapy services as part of the plan of care, to the extent permitted under state law, regardless of whether or not the service establishes eligibility for the patient to be receiving home care. The existing regulations at § 484.55(a) and (b)(2) would continue to apply; rehabilitation skilled professionals would not be permitted to perform assessments in nursing-only cases. We would continue to expect HHAs to match the appropriate discipline that performs the assessment to the needs of the patient to the greatest extent possible. Therapists must act within their state scope of practice laws when performing initial and comprehensive

assessments, and access a registered nurse or other professional to complete sections of the assessment that are beyond their scope of practice. Expanding the category of therapists who may perform initial and comprehensive assessments provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services.

- **12-hour Annual In-service Training Requirement for Home Health Aides.** CMS is modifying the requirement at 42 CFR §484.80(d) that home health agencies must assure that each home health aide receives 12 hours of in-service training in a 12-month period. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This will allow aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care and additional time for staff to complete this requirement.

- **Detailed Information Sharing for Discharge Planning for Home Health Agencies.** CMS is waiving the requirements of 42 CFR §484.58(a) to provide detailed information regarding discharge planning, to patients and their caregivers, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, (another) home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures.

    - This temporary waiver provides facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements.

- **Clinical Records:** In accordance with section 1135(b)(5) of the Act, CMS is extending the deadline for completion of the requirement at 42 CFR §484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days (when requested by the patient). Specifically, CMS will allow HHAs ten business days to provide a patient's clinical record, instead of four.

Home Health Agencies (HHAs) and Hospice

- **Training and Assessment of Aides:** CMS is waiving the requirement at 42 CFR §418.76(h)(2) for Hospice and 42 CFR §484.80(h)(1)(iii) for HHAs, which require a registered nurse, or in the case of an HHA a registered nurse or other appropriate skilled professional (physical therapist/occupational therapist, speech language pathologist) to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the agency. In accordance with section 1135(b)(5) of the Act, we are postponing completion of these visits. All postponed onsite assessments must be completed by these professionals no later than 60 days after the expiration of the PHE.

- **Quality Assurance and Performance Improvement (QAPI).** CMS is modifying the requirement

at 42 CFR §418.58 for Hospice and §484.65 for HHAs, which requires these providers to develop, implement, evaluate, and maintain an effective, ongoing, hospice/HHA-wide, data-driven QAPI program. Specifically, CMS is modifying the requirements at §418.58(a)–(d) and §484.65(a)–(d) to narrow the scope of the QAPI program to concentrate on infection control issues, while retaining the requirement that remaining activities should continue to focus on adverse events. This modification decreases burden associated with the development and maintenance of a broad-based QAPI program, allowing the providers to focus efforts on aspects of care delivery most closely associated with COVID-19, and tracking adverse events during the PHE. The requirement that HHAs and hospices maintain an effective, ongoing, agency-wide, data-driven quality assessment and performance improvement program will remain.

Hospice

- **Waive Requirement for Hospices to Use Volunteers**. CMS is waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and potential quarantine.

- **Comprehensive Assessments.** CMS is waiving certain requirements at 42 CFR §418.54 related to updating comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment found at §418.54(d). Hospices must continue to complete the required assessments and updates; however, the timeframes for updating the assessment may be extended from 15 to 21 days.

- **Waive Non-Core Services.** CMS is waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology.

- **Waived Onsite Visits for Hospice Aide Supervision.** CMS is waiving the requirements at 42 CFR §418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time.

- **Hospice Aide Competency Testing Allow Use of Pseudo Patients.** 42 CFR 418.76(c)(1). CMS is temporarily modifying the requirement in § 418.76(c)(1) that a hospice aide must be evaluated by observing an aide's performance of certain tasks with a patient. This modification allows hospices to utilize pseudo patients such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients, in the competency testing of hospice aides for those tasks that must be observed being performed on a patient. This increases the speed of performing competency testing and allows new aides to

begin serving patients more quickly without affecting patient health and safety during the public health emergency (PHE).

- **12 hour Annual In-service Training Requirement for Hospice Aides.** 42 CFR 418.76(d). CMS is waiving the requirement that hospices must assure that each hospice aide receives 12 hours of in-service training in a 12 month period. This allows aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care.

- **Annual Training.** CMS is modifying the requirement at 42 CFR §418.100(g)(3), which requires hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required. Pursuant to section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This does not alter the minimum personnel requirements at 42 CFR §418.114. Selected hospice staff must complete training and have their competency evaluated in accordance with unwaived provisions of 42 CFR Part 418.

End-Stage Renal Dialysis (ESRD) Facilities

- **Training Program and Periodic Audits.** CMS is waiving the requirement at 42 CFR §494.40(a) related to the condition on Water & Dialysate Quality, specifically that on-time periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.

- **Defer Equipment Maintenance & Fire Safety Inspections.** CMS is waiving the requirement at 42 CFR §494.60(b) for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS is also waiving the requirements under §494.60(d) which requires ESRD facilities to conduct on-time fire inspections. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.

- **Emergency Preparedness.** CMS is waiving the requirements at 42 CFR §494.62(d)(1)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID-19 emergency due to the limited availability of CPR classes.

- **Ability to Delay Some Patient Assessments.** CMS is not waiving subsections (a) or (c) of 42 CFR §494.80, but is waiving the following requirements at 42 CFR §494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility. CMS is waiving the "on-time" requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. These waivers are intended to ensure that

dialysis facilities are able to focus on the operations related to the Public Health Emergency. Specifically, CMS is waiving:

- §494.80(b)(1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
- §494.80(b)(2): A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in §494.90.

- **Time Period for Initiation of Care Planning and Monthly Physician Visits.** CMS is modifying two requirements related to care planning, specifically:
  - 42 CFR §494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments.
  - §494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.

- **Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation.** CMS is waiving the requirement at 42 CFR §494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, reference QSO-20-19-ESRD.

- **Home Dialysis Machine Designation – Clarification.** The ESRD Conditions for Coverage (CFCs) do not explicitly require that each home dialysis patient have their own designated home dialysis machine. The dialysis facility is required to follow FDA labeling and manufacturer's directions for use to ensure appropriate operation of the dialysis machine and ancillary equipment. Dialysis machines must be properly cleaned and disinfected to minimize the risk of infection based on the requirements at 42 CFR §494.30 Condition: Infection Control if used to treat multiple patients.

- **Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded.** CMS authorizes the establishment of SPRDFs under 42 CFR §494.120 to address access to care issues due to COVID-19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care at §494.120(b) as this standard has been met during the period of the national emergency. Approval as a Special Purpose Renal Dialysis Facility related to COVID-19 does not require Federal survey prior to providing services.

- **Dialysis Patient Care Technician (PCT) Certification.** CMS is modifying the requirement at 42 CFR §494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. CMS is aware of the challenges that PCTs are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow PCTs to continue working even if they have not achieved certification within 18 months or have not met on time renewals.

- **Transferability of Physician Credentialing.** CMS is modifying the requirement at 42 CFR §494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. These waivers will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure to provide care at designated isolation locations without separate credentialing at that facility, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan**.**

- **Expanding Availability of Renal Dialysis Services to ESRD Patients.** CMS is waiving the following requirements related to Nursing Home residents:

    - **Furnishing Dialysis Services on the Main Premises:** ESRD requirements at 42 CFR §494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients who reside in the nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents are under the direction of the same governing body and professional staff as the resident's usual Medicare-certified dialysis facility.

Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: 1) furnish all dialysis care and services; 2) provide all equipment and supplies necessary; 3) maintain equipment and supplies in off-premises location; 4) and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer's instructions for use.

- **Clarification for Billing Procedures**. Typically, ESRD beneficiaries are transported from a SNF/NF to an ESRD facility to receive renal dialysis services. In an effort to keep patients in their SNF/NF and decrease their risk of being exposed to COVID-19, ESRD facilities may temporarily furnish renal dialysis services to ESRD beneficiaries in the SNF/NF instead of the offsite ESRD facility. The in-center dialysis center should bill Medicare using Condition Code 71 (Full care unit. Billing for a patient who received staff-assisted dialysis services in a hospital or renal dialysis facility). The in-center dialysis center should also apply condition code DR to claims if all the treatments billed on the claim meet this condition or modifier CR on the line level to identify individual treatments meeting this condition. The ESRD provider would need to have their trained personnel administer the treatment in the SNF/ NF. In addition, the provider must follow the CFCs. In particular, under the CFCs is the requirement that to use a dialysis machine, the FDA-approved labeling must be adhered to § 494.100 and it must be maintained and operated in accordance with the manufacturer's recommendations (§ 494.60) and follow infection control requirements at § 494.30.

Physical Environment for Multiple Providers/Suppliers

Inspection, Testing & Maintenance (ITM) under the Physical Environment Conditions of Participation: CMS is waiving certain physical environment requirements for Hospitals, CAHs, inpatient hospice, ICF/IIDs, and SNFs/NFs to reduce disruption of patient care and potential exposure/transmission of COVID-19. The physical environment regulations require that facilities and equipment be maintained to ensure an acceptable level of safety and quality.

CMS will permit facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.

- **Specific Physical Environment Waiver Information:**
    - 42 CFR §482.41(d) for hospitals, §485.623(b) for CAH, §418.110(c)(2)(iv) for inpatient hospice, §483.470(j) for ICF/IID; and §483.90 for SNFs/NFs all require these facilities and their equipment to be maintained to ensure an acceptable level of safety and quality. CMS is temporarily modifying these requirements to the extent necessary to permit these facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.
    - 42 CFR §482.41(b)(1)(i) and (c) for hospitals, §485.623(c)(1)(i) and (d) for CAHs, §482.41(d)(1)(i) and (e) for inpatient hospices, §483.470(j)(1)(i) and (5)(v) for ICF/IIDs,

and §483.90(a)(1)(i) and (b) for SNFs/NFs require these facilities to be in compliance with the Life Safety Code (LSC) and Health Care Facilities Code (HCFC). CMS is temporarily modifying these provisions to the extent necessary to permit these facilities to adjust scheduled ITM frequencies and activities required by the LSC and HCFC. The following LSC and HCFC ITM are considered critical are not included in this waiver:

- Sprinkler system monthly electric motor-driven and weekly diesel engine-driven fire pump testing.
- Portable fire extinguisher monthly inspection.
- Elevators with firefighters' emergency operations monthly testing.
- Emergency generator 30 continuous minute monthly testing and associated transfer switch monthly testing.
- Means of egress daily inspection in areas that have undergone construction, repair, alterations, or additions to ensure its ability to be used instantly in case of emergency.

- 42 CFR §482.41(b)(9) for hospitals, §485.623(c)(7) for CAHs, §418.110(d)(6) for inpatient hospices, §483.470(e)(1)(i) for ICF/IIDs, and §483.90(a)(7) for SNFs/NFs require these facilities to have an outside window or outside door in every sleeping room. CMS will permit a waiver of these outside window and outside door requirements to permit these providers to utilize facility and non-facility space that is not normally used for patient care to be utilized for temporary patient care or quarantine.

Specific Life Safety Code (LSC) for Multiple Providers - Waiver Information:

CMS is waiving and modifying particular waivers under 42 CFR §482.41(b) for hospitals; §485.623(c) for CAHs; §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs and §483.90(a) for SNF/NFs. Specifically, CMS is modifying these requirements as follows:

- **Alcohol-based Hand-Rub (ABHR) Dispensers:** We are waiving the prescriptive requirements for the placement of alcohol-based hand rub (ABHR) dispensers for use by staff and others due to the need for the increased use of ABHR in infection control. However, ABHRs contain ethyl alcohol, which is considered a flammable liquid, and there are restrictions on the storage and location of the containers. This includes restricting access by certain patient/resident population to prevent accidental ingestion. Due to the increased fire risk for bulk containers (over five gallons) those will still need to be stored in a protected hazardous materials area.

  Refer to: 2012 LSC, sections 18/19.3.2.6. In addition, facilities should continue to protect ABHR dispensers against inappropriate use as required by 42 CFR §482.41(b)(7) for hospitals; §485.623(c)(5) for CAHs; §418.110(d)(4) for inpatient hospice; §483.470(j)(5)(ii) for ICF/IIDs and §483.90(a)(4) for SNF/NFs.

- **Fire Drills:** Due to the inadvisability of quarterly fire drills that move and mass staff together, we will instead permit a documented orientation training program related to the current fire plan, which considers current facility conditions. The training will instruct employees,

including existing, new or temporary employees, on their current duties, life safety procedures and the fire protection devices in their assigned area.

Refer to: 2012 LSC, sections 18/19.7.1.6.

- **Temporary Construction:** CMS is waiving requirements that would otherwise not permit temporary walls and barriers between patients.

  Refer to: 2012 LSC, sections 18/19.3.3.2.

Intermediate Care Facility for Individuals with Intellectual Disabilities

- **Staffing Flexibilities.** CMS is waiving the requirements at 42 CFR §483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. DSS perform activities such as cleaning of the facility, cooking, and laundry services. DSC perform activities such as teaching clients appropriate hygiene, budgeting, or effective communication and socialization skills. During the time of this waiver, DCS may be needed to conduct some of the activities normally performed by the DSS. This will allow facilities to adjust staffing patterns, while maintaining the minimum staffing ratios required at §483.430(d)(3).

- **Suspension of Community Outings.** CMS is waiving the requirements at 42 CFR §483.420(a)(11) which requires clients have the opportunity to participate in social, religious, and community group activities. The federal and/or state emergency restrictions will dictate the level of restriction from the community based on whether it is for social, religious, or medical purposes. States may have also imposed more restrictive limitations. CMS is authorizing the facility to implement social distancing precautions with respect to on and off-campus movement. State and Federal restrictive measures should be made in the context of competent, person-centered planning for each client.

- **Suspend Mandatory Training Requirements.** CMS is waiving, in-part, the requirements at 42 CFR §483.430(e)(1) related to routine staff training programs unrelated to the public health emergency. CMS is not waiving 42 CFR §483.430(e)(2)-(4) which requires focusing on the clients' developmental, behavioral and health needs and being able to demonstrate skills related to interventions for inappropriate behavior and implementing individual plans. We are not waiving these requirements as we believe the staff ability to develop and implement the skills necessary to effectively address clients' developmental, behavioral and health needs are essential functions for an ICF/IID. CMS is also not waiving initial training for new staff hires or training for staff around prevention and care for the infection control of COVID-19. It is critical that new staff gain the necessary skills and understanding of how to effectively perform their role as they work with this complex client population and that staff understand how to prevent and care for clients with COVID-19.

- **Modification of Adult Training Programs and Active Treatment.** CMS recognizes that during the public health emergency, active treatment will need to be modified. The requirements at 42 CFR §483.440(a)(1) require that each client must receive a continuous active treatment program, which includes consistent implementation of a program of specialized and generic training, treatment, health services and related services.

  CMS is waiving those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only. For example, although day habilitation programs and supported employment are important opportunities for training and socialization of clients at intermediate care facilities for individuals with developmental disabilities, these programs pose too high of a risk to staff and clients for exposure to a person with suspected or confirmed COVID-19. In accordance with §483.440(c)(1), any modification to a client's Individual Program Plan (IPP) in response to treatment changes associated with the COVID-19 crisis requires the approval of the interdisciplinary team. For facilities that have interdisciplinary team members who are unavailable due to the COVID-19, CMS would allow for a retroactive review of the IPP under 483.440(f)(2) in order to allow IPPs to receive modifications as necessary based on the impact of the COVID-19 crisis.

Ambulatory Surgical Centers (ASCs)

- **Medical Staff.** 42 CFR 416.45(b). CMS is waiving the requirement at § 416.45(b) that medical staff privileges must be periodically reappraised, and the scope of procedures performed in the ASC must be periodically reviewed. This will allow for physicians whose privileges will expire to continue practicing at the ambulatory surgical center, without the need for reappraisal, and for ASCs to continue operations without performing these administrative tasks during the PHE. This waiver will improve the ability of ASCs to maintain their current workforce during the PHE.

Community Mental Health Clinics (CMHCs)

- **Quality assessment and performance improvement (QAPI).** 42 CFR 485.917(a)-(d) We are modifying the requirements for CMHC's quality assessment and performance improvement (QAPI). Specifically, we are retaining the overall requirement that CMHC's maintain an effective, ongoing, CMHC-wide, data-driven QAPI program, while providing flexibility for CMHCs to use their QAPI resources to focus on challenges and opportunities for improvement related to the PHE by waiving the specific detailed requirements for the QAPI program's organization and content at § 485.917(a)-(d). Waiving the requirements related to the details of the QAPI program's organization and content will make it easier for CMHCs to reconfigure their QAPI programs, as needed, to adapt to specific needs and circumstances that arise during the PHE. These flexibilities may be implemented so long as they are consistent with a state's emergency preparedness or pandemic plan.

- **Provision of Services.** 42 CFR 485.918(b)(1)(iii). We are waiving the specific requirement at § 485.918(b)(1)(iii) that prohibits CMHCs from providing partial hospitalization services and other CMHC services in an individual's home so that clients can safely shelter in place during the PHE while continuing to receive needed care and services from the CMHC. This waiver is a companion to recent regulatory changes (INSERT IFR CITATION WHEN RELEASED) that clarify how CMHCs should bill for services provided in an individual's home, and how such services should be documented in the medical record. While this waiver will now allow CMHCs to furnish services in client homes, including through the use of using telecommunication technology, CMHCs continue to be, among other things, required to comply with the non-waived provisions of 42 CFR Part 485, Subpart J, requiring that CMHCs: 1) assess client needs, including physician certification of the need for partial hospitalization services, if needed; 2) implement and update each client's individualized active treatment plan that sets forth the type, amount, duration, and frequency of the services; and 3) promote client rights, including a client's right to file a complaint.

- **40 Percent Rule.** 42 CFR 485.918(b)(1)(v) We are waiving the requirement at § 485.918(b)(1)(v) that a CMHC provides at least 40 percent of its items and services to individuals who are not eligible for Medicare benefits. Waiving the 40 percent requirement will facilitate appropriate timely discharge from inpatient psychiatric units and prevent admissions to these facilities because CMHCs will be able to provide PHP services to Medicare beneficiaries without restrictions on the proportion of Medicare beneficiaries that they are permitted to treat at a time. This will allow communities greater access to health services, including mental health services.

Ambulance Services: Medicare Ground Ambulance Data Collection System *(New since May 11 Release)*

- CMS is modifying the data collection period and data reporting period, as defined at 42 CFR § 414.626(a), for ground ambulance organizations (as defined at 42 CFR § 414.605) that were selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626. Under this modification, these ground ambulance organizations can select a new continuous 12-month data collection period that begins between January 1, 2021 and December 31, 2021, collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument during their selected data collection period, and submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. CMS is modifying this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020-2021 so that they can focus on their operations and patient care.

  As a result of this modification, ground ambulance organizations selected for year 1 data collection and reporting will collect and report data during the same period of time that will

apply to ground ambulance organizations selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626.

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)

- When DMEPOS is lost, destroyed, irreparably damaged, or otherwise rendered unusable, CMS is allowing DME Medicare Administrative Contractors (MACs) to have the flexibility to waive replacements requirements such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable as a result of the emergency.

Practitioner Locations

CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: 1) must be enrolled as such in the Medicare program; 2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; 3) is furnishing services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, 4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

- In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the state. Therefore, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state.

Provider Enrollment

- **Non-Waiver CMS Action:** CMS has a toll-free hotline for physicians and non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges.

- Waive the following screening requirements:
    - Application Fee - (to the extent applicable).
    - Criminal background checks associated with fingerprint-based criminal background checks (FCBC) (to the extent applicable) - 42 CFR §424.518.
    - Site visits (to the extent applicable) - 42 CFR §424.517.
- Postpone all revalidation actions.
- Allow licensed providers to render services outside of their state of enrollment.
- Expedite any pending or new applications from providers.
- Allow physicians and other practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location.
- Allow opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

Modification of 60-Day Limit for Substitute Billing Arrangements (Locum Tenens)

CMS is modifying the 60-day limit in section 1842(b)(6)(D)(iii) of the Social Security Act to allow a physician or physical therapist to use the same substitute for the entire time he or she is unavailable to provide services during the COVID-19 emergency plus an additional period of no more than 60 continuous days after the public health emergency expires. On the 61st day after the public health emergency ends (or earlier if desired), the regular physician or physical therapist must use a different substitute or return to work in his or her practice for at least one day in order to reset the 60-day clock. Without this flexibility, the regular physician or physical therapist generally could not use a single substitute for a continuous period of longer than 60 days, and would instead be required to secure a series of substitutes to cover sequential 60-day periods. The modified timetable applies to both types of substitute billing arrangements under Medicare fee-for-service (i.e., reciprocal billing arrangements and fee-for-time compensation arrangements (formerly known as locum tenens)).

Notes: Under the Medicare statute, only 1) physicians and 2) physical therapists who furnish outpatient physical therapy services in a health professional shortage area (HPSA), a medically underserved area (MUA), or a rural area can receive Medicare fee-for-service payment for services furnished by a substitute under a substitute billing arrangement. In addition, Medicare can pay for services under a substitute billing arrangement only when the regular physician or physical therapist is unavailable to provide the services. Finally, as provided by law, a regular physician or physical therapist who has been called or ordered to active duty as a member of a reserve component of the Armed Forces may continue to use the same substitute for an unlimited time even after the emergency ends.

Medicare Appeals in Fee for Service (FFS), Medicare Advantage (MA) and Part D

CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program pursuant to 42 CFR §405.942 and 42 CFR §405.962 (including for MA and Part D plans), as well as the MA and Part D Independent Review Entities (IREs) under 42 CFR §422.562, 42 CFR §423.562, 42 CFR §422.582 and 42 CFR §423.582, to allow extensions to file an appeal**.** CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 and the MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals.

- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.910 and MA and Part D plans, as well as the MA and Part D IREs, to process an appeal even with incomplete Appointment of Representation forms as outlined under 42 CFR §422.561 and 42 CFR §423.560. However, any communications will only be sent to the beneficiary.

- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs, to process requests for appeals that do not meet the required elements using information that is available as outlined within 42 CFR §422.561 and 42 CFR §423.560.

- CMS is allowing MACs and QICs in the FFS program under 42 CFR §405.950 and 42 CFR §405.966 (also including MA and Part D plans), as well as the MA and Part D IREs under 42 CFR §422.562 and 42 CFR §423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Medicaid and CHIP (as of 3/13/2020)

States and territories can request approval that certain statutes and implementing regulations be waived by CMS, pursuant to section 1135 of the Act. To assist states in this process, CMS released an 1135 Waiver Checklist to make it easier for states to receive federal waivers and implement flexibilities in their Medicaid and CHIP programs. States' use of this 1135 checklist will expedite their ability to apply for and receive approval for 1135 waivers that are now available under the President's national emergency declaration.

States and territories may submit a Section 1135 waiver request directly to their Center for Medicaid & CHIP Services (CMCS) state lead or Jackie Glaze, Acting Director, Medicaid & CHIP Operations Group, Center for Medicaid & CHIP Services at CMS by e-mail (**Jackie.Glaze@cms.hhs.gov**) or letter.

The following are examples of flexibilities that states and territories may seek through a Section 1135 waiver request:

- Waive prior authorization requirements in fee-for-service programs.
- Permits providers located out of state/territory to provide care to another state's Medicaid enrollee impacted by the emergency.
- Temporarily suspend certain provider enrollment and revalidation requirements to increase access to care.
- Temporarily waive requirements that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have an equivalent licensing in another state; and,
- Temporarily suspend requirements for certain pre-admission and annual screenings for nursing home residents.

States and territories are encouraged to assess their needs and request these available flexibilities, which are more completely outlined in the Medicaid and CHIP Disaster Response Toolkit. For more information and to access the toolkit and the **1135 waiver checklist**, visit: **https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html**.

ATTACHMENT A

Blanket Waivers of Sanctions under the Physician Self- Referral Law (also known as the "Stark Law")

CMS has issued blanket waivers of sanctions under section 1877(g) of the Act. The blanket waivers may be used now without notifying CMS. Individual waivers of sanctions under section 1877(g) of the Act may be granted upon request. For more information, visit: **https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight.**

For resources and additional information on 1135 Waivers, please also visit:

- **https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page**
- **https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers**

For questions, please email: **1135waiver@cms.hhs.gov**

Blanket Waivers: Stafford Act, Public Health Emergency (PHE) and Section 1135 Waivers

Background

On March 13, 2020, the President issued an emergency declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the "Stafford Act") to declare a national health emergency. The Secretary of the Department of Health and Human Services (the Secretary) is authorized to waive certain Medicare, Medicaid and Children's Health Insurance Program (CHIP) program requirements and conditions of participation under Section 1135 of the Social Security Act once the President has declared an emergency through the Stafford Act[1] and the Secretary has declared a Public Health Emergency (PHE). The Secretary issued a PHE on January 31, 2020[2]. As a result of this authority, CMS can grant waivers that will ease certain requirements for affected providers as stated under Section 1135 of the Social Security Act[3].

CMS can issue two types of waivers: blanket waivers and provider/supplier requested waivers. Specifics about the two types of waivers are outlined in detail below. Examples of these 1135 waivers or modifications include:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure)
- Emergency Medical Treatment and Labor Act (EMTALA)
- Sanctions under the physician self-referral law (also known as the "Stark Law")
- Performance deadlines and timetables may be adjusted (but not waived)
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers

Waivers under Section 1135 of the Social Security Act typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published. The Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.

[1] https://www.whitehouse.gov/wp-content/uploads/2020/03/LetterFromThePresident.pdf

[2] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx

[3] https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx

The 1135 waiver authority applies **only** to Federal requirements and **does not apply** to State requirements for licensure or conditions of participation.

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for Skilled Nursing Facilities (SNF) coverage in the absence of a qualifying hospital stay, as long as this action does not increase overall program payments and does not alter the SNF benefit's "acute care nature" (that is, its orientation toward relatively short-term and intensive care).

Federally certified/approved providers must continue to operate under normal rules and regulations, unless they have sought and have been granted modifications under the waiver authority from specific requirements.

In addition, the Coronavirus Preparedness and Response Supplemental Appropriations Act, as signed into law by the President on March 6, 2020, includes a provision allowing the Secretary to waive certain Medicare telehealth payment requirements during the PHE the Secretary declared on January 31, 2020 to allow beneficiaries in all areas of the country to receive telehealth services, including at their home. Under the waiver, limitations on where Medicare patients are eligible for telehealth will be removed during the emergency. In particular, patients outside of rural areas, and patients in their homes will be eligible for telehealth services, effective for services starting March 6, 2020[4].

[4] **https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf**

CMS Section 1135 Waiver Authority: Blanket Waivers, Provider/Supplier Individual Waivers, Medicaid and Special Waivers

Medicare Blanket Waivers

- **Approval:** CMS implements specific waivers or modifications under the 1135 authority on a "blanket" basis when a determination has been made that all similarly situated providers in the emergency area need such a waiver or modification. These waivers prevent gaps in access to care for beneficiaries impacted by the emergency. **Once approved these waivers apply automatically to all applicable providers and suppliers. Providers and suppliers do not need to apply for an individual waiver if a blanket waiver is issued by CMS.**

- **Claims Submission for Blanket Waivers:** When submitting claims covered by the blanket waivers, the "DR" (disaster-related) condition code should be used for institutional billing (i.e., claims submitted using the ASC X12 837 institutional claims format or paper Form CMS-1450). The "CR" (catastrophe/disaster-related) modifier should be used for Part B billing, both institutional and non-institutional (i.e., claims submitted using the ASC X12 837 professional claim format or paper Form CMS-1500 or, for pharmacies, in the NCPDP format). This requirement does not apply for purposes of compliance with waivers (blanket or individual) of sanctions under the physician self- referral law.

Medicare Provider/Supplier Individual Waivers

- **Approval:** Providers and suppliers can submit requests for individual 1135 waivers. These requests must include a justification for the waiver and expected duration of the modification requested. The State Survey Agency and CMS Survey Operations Group will review the provider's request and make appropriate decisions, usually on a case-by- case basis. Providers and suppliers should keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made. Providers are expected to come into compliance with any waived requirements prior to the end of the emergency period.

- With the exception of physician self-referral law waivers, the process for requesting an 1135 waiver is managed through the Survey Operations Group, and CMS locations, previously known as the CMS Regional Offices. More information on the process is located at **https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers**. The website includes contact information for each CMS location. Facilities should ensure to review the process and identify the appropriate contact based on the location of the facility.

Examples of Individual Requests for 1135 Waivers
An individual hospital may request a waiver of COPs related to doubling of single occupancy patient rooms or a waiver of the requirement to discharge to a specified location or situation.

Waiver Request Process
You **do not** have to make a request for a blanket waiver that has already been issued, and you **do not** have to notify CMS if you are taking action in accordance with a waiver during the time period in which the waiver is valid. If you are requesting an 1135 waiver outside of those outlined in this document or are already available at the CMS **Current Emergencies** page, please send your request or questions about a request to **1135waiver@cms.hhs.gov**.

Medicaid Waivers

Approval
CMS works with the states and territories to respond to public health emergencies and disasters. States and territories have multiple strategies available to support Medicaid and CHIP Operations and enrollees in times of crisis. Some of these strategies are available without needing approval from CMS while some disaster-related and Public Health Emergency legal authorities include:

- Medicaid State Plan Amendments;
- CHIP Disaster Relief State Plan Amendments;
- Verification Plans;
- 1915(c) Waivers Appendix K;
- 1135 Waivers; and
- 1115 Demonstrations.

In Medicaid and CHIP, 1135 waivers can be used to implement a range of flexibilities. Some of these include: provider enrollment and participation; Medicaid prior authorization requirements; pre-admission screening and annual resident review (PASARR) Level I and Level II Assessments for 30 days; extend minimum data set authorizations for nursing facility and SNF residents; state fair hearing and appeal process timelines; and reporting and oversight. Under 1135 waivers, states also have flexibility on public notice, tribal consultation, and the effective dates of state plan amendment (SPA) submissions. For public notice, Section 1135 authority can be used to provide flexibility related to the need and timing for public notice associated with cost sharing, Alternative Benefit Plan (ABP) benefit and payment SPAs. Section 1135 authority can be used to provide flexibility related to the timing of tribal consultation including shortening consultation or conducting tribal consultation after submission of the SPA. For SPA submission dates, Section 1135 authority can be utilized to effectively permit states to submit a Medicaid SPA after the end of this quarter and still have an effective date retroactive to the date of the declaration by the Secretary of a Public Health Emergency.

In the event of a disaster or public health emergency, state Medicaid agencies should contact CMS for questions and waiver requests. More information on this process is located at: https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html

Special Waivers

EMTALA:

Only two aspects of the EMTALA requirements can be waived under 1135 Waiver Authority: 1) Transfer of an individual who has not been stabilized, if the transfer arises out of an emergency or, 2) Redirection to another location (offsite alternate screening location) to receive a medical screening exam under a state emergency preparedness or pandemic plan. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate as to source of payment or ability to pay. Hospitals are generally able to manage the separation and flow of potentially infectious patients through alternate screening locations on the hospital campus.

Therefore, waivers to provide Medical Screening Examinations at an offsite alternate screening location not owned or operated by the hospital will be reviewed on a case-by-case basis. Please note, there is no waiver authority available for any other EMTALA requirement.

For the duration of the COVID-19 national emergency, CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and CAHs to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, in accordance with the state emergency preparedness or pandemic plan.

Individual Physician Self-Referral Law Waiver Requests:

CMS has issued blanket waivers of sanctions under the physician self-referral law. The blanket waivers may be used now without notifying CMS. For more information, visit: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight.

Unlike other 1135 waiver requests, any requests for individual waivers of sanctions under the physician self- referral law related to COVID-19 will be handled by CMS Baltimore. Please send your request to 1877CallCenter@cms.hhs.gov and include the words "Request for 1877(g) Waiver" in the subject line of the email. All requests should include the following minimum information:

- Name and address of requesting entity;
- Name, phone number and email address of person designated to represent the entity;
- CMS Certification Number (CCN) or Taxpayer Identification Number (TIN);
- Nature of request.

Individual waivers may be granted only upon request and on a case-by-case basis and require specific details concerning the actual or proposed financial relationship between the referring physician(s) and the referred-to entity. Unless and until a waiver of sanctions under the physician self-referral law (i.e., a waiver of section 1877(g) of the Social Security Act) is granted to the requesting party(ies), such party(ies) must comply with section 1877 of the Social Security Act and the regulations at 42 CFR §411.350 et seq.

Helpful Website Resources

- **Approved 1135 Waivers:** https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf
- **Approved Telehealth Waivers:** https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet
- **1135 Waiver Request Information:** https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers
- **Medicare Fee-For-Service Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only With an §1135 Waiver:** https://www. cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf
- **Blanket Waivers – Claims Submission:** https://www.cms.gov/files/document/se20011.pdf
- **Frequently Asked Questions – 1135 Waivers:** https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/MedicareFFS-EmergencyQsAs1135Waiver.pdf
- **Frequently Asked Questions – non-1135 Waivers:** https://www.cms.gov/About-CMS/ Agency-Information/Emergency/Downloads/Consolidated_Medicare_FFS_Emergency_ QsAs.pdf
- **Medicaid Disaster Response Toolkit:** https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/index.html

CMS Oversight

CMS remains committed to ensuring continuity of oversight activities during a national public health emergency. We continue to work State Survey Agencies and accrediting organizations, charged with inspecting Medicare and Medicaid providers to ensure compliance with Federal requirements, to ensure these activities are prioritized to allow providers to focus on current health and safety threats and provide needed care to beneficiaries. We will continue to monitor program operations to support proper enrollment and accurate billing practices. CMS will coordinate our oversight activities with the OIG and GAO.

Exhibit A-43

Coronavirus Waivers & Flexibilities

In certain circumstances, the Secretary of the Department of Health and Human Services (HHS) using section 1135 of the Social Security Act (SSA) can temporarily modify or waive certain Medicare, Medicaid, CHIP, or HIPAA requirements, called 1135 waivers. There are different kinds of 1135 waivers, including Medicare blanket waivers. When there's an emergency, sections 1135 or 1812(f) of the SSA allow us to issue blanket waivers to help beneficiaries access care. When a blanket waiver is issued, providers don't have to apply for an individual 1135 waiver. When there's an emergency, we can also offer health care providers other flexibilities to make sure Americans continue to have access to the health care they need.

NEW – Waivers & flexibilities for health care providers

Learn how we're easing burden and helping providers care for Americans by offering **new waivers and flexibilities**:

- COVID-19 Emergency Declaration Blanket Waivers & Flexibilities for Health Care Providers (PDF) UPDATED (5/15/20)
- Blanket waivers of Section 1877(g) of the Social Security Act (3/30/20)
- Medicare and Medicaid IFC: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (CMS-5531 IFC) (PDF) (4/30/20)
  - IFC Federal Register Announcement (5/4/20)
- List of Hospital Outpatient Services and List of Partial Hospitalization Program Services Accompanying the 4/30/2020 IFC (ZIP) (4/30/20)
- List of lab test codes for COVID-19, Influenza, RSV (PDF) (5/12/20)
- Medicare IFC: Revisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC) (PDF) (3/30/20)
  - IFC Federal Register Announcement (4/1/20)
- COVID-19 Regulations & Waivers To Enable Health System Expansion (PDF) (5/4/20)
- Graphic Overview of Flexibilities (PDF) (3/30/20)
- Frequently Asked Questions to Assist Medicare Providers (PDF) UPDATED (5/15/20)
- Provider Burden Relief Frequently Asked Questions (PDF) UPDATED (4/23/20)
- Provider Enrollment Relief Frequently Asked Questions (PDF) (3/30/20)
- Updates for State Surveyors and Accrediting Organizations (EMTALA and Infection Control) (3/30/20)
- Reprioritization of PACE, Medicare Parts C and D Program, and Risk Adjustment Data Validation (RADV) Audit Activities (HPMS Memo) (3/30/20)

Read our provider-specific fact sheets on new **waivers and flexibilities**:

- Home Health Agencies (PDF) UPDATED (5/15/20)

- Physicians and Other Practitioners (PDF) UPDATED (4/30/20)
- Ambulances (PDF) UPDATED (5/15/20)
- Hospitals (PDF) UPDATED (5/15/20)
- Teaching Hospitals, Teaching Physicians and Medical Residents (PDF) UPDATED (5/15/20)
- Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities) (PDF) UPDATED (5/15/20)
- Hospices (PDF) UPDATED (5/15/20)
- Inpatient Rehabilitation Facilities (PDF) UPDATED (4/30/20)
- Long Term Care Hospitals & Extended Neoplastic Disease Care Hospitals (PDF) UPDATED (4/30/20)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (PDF) UPDATED (4/30/20)
- Laboratories (PDF) UPDATED (4/30/20)
- End Stage Renal Disease (ESRD) Facilities (PDF) UPDATED (5/15/20)
- Durable Medical Equipment (PDF) UPDATED (4/30/20)
- Participants in the Medicare Diabetes Prevention Program (PDF)-UPDATED (5/14/20)
- Medicare Advantage and Part D Plans (PDF) UPDATED (4/30/20)
- State Medicaid & Basic Health Programs (4/30/20)
- Medicare Shared Savings Program Participants (PDF) (4/30/20)

1135 blanket waivers

What do I need to know about 1135 blanket waivers?

If you're an entity in the declared emergency area, you can apply for an 1135 waiver. You'll usually hear back from us within 2-3 days, but if your request is more complicated, it may take up to a week. If your waiver request has 1 or 2 items, we may get back to you within 24 hours.

Once approved, waivers have a retroactive effective date of **March 1, 2020** and will end no later than when the emergency declaration's ended.

Waivers don't offer grants or financial assistance. They also don't allow you to be paid for services that aren't usually covered or for people to be eligible for Medicare who aren't otherwise eligible. You also shouldn't base your response decisions, like evacuations, on waivers. Once your waiver's approved, as always to be reimbursed accurately, be sure to keep careful records about the services you provide and the beneficiaries you provide them to.

1812(f) waiver

Approved Coronavirus 1812(f) waiver (PDF)

Other 1135 waivers & 1915(c) waivers

Waiver resources

- Section 1135 Waiver Checklist (3/22/20)

- Section 1915 Waiver, Appendix K Template (3/22/20)

Approved states' other Coronavirus 1135 waivers

States' other Coronavirus 1135 waivers

- Alabama-1st request; 2nd request
- Alaska
- Arizona-1st request; 2nd request
- Arkansas-1st request; 2nd request
- California-1st request; 2nd request
- Colorado
- Commonwealth of Northern Mariana Islands
- Connecticut-1st request; updated 1st request
- Delaware
- District of Columbia-1st request; 3rd request
- Florida
- Georgia-1st request; 2nd request
- Hawaii
- Idaho
- Illinois
- Indiana-1st request; updated 1st request
- Iowa-1st request; 2nd request
- Kansas
- Kentucky
- Louisiana-1st request; 2nd & 3rd requests
- Maine
- Maryland-1st request; 2nd request
- Massachusetts-1st request; 3rd request
- Michigan
- Minnesota-1st request; 2nd request
- Mississippi
- Missouri-1st request; updated 1st request
- Montana
- Nebraska-1st request; 2nd request
- Nevada
- New Hampshire
- New Jersey
- New Mexico
- New York-1st request; second request
- North Carolina
- North Dakota
- Ohio
- Oklahoma

- Oregon-1st request; second request
- Pennsylvania
- Puerto Rico
- Rhode Island
- South Carolina
- South Dakota
- Tennessee
- Texas
- U.S. Virgin Islands
- Utah
- Vermont
- Virginia
- Washington-1st request; 2nd request
- West Virginia
- Wisconsin
- Wyoming

Approved states' Coronavirus Home & Community Based (HCBS) 1915(c) Appendix K waivers

States' Coronavirus Emergency Preparedness and Response for HCBS 1915(c) Appendix K waivers

Approved states' 1115 demonstrations

States' Medicaid Coronavirus 1115 demonstrations

Medicaid State Plan amendments

States' Medicaid State Plan amendments

CHIP State Plan amendments

States' CHIP Plan amendments

Learn more about:

- Flexibilities with 1135 waivers (PDF)
- Flexibilities without 1135 waivers (PDF)

Find general information about waivers and flexibilities.

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Help with File Formats and Plug-Ins

Home CMS.gov

A federal government website managed and paid for by the U.S. Centers for Medicare & Medicaid Services. 7500 Security Boulevard, Baltimore,

MD 21244

Receive Email Updates

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Connect with CMS

Exhibit A-44

Emergency Use Authorization

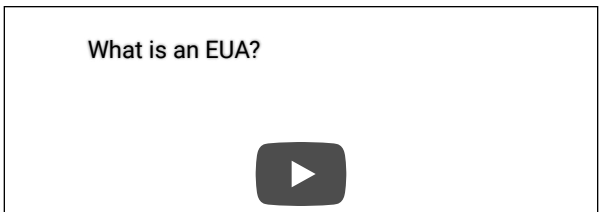
Emergency Use Authorization (EUA) information, and list of all current EUAs

On this page:

Español (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/autorizacion-de-uso-de-emergencia)

About Emergency Use Authorizations (EUAs)

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies.



Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act (/federal-food-drug-and-cosmetic-act-fdc-act)), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Section 564 of the FD&C Act was amended by the Project Bioshield Act of 2004 (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#bioshield) and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra) (PAHPRA), the 21st Century Cures Act (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#21CC) of 2016, and Public Law 115-92 (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#PL11592) of 2017.

Guidance

In January 2017, FDA finalized the guidance: Emergency Use Authorization of Medical Products and Related Authorities (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities). For more information, please see the January 13, 2017 Federal Register notice (https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and).

Printable PDF (288 KB) (/media/97321/download)

In February 2020, FDA issued an Immediately in Effect Guidance on policy for diagnostics testing (/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised) in laboratories certified to perform high complexity testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the public health emergency. For more information, please see the March 6, 2020, Federal Register notice (https://www.federalregister.gov/documents/2020/03/06/2020-04630/policy-for-diagnostics-testing-in-laboratories-certified-to-perform-high-complexity-testing-under).

Questions & Answers

- In March 2020, FDA posted FAQs on Diagnostic Testing for SARS-CoV-2 (/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2).
- In January 2014, FDA issued a question and answer document (/media/87718/download) (PDF, 762K) to respond to questions raised by public health stakeholders about PAHPRA's amendments to the EUA authority and establishment of new authorities related to the emergency use of MCMs during CBRN emergencies.

Emergency Diagnostics Information

- Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) (current device EUAs)
- How to Submit a Pre-EUA for *In vitro* Diagnostics (IVDs) to FDA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda) (for test manufacturers)
- Information for Laboratories Implementing IVD Tests Under EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua)

Coronavirus Disease 2019 (COVID-19) EUA Information

- **Coronavirus Disease (COVID-19) updates from FDA** (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)
- **Overviews:**
  - **FDA Combating COVID-19 With Medical Devices (/media/136702/download)** (PDF, 708 KB)
  - **FDA Combating COVID-19 With Therapeutics** (/media/136832/download) (PDF, 610 KB)
  - **EUA Authorized Serology Test Performance (/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance)**
- **Detailed Information for all COVID-19 EUAs, including authorizations and fact sheets**
  - In Vitro Diagnostic Products
  - High Complexity Molecular-Based Laboratory Developed Tests
  - SARS-CoV-2 Antibody Tests
  - Personal Protective Equipment and Related Devices
  - Ventilators and Other Medical Devices
  - Therapeutics

In Vitro Diagnostic Products

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19. The EUAs subsequently issued by FDA are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency) (February 4, 2020)

In continuing response to the COVID-19 pandemic, on March 24, 2020, and based on the February 4, 2020 HHS EUA determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration) (March 24, 2020)

On February 29, 2020, the FDA issued an immediately in effect guidance (/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised) with policy specific to development of in vitro diagnostic tests during this public health emergency. This guidance was updated on March 16, 2020, May 4, 2020, and May 11, 2020.

CDC has granted a right of reference to the performance data contained in CDC's EUA (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for these EUA submissions (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivdTemplates) are available to help facilitate the preparation, submission, and authorization of an EUA.

If you need additional information, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2 (/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2).

The HHS Secretary issued a Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

- Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures) (February 4, 2020)

Please note: a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020 (https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx), does not enable FDA to issue EUAs. A separate determination and declaration are needed under section 564 of the Federal Food, Drug and Cosmetic Act to enable FDA to issue EUAs,

provided other statutory criteria are met.

Show 10 entries

Date EUA First Issued	Entity	Diagnostic (Most Recent Letter of Authorization) in PDF	Technology	Authorized Setting(s)[1] (ivdnote2)	Authorization Labeling[2] in PDF
+ 05/15/2020	Everlywell, Inc.	Everlywell COVID-19 Test Home Collection Kit (/media/138144/download) (307KB)	Home Collection Kit	N/A	IFU (/media/138145/download) (624KB) EUA Summary (/media/138146/download) (351KB)
+ 05/15/2020	Fulgent Therapeutics, LLC	Fulgent COVID-19 by RT-PCR Test (/media/138147/download) (288KB)	Molecular	H	HCP (/media/138148/download) (138KB) Patients (/media/138149/download) (126KB) EUA Summary (/media/138150/download) (385KB)
+ 05/15/2020	Assurance Scientific Laboratories	Assurance SARS-CoV-2 Panel (/media/138151/download) (287KB)	Molecular	H	HCP (/media/138152/download) (137KB) Patients (/media/138153/download) (125KB) EUA Summary (/media/138154/download) (400KB)
+ 05/14/2020	Hologic, Inc.	Aptima SARS-CoV-2 assay (/media/138097/download) (131KB)	Molecular	H	HCP (/media/138095/download) (108KB) Patients (/media/138098/download) (97KB) IFU (/media/138096/download) (403KB)
+ 05/14/2020	GeneMatrix, Inc.	NeoPlex COVID-19 Detection Kit (/media/138101/download) (135KB)	Molecular	H	HCP (/media/138099/download) (109KB) Patients (/media/138102/download) (98KB) IFU (/media/138100/download) (847KB)
+ 05/13/2020	Applied DNA Sciences, Inc.	Linea COVID-19 Assay Kit (/media/138060/download) (393KB)	Molecular	H	HCP (/media/138058/download) (252KB) Patients (/media/138061/download) (191KB) IFU (/media/138059/download) (210KB)
+ 05/11/2020	1drop Inc.	1copy COVID-19 qPCR Multi Kit (/media/137934/download) (395KB)	Molecular	H	HCP (/media/137933/download) (347KB) Patients (/media/137936/download) (264KB) IFU (/media/137935/download) (2.61MB)
+ 05/11/2020	Abbott Molecular Inc.	Alinity m SARS-CoV-2 assay (/media/137980/download) (394KB)	Molecular	H	HCP (/media/137978/download) (248KB) Patients (/media/137981/download) (189KB) IFU (/media/137979/download) (960KB)
+ 05/08/2020	Quidel Corporation	Sofia 2 SARS Antigen FIA (/media/137886/download) (138KB)	Antigen	H, M, W	HCP (/media/137884/download) (110KB) Patients (/media/137887/download) (100KB) IFU (/media/137885/download) (1.3MB)

Date EUA First Issued	Entity	Diagnostic (Most Recent Letter of Authorization) in PDF	Technology	Authorized Setting(s)[1] (ivdnote2)	Authorization Labeling[2] in PDF
+ 05/08/2020	Gnomegen LLC	Gnomegen COVID-19-RT-qPCR Detection Kit (/media/137892/download) (314KB)	Molecular	H	HCP (/media/137893/download) (135KB) Patients (/media/137894/download) (123KB) IFU (/media/137895/download) (1.36MB)

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[1] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

High Complexity Molecular-Based Laboratory Developed Tests

On March 31, 2020, the FDA concluded based on the totality of scientific evidence available that molecular-based laboratory developed tests (LDTs) that are authorized for use by the singular developing laboratory are appropriate to protect the public health or safety (as described under the Scope of Authorization (Section II)) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. Â§ 360bbb-3). Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. Â§263a to perform high complexity tests.

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/media/136598/download) (144KB)
- Fact Sheet for Healthcare Providers (/media/136599/download) (134KB)
- Fact Sheet for Patients (/media/136600/download) (123KB)
- See the table below for a current list of included laboratories and their LDTs

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Date of EUA Issuance	Laboratory	Letter Granting Inclusion Under EUA in PDF	EUA Summary in PDF
05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/media/138062/download) (222KB)	EUA Summary (/media/138063/download) (394KB
05/13/2020	Cedars-Sinai Medical Center, Department of Pathology and Laboratory Medicine	SARS-CoV-2-Assay (/media/138064/download) (223KB)	EUA Summary (/media/138065/download) (424KB)
05/12/2020	Columbia University Laboratory of Personalized Genomic Medicine	Triplex CII-CoV-1 rRT-PCR Test (/media/137982/download) (214KB)	EUA Summary (/media/137983/download) (768KB)
05/07/2020	Biocollections Worldwide, Inc.	Biocollections Worldwide SARS-Co-V-2 Assay (/media/137896/download) (120KB)	EUA Summary (/media/137897/download) (365KB)
05/03/2020	UTMG Pathology Laboratory	UTHSC/UCH SARS-CoV-2-RT-PCR Assay (/media/137654/download) (218KB)	EUA Summary (/media/137656/download) (269KB)
04/30/2020	Altru Diagnostics, Inc.	Altru Dx SARS-CoV-2 RT-PCR assay (/media/137545/download) (78KB)	EUA Summary (/media/137546/download) (143KB)
04/28/2020	Biocerna	SARS-CoV-2 Test (/media/137451/download) (218KB)	EUA Summary (/media/137450/download) (307KB)

Date of EUA Issuance	Laboratory	Letter Granting Inclusion Under EUA in PDF	EUA Summary in PDF
04/27/2020	Nationwide Children's Hospital	SARS-CoV-2 Assay (/media/137424/download) (67KB)	EUA Summary (/media/137423/download) (185KB)
04/24/2020	AIT Laboratories	SARS-CoV-2 Assay (/media/137373/download) (120KB)	EUA Summary (/media/137374/download) (423KB)
04/24/2020	Ultimate Dx Laboratory	UDX SARS-CoV-2 Molecular Assay (/media/137371/download) (120KB)	EUA Summary (/media/137372/download) (554KB)

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SARS-CoV-2 Antibody Tests

On April 28, 2020, FDA issued an Emergency Use Authorization for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by FDA, and are confirmed by FDA to meet the criteria set forth in the Scope of Authorization (Section II) in the Letter of Authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized devices are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies (IgG, or IgG and IgM, or total), as specified in each authorized device's instructions for use, to SARS-CoV-2 in human plasma and/or serum.

Emergency use of the authorized devices is limited to the authorized laboratories. Authorized Laboratories are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests. Authorized devices will be added to Appendix A (below) upon submission of the information set forth in the Scope of Authorization (Section II) and after confirmation that the applicable performance and labeling criteria set forth in the Scope of Authorization (Section II) have been met.

- Letter of Authorization – Serology IVD Umbrella (/media/137470/download) (PDF, 83KB)
- Fact Sheet for Healthcare Providers (/media/137468/download) (PDF, 79KB)
- Fact Sheet for Recipients (/media/137469/download) (PDF, 102KB)
- Appendix A Table (/media/137471/download) (PDF, 72KB)

Personal Protective Equipment and Related Devices

For information on the applicable HHS Secretary determination and declaration supporting a particular EUA in the table below, as well as a link to any applicable PREP Act declaration, please use the expansion buttons on the left hand side of the table.

For additional information, please see Recent Final Medical Device Guidance Documents (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents) and Coronavirus (COVID-19) Update: FDA takes action to increase U.S. supplies through instructions for PPE and device manufacturers (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-increase-us-supplies-through-instructions-ppe-and).

Please also see the Non-NIOSH Approved Respirator FAQ (/medical-devices/emergency-situations-medical-devices/non-niosh-approved-respirator-eua-faq) for additional information.

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Date of First EUA Issuance	Most Recent Letter of Authorization in PDF	Appendix in PDF	Authorized Labeling in PDF

Date of First EUA Issuance	Most Recent Letter of Authorization in PDF	Appendix in PDF	Authorized Labeling in PDF
+ 05/07/2020	Duke Decontamination System (/media/137762/download) (379KB)		• Fact Sheet for Healthcare Personnel (/media/137758/download) (296KB) • Instructions for Decontamination Facility (/media/137760/download) (410KB) • Instructions for Healthcare Facilities (/media/137763/download) (406KB) • Instructions for Healthcare Personnel (/media/137757/download) (583KB)
+ 05/01/2020	Protective Barrier Enclosures (/media/137584/download) (295KB)		• Fact Sheet for Healthcare Providers (/media/137585/download) (135KB) • Fact Sheet for Patients (/media/137586/download) (127KB)
+ 04/20/2020	Sterilucent, Inc. Sterilization System (/media/137167/download) (167KB)		• Fact Sheet for Healthcare Personnel (/media/137170/download) (85KB) • Instructions for Healthcare Facilities (/media/137169/download) (657KB) • Instructions for Healthcare Personnel (/media/137168/download) (261KB)
+ 04/15/2020	Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle (/media/136976/download) (102KB)		• Fact Sheet for Healthcare Personnel (/media/136977/download) (94KB) • Instructions for Healthcare Facilities (/media/136979/download) (182KB) • Instructions for Healthcare Personnel (/media/136980/download) (221KB)
+ 04/11/2020	Advanced Sterilization Products (ASP) STERRAD Sterilization System (/media/136884/download) (96KB)		• Fact Sheet for Healthcare Personnel (/media/136881/download) (106KB) • Instructions for Healthcare Facilities (/media/136882/download) (281KB) • Instructions for Healthcare Personnel (/media/136883/download) (210KB)
+ 04/09/2020	Face Shields (/media/136842/download) (209KB) (Reissued 04/13/2020)		
+ 04/09/2020	STERIS Sterilization Systems for Decontamination of N95 Respirators (/media/136843/download) (342KB)		• Fact Sheet for Healthcare Providers (/media/136846/download) (229KB) • Instructions for Healthcare Facilities (/media/136845/download) (1.9MB) • Instructions for Healthcare Personnel (/media/136844/download) (280KB)
+ 04/03/2020	Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (/media/136664/download) (332KB) (Reissued May 7, 2020)	• Appendix A: Authorized Respirators (/media/136663/download) (115KB) (updated May 7, 2020) • Non-NIOSH Approved Disposable Filtering Facepiece Respirators EUA FAQs (/medical-devices/emergency-situations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic) • Respirator Models No Longer Authorized - COVID-19 (updated May 11, 2020) (/media/137928/download) (150KB)	

Date of First EUA Issuance	Most Recent Letter of Authorization in PDF	Appendix in PDF	Authorized Labeling in PDF
+ 03/29/2020	Battelle Decontamination System (/media/136529/download) (151KB)		• Fact Sheet for Healthcare Providers (/media/136530/download) (273KB) • Instructions for Healthcare Facilities (/media/136531/download) (212KB) • Instructions for Healthcare Personnel (/media/136532/download) (183KB)
+ 03/24/2020	Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (/media/136403/download) (208KB) (Reissued 03/28/2020)	• Exhibit 1: Authorized Respirators (/media/136731/download) (100KB) • Non-NIOSH Approved Respirator EUA FAQ (/medical-devices/emergency-situations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic)	

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Ventilators and Other Medical Devices

In continuing response to the COVID-19 pandemic, on March 24, 2020, and based on the February 4, 2020 HHS EUA determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak. The EUAs FDA subsequently authorized based on this determination and declaration are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration) (March 24, 2020)

The HHS Secretary issued a Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

- Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures) (February 4, 2020)

Templates for these EUA submissions (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ventilators) are available to help facilitate the preparation, submission, and authorization of an EUA.

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Date EUA First Issued	Device Type	Most Recent Letter of Authorization in PDF	Appendix to Letter and Other Documents in PDF	Fact Sheets in PDF
+ 05/14/2020	Remote Patient QT Interval Monitor	G Medical Innovations, Ltd., VSMS Patch (/media/138105/download) (107KB)	• Professional User Guide, VSMS Patch (/media/138108/download) (2.07MB) • Quick Start Guide, VSMS Patch (/media/138109/download) (943KB)	• Healthcare Providers (/media/138104/download) (112KB) • Patients (/media/138107/download) (110KB)
+ 05/13/2020	Infusion Pumps and Infusion Pump Accessories	Infusion Pumps and Infusion Pump Accessories (/media/138057/download) (471KB)	• Appendix A: Authorized Infusion Pumps and Infusion Pump Accessories (/media/138067/download) (227KB)	• Healthcare Providers (/media/138068/download) (246KB) • Patients (/media/138069/download) (202KB)

Date EUA First Issued	Device Type	Most Recent Letter of Authorization in PDF	Appendix to Letter and Other Documents in PDF	Fact Sheets in PDF
+ 05/11/2020	LVEF Screen	Eko Devices, Inc, ELEFT (/media/137932/download) (379KB)	• IFU (/media/137931/download) (249KB)	• Healthcare Providers (/media/137930/download) (248KB) • Patients (/media/137929/download) (179KB)
+ 05/11/2020	Nurse Call System	Ascom (US), Inc., teleCARE (/media/137943/download) (357KB)	• IFU (/media/137941/download) (578KB) • IFU - Installation Guide (/media/137945/download) (8.85MB)	• Healthcare Providers (/media/137942/download) (204KB) • Patients (/media/137944/download) (243KB)
+ 05/08/2020	Patient Isolation Transport Unit (PITU)	Patient Isolation Transport Unit (PITU) Device (/media/137856/download) (400KB)	• PITU Set Up and Operation Guide (/media/137859/download) (681KB) • PITU User Manual (/media/137860/download) (70KB)	• Healthcare Providers (/media/137857/download) (142KB) • Patients (/media/137858/download) (127KB)
+ 05/05/2020	Remote Patient QT Interval Monitor	PhysiolGuard, ECG-QT Analysis System (/media/137693/download) (109KB)	• Lay User Instructions for Use (/media/137692/download) (166KB) • MiCorA100 User Manual (/media/137694/download) (1.27MB) • Analysis Platform User Manua (/media/137696/download)l (1.15MB)	• Healthcare Providers (/media/137691/download) (207KB) • Patients (/media/137695/download) (201KB)
+ 05/01/2020	Respiratory Muscle Stimulator	Liberate Medical, LLC VentFree Respiratory Muscle Stimulator Device (/media/137587/download) (347KB)	• IFU - Model A (/media/137590/download) (3.73MB) • IFU - Model B (/media/137591/download) (3.79MB)	• Healthcare Providers (/media/137588/download) (91KB) • Patients (/media/137589/download) (93KB)
+ 04/30/2020	Continuous Renal Replacement Therapy (CRRT)	Fresenius Medical, multiFiltrate PRO System and multiBic/multiPlus Solutions (/media/137520/download) (171KB)	• Instructions for Use, Bloodline/ Tubing (/media/137523/download) (83KB) • Instructions for Use, UltraFlux (/media/137527/download) (147KB) • Instructions for Use, multiFiltratePRO (/media/137528/download) (15.07MB) • Summary of Product Characteristics (SmPC) (/media/137524/download) (308KB) • Instructions for Use, MultiPlus (/media/137526/download) (110KB)	• Healthcare Providers (/media/137522/download) (135KB) • Patients (/media/137521/download) (125KB)
+ 04/26/2020	Remote Patient Monitor	VitalConnect, Inc., VitalPatch (/media/137397/download) (106KB)	• Instructions for Use, VitalPatch Biosensor (/media/137398/download) (1.52MB)	• Healthcare Providers (/media/137399/download) (111KB) • Patients (/media/137400/download) (110KB)
+ 04/22/2020	Extracorporeal Blood Purification (EBP)	Baxter Healthcare Corporation Extracorporeal Blood Purification (EBP) Device (/media/137267/download) (744KB)	• IFU (/media/137266/download) (6.03MB)	• Healthcare Providers (/media/137265/download) (255KB) • Patients (/media/137268/download) (320KB)

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Therapeutics

On March 28, 2020, FDA issued an EUA to allow hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (https://www.phe.gov/about/sns/Pages/default.aspx) (SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with

COVID-19, as appropriate, when a clinical trial is not available or feasible. The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions. The SNS, managed by ASPR, will work with the Federal Emergency Management Agency (FEMA) to ship donated doses to states.

See frequently asked questions on the EUA for Chloroquine Phosphate and Hydroxychloroquine Sulfate (/media/136784/download).

On May 1, 2020, FDA issued an EUA to allow remdesivir to be distributed and used by licensed health care providers to treat adults and children hospitalized with severe COVID-19. Severe COVID-19 is defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine. The EUA requires that fact sheets that provide important information about using remdesivir in treating COVID-19 be made available to health care providers and patients.

See frequently asked questions for the EUA for remdesivir (/media/137574/download).

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Date of First EUA Issuance	Most Recent Letter of Authorization in PDF	Fact Sheets and Manufacturer Instructions/ Package Insert in PDF
+ 05/08/2020	Fresenius Kabi Propoven 2% (/media/137888/download) (209KB)	Healthcare Providers (/media/137889/download) (288KB) Patients and Parent/Caregivers (/media/137890/download) (39KB) Propoven 2% Wall Chart (/media/137891/download) (2.4MB)
+ 05/01/2020	Remdesivir for Certain Hospitalized COVID-19 Patients (/media/137564/download) (365KB)	Healthcare Providers (/media/137566/download) (537KB) Patients and Parent/ Caregivers (/media/137565/download) (145KB) • Spanish (https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fact-sheet-for-patients-and-caregivers_spanish-language_12may2020.pdf?la=en&hash=D7B0CB181773DE3AFB8518FAEFFA0E8E) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (33KB)
+ 03/28/2020	Chloroquine phosphate and hydroxychloroquine sulfate for treatment of COVID-19 (/media/136534/download) (229KB)	Chloroquine Phosphate Fact Sheet for Healthcare Providers (/media/136535/download) (217KB) • Chinese (/media/137439/download) (610KB) | Korean (/media/137438/download) (304KB) | Spanish (/media/137437/download) (179KB) | Vietnamese (/media/137432/download) (221KB) Chloroquine Phosphate Fact Sheet for Patients (/media/136536/download) (147KB) • Chinese (/media/137436/download) (206KB) | Korean (/media/137435/download) (259KB) | Spanish (/media/137434/download) (108KB) | Vietnamese (/media/137433/download) (146KB) Hydroxychloroquine Sulfate Fact Sheet for Healthcare Providers (/media/136537/download) (206KB) • Chinese (/media/137347/download) (607KB) | Korean (/media/137348/download) (315KB) | Spanish (/media/137346/download) (205KB) | Vietnamese (/media/137349/download) (358KB) Hydroxychloroquine Sulfate Fact Sheet for Patients (/media/136538/download) (148KB) • Chinese (/media/137350/download) (213KB) | Korean (/media/137351/download) (264KB) | Spanish (/media/137352/download) (113KB) | Vietnamese (/media/137353/download) (144KB)

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Other Current EUAs

The tables below provide information on current EUAs:

- Anthrax EUAs
- Ebola Virus EUA Information
- Enterovirus D68 (EV-D68) EUA Information
- Freeze Dried Plasma Information
- H7N9 Influenza EUA Information

- Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EUA Information
- Nerve Agent EUA Information
- Zika Virus EUA Information

Information about EUAs that are no longer in effect is available on our EUA archive page (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

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Anthrax EUAs

The 2016 FDA Doxycycline Emergency Dispensing Order (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders#doxy) and CDC Doxycycline Emergency Use Instructions (EUI) (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders#doxy) together replace the need for the doxycycline mass dispensing EUA (issued on July 21, 2011). Therefore, the doxycycline emergency dispensing order and EUI should be used by stakeholders for anthrax preparedness and response instead of the mass dispensing EUA.

The July 21, 2011, doxycycline mass dispensing EUA, and the October 14, 2011, National Postal Model anthrax EUA will be terminated by FDA, and notice of such termination will be published in the *Federal Register*. For additional information, see Emergency Use Authorization--Archived Information (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

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Ebola Virus EUA Information

Ebola preparedness and response updates from FDA (/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda) (all agency activities)

For more information about the diagnostics below, also see Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) **(current device EUAs).**

Ebola Diagnostic Tests with De Novo, 510(k) or PMA

- **OraQuickEbola Rapid Antigen Test** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN190025)- On October 10, 2019, FDA allowed marketing (https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190025.pdf) (PDF, 255 KB) of a rapid diagnostic test (RDT) to detect Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to have died from Ebola (cadaveric oral fluid). The OraQuick Ebola Rapid Antigen Test is the first rapid diagnostic test the FDA has allowed to be marketed in the U.S. for Ebola virus disease (EVD). The test provides a rapid, presumptive diagnosis that must be confirmed. *Also see the FDA news release: FDA allows marketing of first rapid diagnostic test for detecting Ebola virus antigens (/news-events/press-announcements/fda-allows-marketing-first-rapid-diagnostic-test-detecting-ebola-virus-antigens)*

  The OraQuick Ebola Test was reviewed under the De Novo premarket review pathway (/medical-devices/premarket-submissions/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this marketing authorization, the FDA is establishing criteria, called special controls, that determine the requirements for demonstrating accuracy, reliability and effectiveness of tests intended to identify Ebola virus antigens. These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	El

EZ1 Real-time RT-PCR Assay (DoD)	August 5, 2014 (initial issuance) October 10, 2014 (reissuance)	Authorization (/media/89984/download) (PDF, 61 KB)	FR notice (https://www.federalregister.gov/articles/2014/09/17/2014-22086/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/89986/download) (PDF, 58 KB) • Patients (/media/89988/download) (PDF, 59 KB) • Instruction Booklet (/media/89989/download) (PDF, 1.1 MB)	D D (h 1 di
CDC Ebola Virus NP Real-time RT-PCR Assay (CDC)	October 10, 2014 (initial issuance) March 2, 2015 (reissuance) October 8, 2019 (amended)	Authorization (/media/91083/download) (PDF, 282 KB) Letter granting EUA amendment(s) (PDF, 134 KB) (/media/131606/download)	FR notice (https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/91087/download) (PDF, 207 KB) • Patients (/media/91092/download) (PDF, 149 KB) • Instructions for Use (/media/91097/download) (PDF, 496 KB)	D D (h 1 di
CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC)	October 10, 2014 (initial issuance) March 2, 2015 (reissuance) October 8, 2019 (amended)	Authorization (/media/91105/download) (PDF, 285 KB) Letter granting EUA amendment(s) (PDF, 135 KB) (/media/131605/download)	FR notice (https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/91111/download) (PDF, 207 KB) • Patients (/media/91118/download) (PDF, 149 KB) • Instructions for Use (/media/91142/download) (PDF, 494 KB)	D D (h 1 di
FilmArray NGDS BT-E Assay (Biofire Defense, LLC)	October 25, 2014 (initial issuance) March 2, 2015 (reissuance)	Authorization (/media/91070/download) (PDF, 326 KB)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/91149/download) (PDF, 40 KB) • Patients (/media/91153/download) (PDF, 40 KB) • Instructions for Use (/media/91077/download) (PDF, 740 KB)	D D (h 1 di
FilmArray Biothreat-E test (Biofire Defense, LLC)	October 25, 2014 November 12, 2019 (amended)	Authorization (/media/89580/download) (PDF, 73 KB) Letter granting EUA amendment(s) (PDF, 152 KB) (/media/132517/download)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/89585/download) (PDF, 227 KB) • Patients (/media/89604/download) (PDF, 191 KB) • Instructions for Use (/media/89614/download) (PDF, 1.6 MB)	D D (h 1 di
RealStar Ebolavirus RT-PCR Kit 1.0 (altona Diagnostics, GmbH)	November 10, 2014 (initial issuance) November 26, 2014 (reissuance)	Authorization (/media/123410/download) (PDF, 263 KB)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/120428/download) (PDF, 81 KB) • Patients (/media/120429/download) (PDF, 92 KB) • Instructions for Use (/media/120430/download) (PDF, 634 KB)	D D (h 1 di
LightMix Ebola Zaire rRT-PCR Test (Roche Molecular Systems, Inc.)	December 23, 2014	Authorization (/media/120431/download) (PDF, 2.2 MB)	FR notice (https://www.federalregister.gov/articles/2015/03/17/2015-06039/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/120432/download) (PDF, 59 KB) • Patients (/media/120433/download) (PDF, 60 KB) • Instructions for Use (/system/404) (PDF, 328 KB)	D D (h 1 di

Xpert Ebola Assay (Cepheid)	March 23, 2015	Authorization (/media/91315/download) (PDF, 240 KB)	FR notice (https://www.federalregister.gov/articles/2015/06/05/2015-13699/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/91934/download) (PDF, 310 KB) • Patients (/media/91939/download) (PDF, 211 KB) • Instructions for Use (/media/91944/download) (PDF, 625 KB)	D D (h 1 di
Idylla Ebola Virus Triage Test (Biocartis NV)	May 26, 2016	Authorization (/media/98460/download) (PDF, 321 KB)	FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16176/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/98451/download)(PDF, 203 KB) • Patients (/media/98442/download) (PDF, 163 KB) • Instructions for Use (/media/98434/download) (PDF, 2.1 MB)	D D (h 1 di
DPP Ebola Antigen System (Chembio Diagnostic Systems, Inc.)	November 9, 2018 April 2, 2019 (amended)	Authorization (/media/117735/download) (PDF, 103 KB) Letter Granting EUA Amendment(s) (/media/122553/download) (PDF, 87 KB)	FR notice (https://www.federalregister.gov/documents/2019/02/13/2019-02134/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-virus)	• Healthcare (/media/117736/download)(PDF, 122 KB) • Patients (/media/117737/download) (PDF, 119 KB) • Instructions for Use (/media/117738/download) (PDF, 2 MB)	D D (h 1 di

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Enterovirus D68 (EV-D68) EUA Information

For more information about the diagnostics below, also see Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) **(current device EUAs).**

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determination and De
CDC Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR)	May 12, 2015	Authorization (/media/120425/download) (PDF, 229 KB)	FR notice (https://www.federalregister.gov/articles/2015/07/01/2015-16125/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-enterovirus-d68)	• Healthcare (/media/92008/download) (PDF, 214 KB) • Patients (/media/120426/download) (PDF, 150 KB) • Instructions for Use (/media/120427/download)(PDF, 531 KB)	Determination and Declarat New *In Vitro* Diagnostics fo (https://www.federalregiste 04121/determination-and-d use-of-new-in-vitro-diagnos 2015)

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Freeze Dried Plasma Information

Also see FDA News Release: FDA takes action to support American military personnel by granting an authorization for freeze-dried plasma product to enable broader access while the agency works toward approval of the product (/news-events/press-announcements/fda-takes-action-support-american-military-personnel-granting-authorization-freeze-dried-plasma) (July 10, 2018)

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determination and
Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma (Centre de Transfusion Sanguine des Armées)	July 9, 2018 (initial issuance) May 8, 2020 (amendment)	Authorization (/media/114282/download) (PDF, 203 KB) Letter granting EUA amendments (/media/137970/download) (PDF, 60 KB)	FR notice (https://www.federalregister.gov/documents/2018/08/13/2018-17303/authorization-of-emergency-use-of-a-freeze-dried-plasma-treatment-for-hemorrhage-or-coagulopathy)	• Fact Sheet for U.S. Military Medical Personnel (/media/119949/download) (PDF, 132 KB) • Fact Sheet for Recipients (/media/119948/download) (PDF, 101 KB)	Determination by DoD (. Declaration Regarding E Hemorrhage or Coagulc Agents of Military Comb (https://www.federalreg 16331/emergency-use-c hemorrhage-due-to-age 9, 2018)

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H7N9 Influenza EUA Information

For more information about the diagnostics below, also see Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) **(current device EUAs).**

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheet and Manufacturer Instructions/Package Insert	EUA Determination and Declarat
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay	April 22, 2013 (initial issuance) March 27, 2018 (reissuance)	Authorization (/media/85910/download) (PDF, 301 KB), re-issued March 27, 2018	FR notice (https://www.federalregister.gov/articles/2013/06/25/2013-15096/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-the-novel-avian-influenza)	• Healthcare (/media/85915/download) (PDF, 46 KB) • Patients (/media/85446/download) (PDF, 32 KB) • Instructions for Use (/media/85454/download) (PDF, 433 KB)	Determination and Declaration R Diagnostics for Detection of the (https://www.federalregister.gov 10055/determination-and-declar vitro-diagnostics-for-detection-o Additional information from HHS (http://www.phe.gov/emergency influenza-virus.aspx)
Quidel Lyra Influenza A Subtype H7N9 Assay	February 14, 2014	Authorization (/media/87767/download) (PDF, 57 KB)	FR notice (https://www.federalregister.gov/articles/2014/04/17/2014-08706/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a)	• Healthcare (/media/87775/download) (PDF, 42 KB) • Patients (/media/87780/download) (PDF, 40 KB)	Determination and Declaration R Diagnostics for Detection of the (https://www.federalregister.gov 10055/determination-and-declar vitro-diagnostics-for-detection-o Additional information from HHS (http://www.phe.gov/emergency influenza-virus.aspx)

A/H7N9 Influenza Rapid Test	April 25, 2014	Authorization (/medical-devices/emergency-situations-medical-devices/ah7n9-influenza-rapid-test-letter-authorization)	FR notice (https://www.federalregister.gov/articles/2014/06/23/2014-14547/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a)	• Healthcare (/medical-devices/emergency-situations-medical-devices/fact-sheet-health-care-providers-interpreting-ah7n9-influenza-rapid-test-results) • Patients (/medical-devices/emergency-situations-medical-devices/fact-sheet-patients-understanding-results-ah7n9-influenza-rapid-test)	Determination and Declaration R Diagnostics for Detection of the (https://www.federalregister.gov 10055/determination-and-declar vitro-diagnostics-for-detection-o Additional information from HHS (http://www.phe.gov/emergency influenza-virus.aspx)

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Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EUA Information

For more information about the diagnostics below, also see Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) **(current device EUAs).**

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determination
CDC Novel Coronavirus 2012 Real-time RT-PCR Assay	June 5, 2013 (initial issuance) June 10, 2014 (reissuance)	Authorization (/media/88518/download) (PDF, 2.2 MB)	FR notice (https://www.federalregister.gov/documents/2013/07/17/2013-17103/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-middle-east-respiratory)	• Healthcare (/medical-devices/emergency-situations-medical-devices/fact-sheet-health-care-professionals-interpreting-cdc-novel-coronavirus-2012-real-time-rt-pcr-assay) • Patients (/medical-devices/emergency-situations-medical-devices/fact-sheet-patients-understanding-results-cdc-novel-coronavirus-2012-real-time-rt-pcr-assay) • Contacts (/media/88505/download) (PDF, 1.2 MB) • Instructions for Use (/media/85951/download) (PDF, 743 KB)	Determination and D Diagnostics for Dete Coronavirus (MERS- (https://www.federa 13333/determinatio vitro-diagnostics-for Additional informati (http://www.phe.gov cov.aspx)
RealStar MERS-CoV RT-PCR Kit U.S.	July 17, 2015 (initial issuance) February 12, 2016 (reissuance)	Authorization (/media/93040/download) (PDF, 238 KB)	FR notice (https://www.federalregister.gov/documents/2015/09/01/2015-21585/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-middle-east)	• Healthcare (/media/93048/download) (PDF, 269 KB) • Patients (/media/93056/download) (PDF, 241 KB) • Instructions for Use (/media/120434/download) (PDF, 840 KB) • Fact Sheet for Asymptomatic Individuals Suspected of Exposure to MERS-CoV Cases (/media/95614/download) (PDF, 285 KB)	Determination and D Diagnostics for Dete Coronavirus (MERS- (https://www.federa 13333/determinatio vitro-diagnostics-for Additional informati (http://www.phe.gov cov.aspx)

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Nerve Agent EUA Information

On July 9, 2018, FDA approved (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/212319Orig1s000ltr.pdf) (PDF, 49 KB) the 2 mg Atropine Auto-Injector manufactured by Rafa Laboratories, Ltd., for the treatment of poisoning by susceptible organophosphorous nerve agents having cholinesterase activity as well as organophosphorous or carbamate insecticides in adults and pediatric patients weighing over 90 lbs [41 kg] (generally over 10 years of age). For more information about the approved 2 mg Rafa Atropine Auto-Injector, see the product label (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/212319s000lbl.pdf) (PDF, 482 KB). The EUA detailed in the table below is still in effect.

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determination and D
Atropine Auto-Injector (Rafa Laboratories Ltd.)	April 11, 2017 (initial issuance) May 23, 2017 (amended) January 24, 2018 (amended) March 6, 2018 (amended) May 15, 2018 (amended)	Letter of Authorization (/media/104550/download) (PDF, 514 KB) Letter granting EUA amendment(s) (/media/105590/download) (PDF, 28 KB) 2nd letter granting EUA amendment(s) (/media/110881/download) (PDF, 33 KB) 3rd letter granting EUA amendment(s) (/media/111656/download) (PDF, 85 KB) 4th letter granting EUA amendment(s) (/media/113102/download) (PDF, 42 KB)	FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13664/emergency-use-authorizations-injectable-treatment-for-nerve-agent-or-certain-insecticide)	• Healthcare (/media/104559/download) (PDF, 531 KB) • Patients and Caregivers (/media/104564/download) (PDF, 675 KB)	Determination and Declar Certain Insecticide (Orgar Poisoning (https://www.federalregis 07685/determination-and of-injectable-treatments-f

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Zika Virus EUA Information

Zika virus response updates from FDA (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda)

Zika virus diagnostic development information (/emergency-preparedness-and-response/mcm-issues/zika-virus-diagnostic-development)

For more information about the diagnostics below, also see Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) (current device EUAs).

Draft EUA review templates for Zika are available by email request to: CDRH-ZIKA-Templates@fda.hhs.gov (mailto:CDRH-ZIKA-Templates@fda.hhs.gov?Subject=EUA template request)

Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov (mailto:CDRH-EUA-Reporting@fda.hhs.gov), in addition to reporting concerns to the manufacturer.

Zika Diagnostic Tests with De Novo, 510(k), or PMA

- **ZIKV Detect 2.0 IgM Capture ELISA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN180069)** - On May 23, 2019, FDA authorized marketing (https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf) (PDF, 175 KB) of the ZIKV Detect 2.0 IgM Capture

ELISA to detect Zika virus immunoglobulin (IgM) antibodies in human blood. The ZIKV Detect 2.0 IgM Capture ELISA is the first Zika diagnostic test the FDA has allowed to be marketed in the U.S.; previously, tests for detecting Zika virus IgM antibodies—including the ZIKV Detect 2.0 IgM Capture ELISA—had been authorized only for emergency use under the FDA's EUA authority. *Also see the FDA news release: FDA authorizes marketing of first diagnostic test for detecting Zika virus antibodies (/news-events/press-announcements/fda-authorizes-marketing-first-diagnostic-test-detecting-zika-virus-antibodies)*

- **ADVIA Centaur Zika test** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191578) – On July 17, 2019, FDA cleared the ADVIA Centaur Zika test. This is the second Zika diagnostic test FDA has allowed to be marketed in the U.S. for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.
- **LIAISON XL Zika Capture IgM Assay II** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192046) – On October 28, 2019, FDA cleared the LIAISON XL Zika Capture IgM Assay II for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.

Medical Product	Date of EUA Issuance	Letters	Federal Register Notice for EUA	Fact Sheets Instruction
CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay *CDC statement on this EUA (http://www.cdc.gov/media/releases/2016/s0226-laboratory-test-for-zika-virus.html)*	February 26, 2016 (initial issuance) June 29, 2016 (amended) November 15, 2016 (amended) December 6, 2016 (amended) May 3, 2017 (amended) July 31, 2017 (amended) April 16, 2018 (amended) September 26, 2018 (amended)	Letter granting EUA amendment(s) (/media/101616/download) (PDF, 155 KB) Letter granting EUA amendment(s) (/media/101586/download) (PDF, 123 KB) Letter granting EUA amendment(s) (/media/120186/download) (PDF, 110 KB) Letter granting EUA amendment(s) (/media/120187/download) (PDF, 113 KB) Letter granting EUA amendment(s) (/media/120188/download) (PDF, 131 KB) Letter granting EUA amendment(s) (/media/120189/download) (PDF, 131 KB)	FR notice (https://www.federalregister.gov/articles/2016/03/28/2016-06888/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-diagnosis-of-zika-virus)	• Hea (/m KB) • Pati (PD • Inst (/m MB)
CDC Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) *CDC statement on this EUA (http://www.cdc.gov/media/releases/2016/s0318-zika-lab-test.html)*	March 17, 2016 (initial issuance) September 21, 2016 (amended) January 12, 2017 (amended) February 28, 2017 (amended) April 6, 2017 (amended)	Authorization (/media/96683/download) (PDF, 82 KB) Letter granting EUA amendment(s) (/media/100200/download) (PDF, 223 KB) Letter granting EUA amendment(s) (/media/102439/download) (PDF, 223 KB) Letter granting EUA amendment(s) (/media/103400/download) (PDF, 223 KB) Letter granting EUA amendment(s) (/media/120192/download) (PDF, 126 KB)	FR notice (https://www.federalregister.gov/articles/2016/04/22/2016-09370/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)	• Hea (/m KB) • Pati (PD • Inst (/m MB)
Zika Virus RNA Qualitative Real-Time RT-PCR (Quest Diagnostics Infectious Disease, Inc.)	April 28, 2016 (initial issuance) October 7, 2016 (reissuance) April 11, 2017 (amended)	Authorization (/media/122435/download) (PDF, 339 KB) Letter granting EUA amendment(s) (/media/120127/download) (PDF, 126 KB)	FR notice (https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m KB) • Pati (PD • Inst (/m (/m KB)

RealStar Zika Virus RT-PCR Kit U.S. (altona Diagnostics GmbH)	May 13, 2016 (initial issuance) October 31, 2016 (amended) March 6, 2017 (amended)	Authorization (/media/120121/download) (PDF, 342 KB) Letter Granting EUA Amendment(s) (/media/120122/download) (PDF, 130 KB) Letter Granting EUA Amendment(s) (/media/120123/download) (PDF, 130 KB)	FR notice (https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m (/m KB) • Pati (PD • Inst (/m KB)
Aptima Zika Virus assay (Hologic, Inc.)	June 17, 2016 (initial issuance) September 7, 2016 (amended) April 12, 2017 (amended) March 8, 2018 (amended)	Authorization (/media/120114/download) (PDF, 305 KB) Letter granting EUA amendment(s) (/media/122434/download) (PDF, 126 KB) Letter granting EUA amendment(s) (/media/120116/download)(PDF, 124 KB) Letter granting EUA amendment(s) (/media/120117/download)(PDF, 130 KB)	FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16177/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-zika-virus)	• Hea (/m (PD • Pati (PD • Inst (/m (PD
Zika Virus Real-time RT-PCR Test (Viracor Eurofins)	July 19, 2016 (initial issuance) February 28, 2017 (amended)	Authorization (/media/120033/download) (PDF, 334 KB) Letter granting EUA amendment(s) (/media/120034/download) (PDF, 124 KB)	FR notice (https://www.federalregister.gov/articles/2016/09/07/2016-21353/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus#h-6)	• Hea (/m (PD • Pati (PD • Inst (/m (PD
VERSANT Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics Inc.)	July 29, 2016 (initial issuance) December 19, 2016 (amended)	Authorization (/media/99444/download) (PDF, 78 KB) Letter granting EUA amendment(s) (/media/120030/download) (PDF, 124 KB)	FR notice (https://www.federalregister.gov/documents/2016/10/28/2016-26066/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-andor-diagnosis-of-zika-virus)	• Hea (/m KB) • Pati (PD • Inst (/m KB)
Sentosa SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)	September 23, 2016	Authorization (/media/120017/download) (PDF, 355 KB)	FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m (PD • Pati (PD • Inst (/m MB)
Zika Virus Detection by RT-PCR Test (ARUP Laboratories)	September 28, 2016	Authorization (/media/120014/download) (PDF, 98 KB)	FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m KB) • Pati (PD • Inst (/m (PD

Abbott RealTime ZIKA (Abbott Molecular Inc.)	November 21, 2016 (initial issuance) January 6, 2017 (amended)	Authorization (/media/101657/download) (PDF, 84 KB) Letter granting EUA amendment(s) (/media/120010/download) (PDF, 150 KB)	FR notice (https://www.federalregister.gov/documents/2016/12/20/2016-30532/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)	• Hea (/m 208 • Pati (PD • Inst (/m MB)
Zika ELITe MGB Kit U.S. (ELITechGroup Inc. Molecular Diagnostics)	December 9, 2016	Authorization (/media/119919/download) (PDF, 312 KB)	FR notice (https://www.federalregister.gov/documents/2017/01/09/2017-00084/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)	• Hea (/m 213 • Pati (PD • Inst (/m (PD
Gene-RADAR Zika Virus Test (Nanobiosym Diagnostics, Inc.)	March 20, 2017	Authorization (/media/119915/download)(PDF, 313 KB)	FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13720/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m 267 • Pati (PD • Inst (/m (PD
TaqPath Zika Virus Kit (Thermo Fisher Scientific)	August 2, 2017	Authorization (/media/119906/download)(PDF, 292 KB)	FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m 252 • Pati (PD • Inst (/m (PD
CII-ArboViroPlex rRT-PCR Assay (Columbia University)	August 11, 2017	Authorization (/media/107073/download) (PDF, 377 KB)	FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m 229 • Pati (PD • Inst (/m (PD
DPP Zika IgM Assay System (Chembio Diagnostic Systems, Inc.)	September 27, 2017 (initial issuance) February 6, 2018 (amended) August 3, 2018 (amended)	Authorization (/media/119895/download) (PDF, 424 KB) Letter granting EUA amendment(s) (/media/119896/download)(PDF, 130 KB) Letter granting EUA amendment(s) (/media/119897/download)(PDF, 129 KB)	FR notice (https://www.federalregister.gov/documents/2017/11/17/2017-25010/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• Hea (/m (PD • Pati (PD • Inst (/m MB)

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Related Links

- Summary of Process for EUA Issuance (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance)

- Emergency Use Authorization--Archived Information (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information)
- Emergency Dispensing Orders (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders)
- Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)
- 21st Century Cures Act: MCM-Related Cures Provisions (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions)
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra)
- Public Readiness and Emergency Preparedness (PREP) Act (https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx)
- HHS Public Health Emergency EUA Authorization Declarations (http://www.phe.gov/emergency/news/healthactions/Lists/EUA/AllItems.aspx)
- Ebola Preparedness and Response Updates from FDA (/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda)
- Zika Virus Response Updates from FDA (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda)
- Emergency Use Authorizations (Medical Devices) (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)
- Historical Information about Device Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/historical-information-about-device-emergency-use-authorizations)

Exhibit A-45

United States Senate
WASHINGTON, DC 20510

April 7, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar,

We write to urge you to reopen the Affordable Care Act's (ACA) online marketplace through a unique Special Enrollment Period (SEP) to allow any American to enroll in a comprehensive health insurance plan. Currently, millions of Americans are uninsured and anxious, not only about what the possibility of contracting COVID-19 could mean for their health and that of their family, but also for their financial stability. Opening up the ACA marketplace would provide an easy pathway to coverage for those who under previous circumstances may have decided to forego health insurance or purchase a substandard, junk insurance plan, but now in a global pandemic are in vital need of comprehensive coverage to protect themselves, their families, and our broader community.

The Trump Administration's reported decision not to open an SEP, despite earlier congressional requests, and leave millions of Americans uninsured and underinsured during this unprecedented public health crisis will inevitably mean fewer individuals seeking testing and treatment—prolonging the spread of the disease—and will put more families in dire financial straits. The COVID-19 pandemic is also causing millions of people to lose their jobs and their employer-provided health insurance. We should be promoting comprehensive health insurance plans to all those impacted, not looking to divert funds appropriated to support hospitals, or promoting junk insurance plans that don't have to provide coverage for needed services or offer consumer protections.

When the ACA was passed, Congress included the authority to establish SEPs because we understood that everyday Americans may face extenuating circumstances for which they should not be penalized. It is inexcusable for you not to exercise that authority during perhaps the largest extenuating circumstance of our lifetimes, and to choose to lock out millions of Americans from the ACA exchanges because they failed to predict a sweeping global pandemic. Furthermore, the Administration's continued promotion of junk plans which are not required to comply with consumer protections that limit out-of-pocket costs or coverage of essential health

benefits, including those that are needed to pay for the treatment and prevention of COVID-19 such as hospital care, emergency care, laboratory services, or preventive services, leave many Americans vulnerable. Families already struggling to make ends meet in light of the global economic downturn should not be exposed to potential financial ruin because of a lack of comprehensive insurance coverage.

An additional benefit of opening an SEP is that it would publicize to all Americans who have lost their jobs that the exchanges are open again and that they can enroll in high-quality health insurance, providing at least a modicum of reassurance during these deeply troubling times. Given the millions of job losses in recent weeks and the likelihood of millions more in the near future, now is the time to open up the health insurance marketplace to everyone so that people know that losing their job does not mean they must also lose access to health insurance coverage.

We believe opening an ACA SEP is the clearest way to cover the millions of uninsured and underinsured Americans in the 38 states that use the federal platform, and to provide comprehensive protections for COVID-19-related treatment and prevention. In a demonstration of the dramatic demand for such a move, all but one of the 13 state-based marketplaces have opened an SEP, with such high levels of interest that many are now extending the period by several weeks.

We urge you to put aside the partisan politics of the past, and to expand health coverage to millions of Americans by opening an SEP expeditiously.

Sincerely,

Senator Christopher S. Murphy
Senator Richard Blumenthal
Senator Robert P. Casey, Jr.
Senator Kirsten Gillibrand
Senator Martin Heinrich
Senator Tina Smith
Senator Chris Van Hollen
Senator Richard J. Durbin
Senator Angus S. King, Jr.
Senator Margaret Wood Hassan
Senator Amy Klobuchar
Senator Mazie K. Hirono
Senator Tim Kaine
Senator Doug Jones

Senator Tammy Baldwin
Senator Joe Manchin III
Senator Jon Tester
Senator Jeffrey A. Merkley
Senator Elizabeth Warren
Senator Dianne Feinstein
Senator Sherrod Brown
Senator Gary C. Peters
Senator Tammy Duckworth
Senator Jeanne Shaheen
Senator Kamala D. Harris
Senator Tom Udall
Senator Tom Carper
Senator Jack Reed

Exhibit A-46

March 19, 2020

The Honorable Mitch McConnell
Senate Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable Charles Schumer
Senate Democratic Leader
United States Senate
Washington, D.C. 20510

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
House Republican Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Speaker Pelosi, Leader McConnell, Leader McCarthy, and Leader Schumer:

We are committed to working with you in every possible way to help America through the COVID-19 emergency. Our mission has always been to cover and care for the people we serve. That mission is more important now than ever before. We have their back – and they have our support.

One of the most important things we can do together is to deliver as much certainty as we can in these uncertain times. The American people need the peace of mind of knowing that their health and financial future are secure. That means knowing that they can count on their health care coverage when they need it most. It also means knowing that their doctors, hospitals, nurses, and other health care professionals have the resources they need to care for them.

This is especially important for Americans working in sectors of the economy facing the biggest hardships from COVID-19. As businesses of all sizes wrestle with mounting economic challenges and make hard decisions about their future, we must do everything we can to ensure that employees do not lose health coverage – which would make the harms and risks of COVID-19 much worse for hundreds of millions of people. We must also ensure that Americans who buy coverage on their own can continue to afford their coverage.

Helping Businesses and Families Get and Maintain Coverage
We believe the following actions will deliver more certainty and support for all Americans – now and long term. We also believe they will provide greater flexibility to respond to evolving economic and health care circumstances:

- Support businesses in their goal to continue providing health coverage to their employees. There are many options for how this support could be provided. It could take the form of

payroll tax relief, or a refundable credit against employment tax withholdings, for firms providing coverage. It could include direct subsidies of the employer's premium obligation for each person covered under the employer's plan beginning on the day the crisis was declared.

- Establish robust new funding to support Americans who lose their jobs to allow them to maintain coverage. Congress should create new funding to support coverage for those who lose their jobs due to the crisis, by providing a 90% subsidy for COBRA or other insurance coverage.

- Establish a temporary, emergency risk mitigation program to ensure that health care premiums do not spike, and that benefits are stable in the future. Health insurance providers are covering COVID-19 tests and needed treatments. As more people seek coverage and care due to this pandemic, this temporary, emergency program would protect Americans from the consequences of potential catastrophic costs. This should be structured as a backstop contingency program that is triggered only if real-world health insurer costs are significantly higher than expected. Given the enormous uncertainty regarding the costs of the epidemic, we recommend that the program cover a portion of related costs for 2020 and 2021 and apply to the individual, employer, Medicare and Medicaid markets.

- Allow a one-time special enrollment period (SEP) for the individual market – regardless of an individual's current health status or whether they have coverage today. Given the risk posed by COVID-19, it is more important than ever for people to have health coverage. This will give people the opportunity to get the security and peace of mind that health care coverage provides.

- Enhance current financial assistance to lower the cost of premiums for those who rely on the individual market. Tax credits for those with incomes over 400% of the federal poverty level should be made available, and adjustments to the tax credit formula by age to would encourage more younger people to get covered.

Meeting the Needs of the Health Care Delivery System

We must also take action to support the doctors, hospitals, nurses, and other health care professionals who treat patients every day by ensuring that our front-line, health care heroes have the resources they need to confront this pandemic. Specifically, we urge the Congress to:

- Provide emergency funding to hospitals to assist the surge in patient needs. This emergency funding can help secure critical supplies and future vaccines, re-purpose treatment units, and expand staffing. Funding could also help build temporary COVID-specific clinics that enable drive-through testing in communities that can help identify those in critical need and alleviate burden on hospitals.

- Support independent health care providers with direct financial support. Small and independent practices are struggling with a wave of cancelations, a dramatic shift from

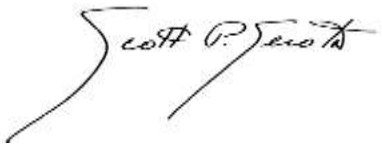
elective procedures to urgent COVID-19 tests and treatment, and their own staffing strains as parents stay home with children. Congress should make Small Business Administration loans and grants available so that practices can remain open, reduce the need to lay off staff, support personnel that must take leave, and shift resources to telehealth services.

- Enhance funding for testing and treatment of COVID-19-related conditions for those who remain uninsured. Congress should expand the new state option through Medicaid to ensure the uninsured are covered for treatment of COVID-19-related illnesses beyond the coverage of the diagnostic test and related visit recently enacted in HR 6201. Similarly, Congress should increase the funding allocation for the National Disaster Medical System (NDMS) to cover treatment of COVID-19-related illnesses for anyone who remains uninsured. This NDMS funding would be in addition to the $1 billion allowance Congress appropriated for coverage of the diagnostic test and related visit in HR 6201.

These changes are critical to help stabilize the coverage and care that hundreds of millions of Americans are depending on right now. Knowing that businesses and employees are supported, and that their care providers have the resources they need, are essential actions to help and support the people we serve. Thank you for the opportunity to work with you as our nation tackles the enormous economic and health care challenges created by COVID-19.

Sincerely,

President and Chief Executive Officer
America's Health Insurance Plans



President and Chief Executive Officer
Blue Cross Blue Shield Association

Exhibit A-47

April 28, 2020

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
U.S. Capitol Building, H-222
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
U.S. Capitol Building, S-230
Washington, DC 20510

The Honorable Kevin McCarthy
Republican Leader
U.S. House of Representatives
U.S. Capitol Building, H-204
Washington, DC 20515

The Honorable Charles E. Schumer
Democratic Leader
U.S. Senate
U.S. Capitol Building, S-221
Washington, DC 20510

Dear Speaker Pelosi, Leader McConnell, Leader McCarthy and Leader Schumer:

Thank you for your swift action to help overcome the COVID-19 crisis. Your action is speeding support to hospitals, doctors, nurses, businesses and workers from critical investments in equipment to direct assistance to cover immediate expenses. More must be done, and we stand united in our commitment to work with you and to work together.

The magnitude of the COVID-19 crisis is extraordinary. It has taxed our health care system like never before, and it has stressed the economy as consumers and businesses limit commerce and adhere to social distancing to reduce the transmission of the disease. These actions have undoubtedly saved lives, but they also have cost millions of jobs – more than 26 million by the latest employment reports. Because nearly 180 million Americans get their health care coverage through their work, it is critical to ensure millions of Americans continue to have employer coverage.

That is why we urge you to take immediate action to support employers and workers by protecting and expanding high quality, affordable health care coverage. That includes our social safety net of unemployment insurance and Medicaid. These programs are struggling to keep up with the increased demand, and state budgets – a significant source of funding for these programs – are increasingly strapped due to loss of tax revenue. As a result, millions of individuals will join the ranks of the uninsured unless you act. Loss of health care coverage will create additional financial and emotional stress on individuals and families, reduce resources available to the health care system at a time where providers must increase capacity to address the COVID-19 surge, and stymie public health interventions that require routine engagement between individuals and the health care system.

Employers need more support – and workers need to be able to continue their stable, secure coverage. As you consider the next round of legislation to overcome COVID-19, we urge you to prioritize maintaining private health benefits for individuals and families

and to increase coverage options for those who are already uninsured. Specifically, we urge you to:

- **Provide Employers with Temporary Subsidies to Preserve Health Benefits**. Many employers experiencing loss of revenue as a result of the economic downturn are compelled reluctantly to reduce benefits as one way to manage expenses. Congress could help employers by providing subsidies to offset the cost of preserving health coverage during this crisis.

- **Cover the Cost of Coverage through the Consolidated Omnibus Budget Reconciliation Act (COBRA)**. The COVID-19 crisis has already triggered significant job loss. Many individuals may have the option to maintain their job-based health coverage through COBRA but find the costs to be prohibitive, especially if they are facing a significant reduction in income. Congress could offset the full cost of coverage through COBRA to former employees through a direct subsidy.

- **Expand Use of Health Savings Accounts (HSA).** Currently, HSAs may only be used for certain qualifying expenses, which do not include premiums. Congress could temporarily lift this limit to provide individuals and families with access to additional resources to cover the cost of coverage.

- **Open a Special Enrollment Period for Health Insurance Marketplaces**. The Health Insurance Marketplaces are an existing source of private coverage for many individuals and families, including those in self-employed households. While individuals who have recently lost employer-based coverage are eligible to enroll in the Marketplaces as a result of an existing Special Enrollment Period (SEP), Congress could create a new, one-time SEP for enrollment in the Marketplaces specifically for those individuals who are uninsured and not otherwise eligible for an existing SEP.

- **Increase Eligibility for Federal Subsidies for the Health Insurance Marketplaces.** Some individuals and families earned too much money to qualify for Health Insurance Marketplace subsidies but too little to afford premiums. Congress could increase access to individual market coverage by increasing eligibility for federal subsidies. We also recommend that Congress temporarily enhance financial assistance for individuals who already rely on the Health Insurance Marketplace for coverage by reducing the required contribution percentage to lower the cost of premiums.

Additionally, the Department of Health and Human Services (HHS) is using a portion of the $100 billion added to the Public Health and Social Services Emergency Fund authorized by the Coronavirus Aid, Relief, and Economic Security Act to cover the costs of the uninsured. This approach will quickly deplete the Emergency Fund and not provide the benefits of comprehensive coverage, which include protections against preexisting conditions and establishing a regular connection between patients and care

providers. The actions outlined above would be far more effective to stabilize businesses and strengthen health care coverage.

These immediate actions will help stabilize the economy, support employers across the country, and secure quality health care coverage for millions of Americans. Thank you for your efforts during this critical time. We are committed to working with you to overcome this crisis.

Sincerely,

Advanced Medical Technology Association
Alliance to Fight for Health Care
Ambulatory Surgery Center Association
America's Essential Hospitals
America's Health Insurance Plans
American Academy of Family Physicians
American Benefit Council
American Dental Association
American Hospital Association
American Medical Association
American Medical Rehabilitation Providers Association
American Nurses Association
American Telemedicine Association
Association of American Medical Colleges
Blue Cross Blue Shield Association
Catholic Health Association of the United States
Children's Hospital Association
Council for Affordable Health Coverage
Council of Insurance Agents and Brokers
Employers Health Purchasing Corporation
Federation of American Hospitals
Healthcare Leadership Council
Healthcare Supply Chain Association
National African American Insurance Association
National Association of Health Underwriters
National Association of Insurance and Financial Advisors
National Rural Health Association
Partnership for Quality Home Healthcare
Pharmaceutical Care Management Association
Rheumatology Nurses Society
Rural Hospital Coalition
U.S. Chamber of Commerce

Exhibit A-48

March 20, 2020

Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Blvd, Baltimore, MD 21244

Mike Pence
Vice President
White House Special Task Force
1600 Pennsylvania Ave NW, Washington, DC 20500

Dear Secretary Azar, Administrator Verma, and Vice President Pence,

With the burgeoning nationwide spread of COVID-19, the Department of Health and Human Services must use all the tools at its disposal to combat the growing crisis. This letter focuses on one agenda item among many: **creating an Emergency, 60-Day Special Enrollment Period,** in both healthcare.gov and state-based exchanges.

Maximizing enrollment of the uninsured into coverage for which they qualify is a critically important strategy for addressing the current pandemic. Disease is typically detected when symptomatic consumers seek care. Consumers without insurance face cost barriers that delay their receipt of necessary care until illness worsens. During the current pandemic, this delays detection and treatment of COVID-19, accelerating the disease's spread.

It is thus no surprise that many states that operate their own exchanges, including Connecticut, the District of Columbia, Maryland, Massachusetts, New York, Rhode Island, and Washington, have already created emergency SEPs. We urge the Department to give Americans who live in the 38 states served by the HealthCare.Gov platform similar access to coverage and care.

The emergency SEP should be open to anyone who wishes to enroll. Limiting the SEP to defined groups who must verify eligibility would not only delay care receipt, it would deter enrollment by healthy consumers, endangering the individual-market risk pool. Additionally, the Department should waive any verification processes that would only delay critical access to coverage. The rapid commencement of treatment also requires an expedited effectuation date, coverage should begin as soon as possible, regardless of when plan selection occurs.

In order to get the word out to consumers the Department should invest significant resources in educating the public about this SEP through digital and television ads. Additionally, the Department should create materials in multiple languages, accessible formats for people with disabilities, and resources for hard-to-reach populations to give diverse populations access to this SEP. Engaging application assisters to help consumers sign up would make the SEP much more successful in reaching its goals. Finally, given the likelihood of rising unemployment and uncertainty among hourly workers, the Department should also focus significant outreach and advertising efforts to employers and employees most at-risk of losing employer-based coverage. These are all important first steps in enrolling the uninsured to limit the scope of the current public health crisis.

Sincerely,

1,000 Days

ABLE NH (Advocates Building Lasting Equality in NH)

ACA Consumer Advocacy

ACCESS (Michigan)

Access Living of Metropolitan Chicago

Advocates for Youth

African Services Committee

AIDS Foundation of Chicago

Alaska Children's Trust

Alliance for a Just Society

American Association on Health and Disability

American Cancer Society Cancer Action Network

American College of Obstetricians and Gynecologists

American Diabetes Association

American Federation of State, County & Municipal Employees

American Federation of Teachers

American Medical Student Association

American Muslim Health Professionals

American Psychological Association

Arcora Foundation

Arkansas Advocates for Children and Families

Asian & Pacific Islander American Health Forum

Association of State and Territorial Dental Directors

Bazelon Center for Mental Health Law

Bi-State Primary Care Association

Black Women's Health Imperative

California Pan-Ethnic Health Network

Catalyst Miami

Center for Health Progress

Center for Independence of the Disabled, NY

Center for Medicare Advocacy, Inc.

Center for Patient Partnerships

Center for Popular Democracy

Center for Public Policy Priorities (Texas)

Central Virginia Health Services

Champaign County Health Care Consumers

Chicago Coalition for the Homeless

Children's Action Alliance

Children's Defense Fund - Texas

Circle Up, United Methodist Women for Moms

Citizen Action of New York

Citizen Action of Wisconsin

Clare Housing

Clay-Battelle Health Services Association

Coalition for Asian American Children and Families

Coalition of Texans with Disabilities

Community Catalyst

Community Dental Health NPO

Consumers for Affordable Health Care

Covering Wisconsin

Detroit Community Solutions

Empire Justice Center

End Domestic Abuse Wisconsin

Epilepsy Florida

Equal Hope

EverThrive Illinois

Faith in Public Life

Families USA

Family and Child Treatment of Southern Nevada

Family Voices of Tennessee

FamilyCare

Farmworker Justice

First Focus on Children

Florida ADAPT

Foley Waite LLC, NJMSA

Foundation Communities Prosper Centers

Future Smiles

Gay Men's Health Crisis, Inc

Georgia Budget and Policy Institute

Georgia Watch

Georgians for a Healthy Future

Get America Covered

GO2 Foundation for Lung Cancer

Health & Medicine Policy Research Group

Health Care for All Massachusetts

Health Care for All New York

Health Care Voter

Hometown Action

Houston Health Department

HRCHC - Hope Rising

Human Rights Campaign

Illinois Academy of Family Physicians

Illinois Action for Children

Illinois Coalition for Immigrant and Refugee Rights

Illinois Primary Health Care Association

Illinois Public Health Institute

Indivisible

Iowa Citizens for Community Improvement

Jen Mishory, Senior Fellow, The Century Foundation

Justice in Aging

Kentucky Equal Justice Center

Kentucky Voices for Health

KidCare Coalition of Miami-Dade

Lakeshore Foundation

Latino Coalition for a Healthy California

Latino Outreach of New Jersey

Legacy Community Health Services

Leukemia & Lymphoma Society

Maine Equal Justice

Manatee Children's Services

Manatee County Habitat for Humanity

March for Moms

March of Dimes

MaryCatherine Jones Consulting, LLC

Maryland Citizens' Health Initiative

Medicaid-Medicare-CHIP Services Dental Association

Medicare Rights Center

Michigan Oral Health Coalition

Mississippi Center for Justice

Missouri Health Care For All

Missouri Rural Crisis Center

Monroe Health Center

Montana Women Vote

NAMI Texas

National Alliance on Mental Illness

National Association of Social Workers

National Association of Social Workers – Texas Chapter

National Council of Jewish Women

National Family Planning & Reproductive Health Association

National Health Council

National Health Law Program

National Institute for Reproductive Health (NIRH)

National Patient Advocate Foundation

National Women's Health Network

Nebraska Appleseed

New Futures

New Hampshire Nurses Association

New Jersey Citizen Action

New Voices for Reproductive Justice

New York Immigration Coalition

North Carolina AIDS Action Network

North Carolina Child

Northwest Health Law Advocates

Oklahoma Policy Institute

OneAmerica

Out2Enroll

Palmetto Project

Partnership for Children's Oral Health

PDI Surgery Center

Pennsylvania Health Access Network

People’s Action

Planned Parenthood Federation of America

PolicyRx

Power to Decide

Preston-Taylor Community Health Centers, Inc.

Prevention Access Campaign

Primary Care Access Network (PCAN)

ProHealth TES

Protect Our Care Illinois

Protect our Care New Hampshire

Public Citizen

Raising Women's Voices for the Health Care We Need

Senior Mobile Dental

Shea Writing and Training Solutions, Inc.

Shriver Center on Poverty Law

Sight & Sound Care LLC

South Carolina Appleseed Legal Justice Center

Southern Vermont Area Health Education Center

TakeAction Minnesota

TeethFirst

Tennessee Disability Coalition

Tennessee Health Care Campaign

Tennessee Justice Center

Texas Association of Community Health Centers, Inc.

Texas Nurses Association

The Actors Fund

The American Institute of Dental Public Health

The Bingham Program

The Commonwealth Institute for Fiscal Analysis

The Connecticut Oral Health Initiative, Inc.

The Kidz Club Prescribed Pediatric Extended Care Center

The Los Angeles Trust for Children's Health

The Praxis Project

The Rhode Island JASYCEE Alliance

Treatment Action Group

Triage Cancer

Trinity Health

Trust for America's Health

UHCAN Ohio

UnidosUS

Union for Reform Judaism

United Action for Idaho

United Vision for Idaho

United Way of Dane County

United Way of Williamson County

United Way Worldwide

United Ways of Texas

Utah Health Policy Project

Virginia Coalition of Latino Organizations

Virginia Health Catalyst

Virginia Organizing

Virginia Poverty Law Center

Voices for Vermont's Children

Washington CAN

Washtenaw Health Plan

West Central Initiative

West Virginia Center on Budget and Policy

West Virginia Citizen Action

West Virginia FREE

West Virginians for Affordable Health Care

Whole Child Manatee

Wisconsin Alliance for Women's Health

Wisconsin Faith Voices for Justice

Women's Health and Family Planning Association of Texas

Young Invincibles

Exhibit A-49

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Center for Consumer Information & Insurance Oversight
200 Independence Avenue SW
Washington, DC 20201

Date: **May 14, 2020**

From: Samara Lorenz, Director, Oversight Group, Center for Consumer Information & Insurance Oversight

Title: Insurance Standards Bulletin Series – INFORMATION

Subject: Temporary Period of Relaxed Enforcement of Certain Timeframes Related to Group Market Requirements under the Public Health Service Act in Response to the COVID-19 Outbreak

Markets: Group

I. Background

On March 13, 2020, President Donald J. Trump signed the Proclamation on Declaring a National Emergency Concerning the Coronavirus Disease 2019 (COVID-19) Outbreak (COVID-19 National Emergency).[1] On April 28, 2020, the Department of Labor (DOL), the Department of the Treasury (Treasury Department), and the Internal Revenue Service (IRS) issued the following guidance so plan participants, beneficiaries, and employers have additional time to make critical health coverage and other decisions affecting benefits and to send certain required notices during the COVID-19 outbreak:

- **Joint Notice Issued by DOL, Treasury Department, and IRS (Joint Federal Register Notice)**. The Joint Federal Register Notice provides group health plans subject to the Employee Retirement Income Security Act of 1974 (ERISA) and the Internal Revenue Code (the Code) and plan participants and beneficiaries additional time to comply with certain deadlines affecting COBRA continuation coverage, special enrollment periods, claims for benefits, appeals of denied claims, and external review of certain claims. The Joint Federal Register Notice is available at https://www.govinfo.gov/content/pkg/FR-2020-05-04/pdf/2020-09399.pdf.

[1] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak, issued March 13, 2020, available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

- **EBSA Disaster Relief Notice 2020-01 (EBSA Notice 2020-01).** EBSA Notice 2020-01 extends the deadlines under which other notices, disclosures and other documents required under the provisions of Title I of ERISA over which DOL has interpretive and regulatory authority must be furnished to participants and beneficiaries if the plan administrator acts in good faith and furnishes such notice, disclosure, or document as soon as administratively practicable under the circumstances. EBSA Notice 2020-01 is available at: https://www.dol.gov/agencies/ebsa/employers-and-advisers/plan-administration-and-compliance/disaster-relief/ebsa-disaster-relief-notice-2020-01.

II. Guidance

The Centers for Medicare & Medicaid Services (CMS) concurs with the relief specified by DOL, the Treasury Department, and IRS in the Joint Federal Register Notice, as well as in EBSA Notice 2020-01 issued by DOL. Between March 1, 2020 and 60 days after the end of the COVID-19 National Emergency, or such other date announced by DOL or jointly by DOL and the Treasury Department/IRS in future guidance, CMS will adopt a temporary policy of relaxed enforcement to extend similar time frames otherwise applicable to non-Federal governmental group health plans and health insurance issuers offering coverage in connection with a group health plan, and their participants and beneficiaries, under applicable provisions of title XXVII of the Public Health Service Act (PHS Act). Under this temporary policy, CMS also will not consider a Small Business Health Options Program (SHOP), a SHOP issuer offering a qualified health plan (QHP) through a SHOP, or small business participating in a SHOP to be out of compliance with rules applicable to the SHOP, to the extent the SHOP, issuer, or small business operates in a manner consistent with this relief. To the extent there are different outbreak period end dates for different parts of the country, the relief provided by this Bulletin will apply in a manner consistent with any additional guidance announced by DOL or jointly by DOL and the Treasury Department/IRS regarding the application of the relief to those different areas.

While the extension of time frames is not mandatory for non-Federal governmental plans, CMS encourages plan sponsors of non-Federal governmental plans to provide relief to participants and beneficiaries similar to that specified in the Joint Federal Register Notice, and encourages, but does not require, states, SHOPs, and health insurance issuers offering coverage in connection with a group health plan to enforce and operate, respectively, in a manner consistent with the relief provided in the Joint Federal Register Notice and EBSA Notice 2020-01. CMS will not consider a state to have failed to substantially enforce the applicable provisions of title XXVII of the PHS Act if the state takes such an approach.

The relief provided by this Bulletin does not apply to health insurance issuers offering individual health insurance coverage. For other COVID-19 related guidance applicable to individual health insurance coverage, visit https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#COVID-19.

We believe this guidance is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA).[2] CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, in light of the COVID-19 public health emergency, prior notice and comment for this guidance is impracticable and contrary to the public interest, and there is good cause to issue this guidance without prior public participation and without a delayed effective date.[3]

Where to get more information: If you have any questions regarding this Bulletin, please email the CCIIO mailbox Marketreform@cms.hhs.gov (use "COVID-19" as the subject of the email).

[2] 5 U.S.C. § 553(b)(3)(A).
[3] 5 U.S.C. § 553(b)(3)(B) and (d)(3).

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CITY OF CHICAGO,

Plaintiff,

vs.

ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, et al.,

Defendants.

Case No. 1:20-cv-1566

[PROPOSED] ORDER GRANTING
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

Plaintiff the City of Chicago has moved for a preliminary injunction to compel Defendants to provide a special enrollment period on the 38 Affordable Care Act Exchanges managed in whole or in part by the federal government on the Healthcare.Gov platform in response to the novel coronavirus pandemic. Chicago alleges that Defendants' refusal to provide a special enrollment period violates the Affordable Care Act, its implementing regulations, and the Administrative Procedure Act. The Court has considered the parties' briefing, evidence, and arguments as well as the authorities cited in support of their positions. For the reasons set forth in Plaintiff's motion and supporting documents, the Court hereby ORDERS that:

1. Plaintiffs' Motion for Preliminary Injunction is GRANTED.

2. Defendants are hereby ENJOINED to provide a special enrollment period on the aforementioned Exchanges starting as of the date of this order and lasting for 60 days. That special enrollment period must allow consumers to enroll in coverage effective as of the first day of the month in which this order is issued.

3. Under the circumstances, the Court dispenses with the requirement that the movant give security for the issuance of the injunction. *See* Fed. R. Civ. P. 65(c).

SO ORDERED.

Dated: _____

_____
United States District Judge

SERVICE LIST

Pursuant to Local Rule 7(k), the undersigned certifies that, because no attorney has yet appeared for Defendants, there are no attorneys other than counsel for Chicago who are entitled to be notified of the entry of this order. Chicago will instead serve a copy of this order with its motion on Defendants at the following addresses:

Alex M. Azar, II
United States Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Seema Verma
Centers for Medicare and Medicaid Services
7500 Security Blvd,
Baltimore, MD 21244

Civil Process Clerk
US Attorney's Office for the District of Columbia
555 4th St NW
Washington, DC 20530

William Barr, Attorney General of the United States
Office of Attorney General of the United States
950 Pennsylvania Avenue, NW
Washington, DC 20530

/s/ John T. Lewis
John T. Lewis