

**In the United States Court of Appeals
for the District of Columbia Circuit**

No. 20-5193

THE AMERICAN HOSPITAL ASSOCIATION, ET AL.,
APPELLANTS

v.

ALEX M. AZAR II,
SECRETARY OF HEALTH AND HUMAN SERVICES,
APPELLEE

APPELLANTS' EMERGENCY MOTION FOR STAY

Pursuant to Federal Rules of Appellate Procedure 8, 18, and 27, appellants American Hospital Association, Association of American Medical Colleges, Federation of American Hospitals, National Association of Children's Hospitals, Memorial Community Hospital and Health System, Providence Health System–Southern California d/b/a Providence Holy Cross Medical Center, and Bothwell Regional Health Center move for an emergency stay of enforcement of the Department of Health and Human Services' (HHS) hospital price transparency rule. *See* Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65,524 (Nov. 27, 2019) (Ex. 4). The rule is scheduled to take effect on January 1, 2021. Emergency

relief is warranted in light of the recent announcement by the Centers for Medicare & Medicaid Services (CMS) that the agency will begin conducting audits in January 2021 to ensure compliance with the rule and enforce its mandates with monetary penalties. Ex. 1. This imminent enforcement regime will force overburdened hospitals to divert resources that hospitals desperately need to respond to the surge of COVID-19 cases and successfully roll out the vaccines that were approved following oral argument in this case. A stay is necessary in these exceptional circumstances.

This Court's intervention is needed by December 31, 2020, the day before the rule takes effect and triggers serious penalties for noncompliance. Appellants have filed the instant motion at least seven days before that date, as required by Circuit Rule 27(f). Appellants' counsel has conveyed the request for expedited relief to both the clerk's office and opposing counsel. *See id.* The government does not consent to the motion for stay.¹ No stay has previously been sought from this Court or the district court.

¹ The parties have agreed on a briefing schedule for the instant motion. The government intends to submit a response brief by December 23, 2020. Appellants will submit their reply by December 24, 2020.

BACKGROUND

At issue in this case is an HHS rule requiring hospitals to make disclosures for each item and service negotiated by each commercial health insurer. *See Price Transparency Requirements for Hospitals to Make Standard Charges Public*, 84 Fed. Reg. 65,524 (Nov. 27, 2019) (Ex. 4). HHS proposed the rule in August 2019 and finalized the rule in November 2019. Even at that time, well before the coronavirus had upended hospital operations across the world, the rule imposed substantial and unworkable reporting burdens. Those burdens, which CMS has coupled with a significant and punitive enforcement regime, have become impossible in the face of a pandemic.

On June 29, 2020, four of the Appellants wrote to Secretary Azar describing those challenges and requesting that HHS delay the effective date of the rule “until the matter is settled by the courts.” Ex. 2. As Appellants explained, “attempting to comply with the rule will require a significant diversion of financial resources and staff time that hospitals and health systems cannot afford to spare as they prepare to or care for patients with COVID-19.” *Id.* Among other challenges, hospitals have had to redeploy both staff and resources to increase their bed capacity, overhaul their telehealth systems, and rapidly acquire protective equipment for doctors and nurses, all at the same

time they are struggling with revenue reductions. *Id.* Whatever the merits of the hospital price transparency rule, Appellants urged Secretary Azar that “advancing this policy is not essential at this moment.” *Id.*

HHS never responded to this request. Far from postponing implementation of the rule, CMS issued a bulletin on December 18, 2020, indicating that it was preparing to flex its enforcement powers. Its notice stated: “CMS plans to audit a sample of hospitals for compliance starting in January, in addition to investigating complaints that are submitted to CMS and reviewing analyses of non-compliance, and hospitals may face civil monetary penalties for non-compliance.” Ex. 1. If CMS finds a hospital has not complied, it may provide a warning, request a corrective action plan, or impose a penalty of \$300 per day if the hospital fails to submit such an action plan or abide by its requirements. *See* 84 Fed. Reg. at 65,604–05; Ex. 1. CMS may also publicize the imposition of the penalty on its web site. *Id.*

Even as CMS prepares to enforce the price transparency rule, hospitals lack clarity about how to implement it. During a web cast on December 8, 2020, CMS advised that a common strategy that hospitals and their vendors

have pursued to comply with the rule would not satisfy its requirements.² Thus, even some hospitals that believed they were on track may find themselves subject to noncompliance penalties after the rule takes effect on January 1, 2021.

The government's notice that it would immediately begin enforcing the rule and accepting reports of potential violations precipitated the emergency motion for stay.

ARGUMENT

This Court may issue an emergency stay upon consideration of the following factors: (1) whether the applicant is likely to succeed on the merits; (2) whether the applicant will be irreparably harmed absent a stay; (3) whether the stay would substantially injure the other interested parties; and (4) where the public interest lies. *See Nken v. Holder*, 556 U.S. 418, 425–26 (2009); D.C. Cir. R. 8(a)(1). A stay is warranted here to prevent the diversion of personnel and resources hospitals have brought to the front lines of the coronavirus pandemic. Absent intervention from this Court, hospitals will be forced to devote

² A recording and transcript of the web cast will be available at the following web address on or about December 22, 2020. *See* <https://www.cms.gov/outreach-and-education/outreach/npcnational-provider-calls-and-events/2020-12-08-hospital>.

staff time to complying with the rule that is now spent expanding bed capacity, planning for the vaccine rollout, and satisfying virus reporting obligations. Whatever the public's interest in hospital price transparency, it pales in comparison to the immediate public interest in an effective coronavirus response.

A. Appellants Are Likely To Succeed on the Merits.

Appellants' opening brief has already presented the reasons why the rule is unconstitutional and invalid under the Administrative Procedure Act. Appellants will not repeat those arguments here, except to emphasize that the rule is invalid because, among other reasons, the burdens associated with compliance far exceed its entirely speculative benefits. *See* AHA Br. 52–62. Meanwhile, the burdens on hospitals in responding to the COVID-19 pandemic have only continued to grow, as explained below.

B. Absent a Stay, Hospitals Will Suffer Irreparable Injury.

Irreparable harm is harm that is both (1) imminent and actual, and not theoretical, and (2) beyond remediation by money damages. *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7–8 (D.C. Cir. 2016). Absent a stay, Appellants and their member hospitals will suffer such harm because they must immediately shift resources from responding to the coronavirus to

implementing the price transparency rule before CMS begins launching compliance audits and imposing fines in January 2021.

Hospital resources are finite, and those resources have been taxed like never before during the COVID-19 pandemic. Hospitals and health systems across the country have had to redeploy “both personnel and financial resources from departments across each organization” to prepare for the surge of coronavirus patients. Ex. 2. Unfortunately, that surge only promises to grow in the coming months. Critical, time-sensitive tasks have included expanding bed capacity and amassing personal protective equipment for health care workers. *Id.* Now that the federal government has approved two vaccines, hospitals are also developing plans to acquire and store the shots and track which patients and hospital staff have and have not received the required second dose. Ex. 3, ¶ 13. And hospitals have undertaken these herculean efforts at a time when they “are facing dramatic reductions in revenue from patients forgoing both non-emergent and emergent care.” Ex. 2.

The experience of Saint Luke’s Health System in Kansas City, Missouri, is representative. As Charles V. Robb, the chief financial officer of Saint Luke’s, testified in the attached declaration, the same information technology

staff charged with implementing HHS’s price transparency rule are also developing a platform for tracking administration of the COVID-19 vaccines and satisfying the hospital system’s reporting obligations to federal and state governments. Ex. 3, ¶¶ 12–13. This platform had to be built because the hospital’s existing infrastructure for tracking the flu shot was not suitable for tracking vaccines approved under an emergency use authorization. *Id.* ¶ 13. Separately from the efforts of the IT department, the same Saint Luke’s billing staff involved in the price transparency project also had to establish a system for billing the federal government for the coronavirus vaccines. *Id.* ¶ 14.

What is more, both the IT and billing departments have played a role in developing the infrastructure necessary to expand the hospital system’s “surge capacity”—that is, to ensure its hospitals have a sufficient number of beds to handle the growing demand. *Id.* ¶ 15. Hospital personnel cannot delay these critical efforts to secure the public health in order to implement the new price transparency rule that CMS will begin enforcing through audits and monetary penalties next month. Devoting staff time to complying with the rule, even as coronavirus cases reach new heights, would be a gross misallocation of resources and a dereliction of hospitals’ mission to serve their patients.

Courts in this circuit have recognized that the forced diversion of critical resources can amount to an irreparable injury justifying a stay. In *District of Columbia v. U.S. Department of Agriculture*, 444 F. Supp. 3d 1 (D.D.C. 2020), for example, the district court enjoined enforcement of a USDA rule that would have caused nearly 700,000 individuals to lose their benefits under the Supplemental Nutrition Assistance Program (SNAP), *id.* at 6. One of the parties challenging the rule, Bread for the City, argued that the rule would cause it irreparable harm by “increasing demand” for its food assistance program and siphoning resources from its other social service programs and advocacy efforts, all in the thick of a global pandemic. *Id.* at 40. The court agreed, holding: “These harms from the forced diversion of resources are similar to those recognized as irreparable harm in other suits.” *Id.* at 42; *see also Pennsylvania v. DeVos*, No. 20-cv-1468, 2020 WL 4673413, at *13 (D.D.C. Aug. 12, 2020) (“And courts in this circuit have considered administrative and compliance costs are part of the irreparable harm analysis.”); *cf. Mexichem Specialty Resins, Inc. v. EPA*, 787 F.3d 544, 555 (D.C. Cir. 2015) (recognizing that financial costs of compliance may be irreparable where no “adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation”). So too here, the HHS rule would irreparably harm hospitals

like Saint Luke's by diverting staff currently assigned to build the pandemic response infrastructure to implementing required disclosures before the CMS audits—and fines—begin in January.

C. Granting the Stay Would Not Harm the Government's Legitimate Interests.

Granting the emergency stay would not harm the government's interest in improving price transparency for consumers, for at least two reasons. First and foremost, hospitals are already required under HHS's previous interpretation of the Affordable Care Act, 42 U.S.C. § 300gg-18(e), to disclose their gross charges to consumers. *See* AHA Br. 13–15. The motion for stay, in other words, does not present a choice between disclosure and secrecy, but between the existing disclosure rubric and a new one. What is more, HHS has acknowledged that, quite apart from the federal mandate, many hospitals have already provided “patient-friendly price transparency tools that calculate individualized out-of-pocket cost estimates.” 84 Fed. Reg. at 65,576. And HHS itself portrays its new rule as merely a “first step” that requires third-party actors to take additional steps before greater transparency can be achieved. *Id.* at 65,528–29; AHA Br. 58. HHS cannot show irreparable injury where there is an existing, effective system in place for meeting its goals of promoting transparency and consumer choice. *See, e.g., Pursuing America's Greatness v.*

FEC, 831 F.3d 500, 511–12 (D.C. Cir. 2016) (enjoining federal regulation where agency had other existing means to promote its objectives).

If anything, the new disclosure system mandated by HHS will cause more confusion than clarity. As Appellants argued in their opening brief, the new rule requires hospitals to release millions of data points reflecting its billing agreements with insurance carriers—data that will likely prove impenetrable to consumers. AHA Br. 59–60. Even HHS has admitted that “the impact resulting from the release of negotiated rates is largely unknown.” 84 Fed. Reg. at 65,542. The agency will suffer no cognizable harm from staying the enforcement of a regulation whose benefits are at best speculative.

Second, even if HHS presently objects to the stay, it is by no means clear that the incoming Administration will share the agency’s assessment of the rule’s supposed benefits. Appellants respectfully submit that the Court stay enforcement of the rule for six months, so that hospitals can discharge their responsibilities in addressing the coronavirus pandemic and vaccine distribution.

D. The Public Interest Heavily Favors a Stay.

There can be no dispute that the public has a surpassing interest in a health system with a capacity to handle the surge of new coronavirus cases.

According to the CDC's COVID Data Tracker, the most recent daily average cases number more than 237,000, the highest at any point since the start of the pandemic.³ Mr. Robb, the chief financial officer of Saint Luke's, testified in the attached declaration that the hospital system predicts that the surge of COVID patients alone will strain its medical-surgical and ICU bed capacity in the coming weeks—even as it continues to treat patients with other serious ailments. Ex. 3, ¶¶ 18–19.

This dire shortage is by no means limited to Saint Luke's. There, as at other hospital systems around the country, the same staff responsible for building surge capacity are also responsible for implementing the new HHS price transparency rule. *Id.* ¶ 15. Even assuming *arguendo* that the new rule serves the public interest in price transparency, that interest is far less pressing and immediate than the public's interest in a hospital system well-equipped to handle the coronavirus pandemic. A stay of enforcement of the new rule will assure that hospitals can deploy their resources to serve both the sick patients who will desperately need them and the healthy patients who look to hospitals to administer the new vaccine regimens.

³ The data are available at https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases.

CONCLUSION

For the reasons given above, Appellants respectfully submit that this Court should stay the enforcement of the price transparency rule for six months as hospitals continue to battle the COVID-19 pandemic.

Respectfully submitted,

s/ Lisa S. Blatt

LISA S. BLATT

WILLIAMS & CONNOLLY LLP

725 Twelfth Street, N.W.

Washington, DC 20005

(202) 434-5000

Counsel for Appellants

DECEMBER 21, 2020

**CERTIFICATE OF COMPLIANCE WITH
TYPEFACE AND WORD-COUNT LIMITATIONS**

I, Lisa S. Blatt, counsel for Appellants and a member of the Bar of this Court, certify pursuant to Federal Rules of Appellate Procedure 27(d) and 32(g) that the foregoing Emergency Motion to Stay is proportionally spaced, has a serif typeface of 14 points or more, and contains 2,425 words.

s/ Lisa S. Blatt
LISA S. BLATT

CERTIFICATE OF SERVICE

I, Lisa S. Blatt, counsel for Appellants and a member of the Bar of this Court, certify that, on December 21, 2020, a copy of the foregoing Emergency Motion for Stay was filed with the Clerk and served on the parties through the Court's electronic filing system. I further certify that all parties required to be served have been served.

s/ Lisa S. Blatt
LISA S. BLATT

Exhibit 1

**MLN Connects Special Edition:
Monitoring for Hospital Price Transparency
(Dec. 18, 2020)**



mlnconnects

Official CMS news from the Medicare Learning Network®

SPECIAL EDITION

Friday, December 18, 2020

Monitoring for Hospital Price Transparency

Hospital Price Transparency requirements go into effect January 1, 2021. CMS plans to audit a sample of hospitals for compliance starting in January, in addition to investigating [complaints that are submitted to CMS](#) and reviewing analyses of non-compliance, and hospitals may face civil monetary penalties for noncompliance.

Is your institution prepared to comply with the requirements of the [Hospital Price Transparency Final Rule](#)? Effective January 1, 2021, each hospital operating in the United States is required to provide publicly accessible standard charge information online about the items and services they provide in 2 ways:

- Comprehensive machine-readable file with all items and services
- Display of 300 shoppable services in a consumer-friendly format

In the final rule, CMS outlined a monitoring and enforcement plan to ensure compliance with the requirements. We finalized a policy that CMS monitoring activities may include, but would not be limited to, the following, as appropriate:

- Evaluation of complaints made by individuals or entities to CMS
- Review of individuals' or entities' analysis of noncompliance
- Audit of hospital websites

If we conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, we may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s)
- Request a Corrective Action Plan (CAP) if noncompliance constitutes a material violation of one or more requirements
- Impose a civil monetary penalty not in excess of \$300 per day and publicize the penalty on a CMS website if the hospital fails to respond to our request to submit a CAP or comply with the requirements of a CAP

See [45 CFR part 180 Subpart C- Monitoring and Penalties for Noncompliance](#).

Visit the [Hospital Price Transparency](#) website for additional information and resources to help hospitals prepare for compliance, including:

- [FAQs \(PDF\)](#)
- [8 Steps to a Machine-Readable File \(PDF\)](#)
- [10 Steps to a Consumer-Friendly Display \(PDF\)](#)
- [Quick Reference Checklists \(PDF\)](#)

[Like the newsletter? Have suggestions? Please let us know!](#)

[Subscribe](#) to MLN Connects. Previous issues are available in the [archive](#).

Follow the MLN on [Twitter](#) #CMSMLN, and visit us on [YouTube](#).

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health and Human Services (HHS).



Exhibit 2

Letter from American Hospital Association
et al. to Sec. Azar (HHS) and Admin. Verma
(Centers for Medicare & Medicaid Services)
(June 29, 2020)



June 29, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Azar and Administrator Verma:

On behalf of America's hospitals and health systems, **we urge you to delay the effective date of the hospital price transparency rule – given the burden it would pose to hospitals and health systems in the midst of responding to the COVID-19 public health emergency – until the matter is settled by the courts.**

The last several months have required all hospitals and health systems to dedicate significant resources to managing the COVID-19-surge and adapting to new ways of caring for patients. The challenges that hospitals and health systems have faced – rapid bed capacity increases, overnight telehealth system overhauls and implementation, and personal protective equipment (PPE) and other supply acquisition – have been nothing short of extraordinary, requiring the redeployment of both personnel and financial resources from departments across each organization. Meanwhile, hospitals and health systems are facing dramatic reductions in revenue from patients forgoing both non-emergent and emergent care. We anticipate the challenges associated with COVID-19 will continue for the foreseeable future, and perhaps until we develop and deploy a vaccine or reliable treatment. Resources of hospitals and health systems at this critical time must be devoted to patient care.

While we disagree with the agency on the value of public disclosure of negotiated rate information (as opposed to estimated out-of-pocket costs), we hope that you will agree that advancing this policy is not essential at this moment. Even attempting to comply with the rule will require a significant diversion of financial resources and staff time that hospitals and health systems cannot afford to spare as they prepare to or care for patients with COVID-19. Asking information technology and clinical care departments to refocus their efforts at this juncture is, at best, unwise, as the past week has

The Honorable Alex M. Azar
The Honorable Seema Verma
June 29, 2020
Page 2 of 2

demonstrated that significant new outbreaks of the virus can occur in locations that were previously unaffected or had very few cases.

Given the current set of circumstances, we urge you to delay implementation of this rule until the issue is settled by the courts. The Administrative Procedure Act (APA) specifically contemplates an agency's postponing the effective date of action taken by it pending judicial review.

In addition, the Centers for Medicare & Medicaid Services (CMS) has recognized a need to relax implementation deadlines for new rules in light of COVID-19 and has said that exercise of its enforcement discretion is not subject to the procedural requirements of the APA. In April, CMS [stated](#): "Due to the public health emergency posed by COVID-19, CMS is exercising ... enforcement discretion ... to adopt a temporary policy of relaxed enforcement in connection to implementation of the *Interoperability and Patient Access final rule*. We believe that the announcement of the exercise of enforcement discretion is a statement of agency policy not subject to the notice and comment requirements of the . . . APA." A similar exercise in enforcement discretion is requested here.

Moreover, we note that, as a result of COVID-19, CMS has waived statutory deadlines that apply to its rulemaking. CMS explained that, "due to CMS prioritizing efforts in support of containing and combatting the COVID-19 [Public Health Emergency], and devoting significant resources to that end, we are hereby waiving the 60-day delay in the effective date of the IPPS and LTCH PPS final rule" 85 Fed. Reg. 32,460, 32,889 (May 29, 2020). CMS should provide hospitals and health systems struggling to meet the needs of patients during the COVID-19 public health emergency the same flexibility the agency itself has needed by delaying the implementation date of the hospital price transparency rule.

We appreciate the support and assistance that the Department of Health and Human Services has regularly provided hospitals and health systems during this pandemic so that they are best positioned to care for their patients and communities. The health and well-being of our nation is our top priority, and we look forward to continuing to work with you to serve that goal.

Sincerely,

American Hospital Association
Federation of American Hospitals
Association of American Medical Colleges
Children's Hospital Association

Exhibit 3

Declaration of Charles V. Robb in Support of
Appellants' Emergency Motion to Stay
(Dec. 21, 2020)

**In the United States Court of Appeals
for the District of Columbia Circuit**

No. 20-5193

AMERICAN HOSPITAL ASSOCIATION ET AL.,
APPELLANTS

v.

ALEX M. AZAR II,
SECRETARY OF HEALTH AND HUMAN SERVICES,
APPELLEE

**DECLARATION OF CHARLES V. ROBB IN SUPPORT OF
APPELLANTS' EMERGENCY MOTION TO STAY**

1. I, Charles V. Robb, am the senior vice president and chief financial officer of Saint Luke's Health System in Kansas City, Missouri.
2. Saint Luke's is a member of the American Hospital Association.
3. I make this declaration in support of Appellants' emergency motion to stay the Centers for Medicare & Medicaid Services (CMS) from enforcing the disclosure requirements set forth in the rule titled Price Transparency Requirements for Hospitals to Make Standard Charges Public, 84 Fed. Reg. 65,524 (Nov. 27, 2019).
4. The rule is scheduled to take effect on January 1, 2021.

5. Several of the Appellants sent a letter to Alex M. Azar II, secretary of the Department of Health and Human Services, and Seema Verma, administrator of CMS, on June 29, 2020, urging them “to delay the effective date of the hospital price transparency rule [] given the burden it would pose to hospitals and health systems in the midst of responding to the COVID-19 public health emergency.” Appellants did not receive a response.

6. CMS issued a notice on December 18, 2020, that it “plans to audit a sample of hospitals for compliance starting in January, in addition to investigating complaints that are submitted to CMS and reviewing analyses of non-compliance, and hospitals may face civil monetary penalties for noncompliance.” A copy of that notice may be found at <https://www.cms.gov/files/document/2020-12-18-mlnc-se.pdf>.

7. Saint Luke’s operates a network of 16 hospitals and hospital campuses in the greater Kansas City area and in rural Missouri and Kansas.

8. Since the Department of Health and Human Services published the final price transparency rule in 2019, Saint Luke’s has made preparations to publish the required information to consumers.

9. Saint Luke’s has devoted hundreds of hours to developing the list of negotiated rates for 300 “shoppable services” and checking their accuracy.

10. Separately, Saint Luke's has been building the required "machine-readable" digital file containing standard charges for each hospital item or service. This file presently contains more than seven million lines of information.

11. Notwithstanding these diligent efforts, the COVID-19 pandemic has impaired our hospital system's ability to develop the systems and infrastructure needed to comply with the rule.

12. Many of the same finance, billing, and information technology staff charged with implementing the HHS rule are also involved in addressing the manifold challenges to hospital operations created by the pandemic.

13. Saint Luke's information technology (IT) staff are building a system for tracking administration of the new COVID-19 vaccines and complying with our reporting obligations under state and federal law. That project has required significant manpower because the existing software platform Saint Luke's uses to track the administration of flu vaccines was not suitable for tracking the vaccines approved under emergency use authorizations. Saint Luke's must report its administration of the COVID-19 vaccines to two different states, Kansas and Missouri, each with distinct reporting requirements.

14. Meanwhile, the Saint Luke's revenue and billing staff are presently establishing systems for billing the federal government for the administration of COVID-19 vaccines.

15. Employees in both the revenue and IT departments are also involved in building Saint Luke's "surge capacity," that is, our ability to bring into service additional hospital beds or repurpose clinical units to handle the surge of patients infected with COVID-19.

16. Many of the same employees from the IT and billing departments involved in these projects also have responsibility for developing systems needed to comply with HHS's price transparency rule.

17. The time and resources these employees devote to implementing are time and resources diverted from responding to the COVID-19 pandemic.

18. Saint Luke's projects that demand from COVID-19 patients alone will continue to strain its supply of medical-surgical and ICU beds.

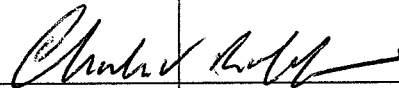
19. The hospital system continues to receive and treat patients with other serious ailments as well. Because other hospitals are also full, Saint Luke's is forced off "high volume" diversion by local authorities, and we must take care of these patients when they arrive by ambulance in our emergency departments despite strained resources.

20. Responding to this public health emergency requires all available hospital resources. Deploying Saint Luke's personnel to implementing the HHS rule is not, in my professional experience, the highest and best use of their time.

I declare under penalty of perjury that the foregoing is true and correct.
See 28 U.S.C. § 1746(2).

Executed on December 21, 2020.

Respectfully submitted,



CHARLES V. ROBB

Senior Vice President and Chief Financial Officer, Saint Luke's Health System

Exhibit 4

Medicare and Medicaid Programs: CY 2020
Hospital Outpatient PPS Policy Changes
and Payment Rates and Ambulatory
Surgical Center Payment System Policy
Changes and Payment Rates. Price
Transparency Requirements for Hospitals to
Make Standard Charges Public,
84 Fed. Reg. 65,524 (Nov. 27, 2019)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subchapter E

[CMS-1717-F2]

RIN 0938-AU22

Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals To Make Standard Charges Public

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule establishes requirements for hospitals operating in the United States to establish, update, and make public a list of their standard charges for the items and services that they provide. These actions are necessary to promote price transparency in health care and public access to hospital standard charges. By disclosing hospital standard charges, we believe the public (including patients, employers, clinicians, and other third parties) will have the information necessary to make more informed decisions about their care. We believe the impact of these final policies will help to increase market competition, and ultimately drive down the cost of health care services, making them more affordable for all patients.

DATES: This final rule is effective on January 1, 2021.

FOR FURTHER INFORMATION CONTACT:

Price Transparency of Hospital Standard Charges, contact Dr. Terri Postma or Elizabeth November, (410) 786-8465 or via email at PriceTransparencyHospitalCharges@cms.hhs.gov.

Quality Measurement Relating to Price Transparency, contact Dr. Reena Duseja or Dr. Terri Postma via email at PriceTransparencyHospitalCharges@cms.hhs.gov.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov/>. Follow the search

instructions on that website to view public comments.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2018 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

- I. Summary and Background
 - A. Executive Summary
 - B. Statutory Basis and Current Guidance
- II. Requirements for Hospitals To Make Public a List of Their Standard Charges
 - A. Introduction and Overview
 - B. Definition of "Hospital" and Hospitals Regarded as Having Met Requirements
 - C. Definition of "Items and Services" Provided by Hospitals
 - D. Definitions for Types of "Standard Charges"
 - E. Requirements for Public Disclosure of All Hospital Standard Charges for All Items and Services in a Comprehensive Machine-Readable File
 - F. Requirements for Displaying Shoppable Services in a Consumer-Friendly Manner
 - G. Monitoring and Enforcement of Requirements for Making Standard Charges Public
 - H. Appeals Process
- III. Comments Received in Response To Request for Information: Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information
- IV. Collection of Information Requirements
 - A. Response to Comments
 - B. ICR for Hospital Price Transparency
- V. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Anticipated Effects
 - D. Alternatives Considered
 - E. Accounting Statement and Table
 - F. Regulatory Reform Analysis Under E.O. 13771
 - G. Conclusion

Regulation Text

I. Summary and Background

A. Executive Summary

1. Purpose

In this final rule, we establish requirements for all hospitals (including hospitals not paid under the Medicare Outpatient Prospective Payment System (OPPS)) in the United States for making hospital standard charges available to the public pursuant to section 2718(e) of the PHS Act, as well as an enforcement

scheme under section 2718(b)(3) of the PHS Act to enforce those requirements. These requirements, as well as the enforcement scheme, are additionally authorized by section 1102(a) of the Social Security Act.

This final rule also addresses comments we received on our proposals to implement section 2718(b) and (e), as well as a request for information on quality measurement relating to price transparency included in the "Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals" (84 FR 39398 through 39644), herein referred to as the "CY 2020 OPPS/ASC proposed rule," which was displayed in the **Federal Register** on July 29, 2019, with a comment period that ended on September 27, 2019.

The final rule with comment period titled "Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots," referred to hereinafter as the "CY 2020 OPPS/ASC final rule with comment period," was displayed in the **Federal Register** on November 1, 2019. In that final rule with comment period, we explained our intent to summarize and respond to public comments on the proposed requirements for hospitals to make public their standard charges in a forthcoming final rule. This final rule is being published as a supplement to the CY 2020 OPPS/ASC final rule with comment period.

2. Summary of the Major Provisions

We are adding a new Part 180—Hospital Price Transparency to Title 45 of the Code of Federal Regulations (CFR) that will codify our regulations on price transparency that implement section

2718(e) of the PHS Act. In this final rule, we are finalizing the following policies: (1) A definition of “hospital”; (2) definitions for five types of “standard charges” (specifically, gross charges and payer-specific negotiated charges, as proposed, plus the discounted cash price, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge) that hospitals would be required to make public; (3) a definition of hospital “items and services” that would include all items and services (both individual and packaged) provided by the hospital to a patient in connection with an inpatient admission or an outpatient department visit; (4) federally owned/operated facilities are deemed to have met all requirements; (5) requirements for making public a machine-readable file that contains a hospital’s gross charges and payer-specific negotiated charges, as proposed, plus discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for all items and services provided by the hospital; (6) requirements for making public payer-specific negotiated charges, as proposed, plus discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge, for 300 “shoppable” services that are displayed and packaged in a consumer-friendly manner, plus a policy to deem hospitals that offer internet-based price estimator tools as having met this requirement; (7) monitoring hospital noncompliance with requirements for publicly disclosing standard charges; (8) actions that would address hospital noncompliance, which include issuing a written warning notice, requesting a corrective action plan (CAP), and imposing civil monetary penalties (CMPs) on noncompliant hospitals and publicizing these penalties on a CMS website; and (9) appeals of CMPs.

3. Summary of Costs and Benefits

We estimate the total burden for hospitals to review and post their standard charges for the first year to be 150 hours per hospital at \$11,898.60 per hospital for a total burden of 900,300 hours (150 hours × 6,002 hospitals) and total cost of \$71,415,397 (\$11,898.60 × 6,002 hospitals), as discussed in section V of this final rule. We estimate the total annual burden for hospitals to review and post their standard charges for subsequent years to be 46 hours per hospital at \$3,610.88 per hospital for a total annual burden for subsequent years of 276,092 hours (46 hours × 6,002 hospitals) and total annual cost of

\$21,672,502 (\$3,610.88 × 6,002 hospitals).

B. Statutory Basis and Current Guidance

Section 1001 of the Patient Protection and Affordable Care Act (ACA) (Pub. L. 111–148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended Title XXVII of the PHS Act, in part, by adding a new section 2718(e) of the PHS Act. Section 2718 of the PHS Act, entitled “Bringing Down the Cost of Health Care Coverage,” requires each hospital operating within the United States for each year to establish (and update) and make public a list of the hospital’s standard charges for items and services provided by the hospital, including for diagnosis related groups (DRGs) established under section 1886(d)(4) of the Social Security Act (SSA).

In the FY 2015 inpatient prospective payment system (IPPS)/long-term care hospital (LTCH) prospective payment system (PPS) proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and provided guidelines for its implementation. At that time, we required hospitals to either make public a list of their standard charges or their policies for allowing the public to view a list of those charges in response to an inquiry. In addition, we stated that we expected hospitals to update the information at least annually, or more often as appropriate, to reflect current charges. We also encouraged hospitals to undertake efforts to engage in consumer-friendly communication of their charges to enable consumers to compare charges for similar services across hospitals and to help consumers understand what their potential financial liability might be for items and services they obtain at the hospital.

In the FY 2019 IPPS/LTCH PPS proposed rule and final rule (83 FR 20164 and 83 FR 41144, respectively), we again reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the PHS Act and updated our guidelines for its implementation. The announced update to our guidelines became effective January 1, 2019, and took one step to further improve the public accessibility of standard charge information. Specifically, we updated our guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate. We subsequently published

two sets of Frequently Asked Questions (FAQs)¹ that provided additional guidance to hospitals, including a FAQ clarifying that while hospitals could choose the format they would use to make public a list of their standard charges, the publicly posted information should represent their standard charges as reflected in the hospital’s chargemaster. We also clarified that the requirement applies to all hospitals operating within the United States and to all items and services provided by the hospital.

II. Requirements for Hospitals To Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Background

As healthcare costs continue to rise, healthcare affordability has become an area of intense focus. Healthcare spending is projected to consume almost 20 percent of the economy by 2027.² One reason for this upward spending trajectory is the lack of transparency in healthcare pricing.^{3 4 5 6} Numerous studies suggest that consumers want greater healthcare pricing transparency. For example, a study of high deductible health plan enrollees found that respondents wanted additional healthcare price information so they could make more informed decisions about where to seek

¹ Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FAQs-Req-Hospital-Public-List-Standard-Charges.pdf> and <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystem/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-internet.pdf>.

² CMS, National Health Expenditures Projections, 2018–2027: Forecast Summary. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf>.

³ Scheurer D. Lack of Transparency Plagues U.S. Health Care System. *The Hospitalist*. 2013 May; 2013(5). Available at: <https://www.thehospitalist.org/hospitalist/article/125866/health-policy/lack-transparency-plagues-us-health-care-system>.

⁴ Bees J. Survey Snapshot: Is Transparency the Answer to Rising Health Care Costs? *New England Journal of Medicine* Catalyst. March 20, 2019. Available at: <https://catalyst.nejm.org/health-care-cost-transparency-answer/>.

⁵ Wetzell S. Transparency: A Needed Step Towards Health Care Affordability. *American Health Policy Institute*. March, 2014. Available at: <http://www.americanhealthpolicy.org/Content/documents/resources/Transparency%20Study%20%20-%20The%20Need%20for%20Health%20Care%20Transparency.pdf>.

⁶ Robert Wood Johnson Foundation. How Price Transparency Can Control the Cost of Health Care. March 1, 2016. Available at: <https://www.rwjf.org/en/library/research/2016/03/how-price-transparency-controls-health-care-cost.html>.

care based on price.⁷ Health economists and other experts state that significant cost containment cannot occur without widespread and sustained transparency in provider prices.⁸ We believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs. We believe healthcare markets could work more efficiently and provide consumers with higher-value healthcare if we promote policies that encourage choice and competition.⁹ As we have stated on numerous occasions, we believe that transparency in healthcare pricing is critical to enabling patients to become active consumers so that they can lead the drive towards value.¹⁰

Many empirical studies have investigated the impact of price transparency on markets, with most research, consistent with predictions of standard economic theory, showing that price transparency leads to lower and more uniform prices.¹¹ Traditional economic analysis suggests that if consumers were to have better pricing information for healthcare services, providers would face pressure to lower prices and provide better quality care.¹² Falling prices may, in turn, expand consumers' access to healthcare.¹³

Presently, however, the information that healthcare consumers need to make informed decisions based on the prices of healthcare services is not readily available. The Government Accountability Office (GAO) report (2011), "Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers

to Obtain Prior to Receiving Care,"¹⁴ found that healthcare price opacity, coupled with the often wide pricing disparities for particular procedures within the same market, can make it difficult for consumers to understand healthcare prices and to effectively shop for value. The report references a number of barriers that make it difficult for consumers to obtain price estimates in advance for healthcare services. Such barriers include the difficulty of predicting healthcare service needs in advance, a complex billing structure resulting in bills from multiple providers, the variety of insurance benefit structures, and concerns related to the public disclosure of rates negotiated between providers and third party payers. The GAO report goes on to explore various price transparency initiatives, including tools that consumers could use to generate price estimates in advance of receiving a healthcare service. The report notes that pricing information displayed by tools varies across initiatives, in large part due to limits reported by the initiatives in their access or authority to collect certain necessary price data. According to the GAO report, transparency initiatives with access to and integrated pricing data from both providers and insurers were best able to provide reasonable estimates of consumers' complete costs.

The concept of making healthcare provider charges and insurance benefit information available to consumers is not new; some States have required disclosure of pricing information by providers and payers for a number of years. More than half of the States have passed legislation establishing price transparency websites or mandating that health plans, hospitals, or physicians make price information available to consumers.¹⁵ As of early 2012, there were 62 consumer-oriented, State-based healthcare price comparison websites.¹⁶ Half of these websites were launched after 2006, and most were developed and funded by a State government agency (46.8 percent) or hospital

association (38.7 percent).¹⁷ Most websites report prices of inpatient care for medical conditions (72.6 percent) or surgeries (71.0 percent). Information about prices of outpatient services such as diagnostic or screening procedures (37.1 percent), radiology studies (22.6 percent), prescription drugs (14.5 percent), or laboratory tests (9.7 percent) are reported less often.¹⁸

Since the early 2000s, California-licensed hospitals have been required to annually submit to the State, for public posting on a State website: The charge description master (CDM, also known as a "chargemaster"); a list of the hospital's average charges for at least 25 common outpatient procedures, including ancillary services; and the estimated percentage increase in gross revenue due to price changes.¹⁹ The information is required to be submitted in plain language using easily understood terminology.²⁰ In 2012, Massachusetts began requiring insurers to provide, upon request, the estimated amount insured patients will be responsible to pay for proposed admissions, procedures, or services based upon the information available to the insurer at the time, and also began requiring providers to disclose the charge for the admission, procedure, or service upon request by the patient within 2 working days.²¹ Since 2015, Oregon has offered pricing data for the top 100 common hospital outpatient procedures and top 50 common inpatient procedures on its *OregonHospitalGuide.org* website, which displays the median negotiated amount of the procedure by hospital and includes patient paid amounts such as deductibles and copayments. The data are derived from State-mandated annual hospital claims collection by the State's all payer claims database (APCD) and represent the service package cost for each of the procedures, including ancillary services and elements related to the procedure, with the exception of professional fees which are billed separately.²² More recently, in 2018, Colorado began requiring hospitals to post the prices of the 50 most used DRG codes and the 25 most used outpatient CPT codes or healthcare services

⁷ Sinaiko AD, et al. Cost-Sharing Obligations, High-Deductible Health Plan Growth, and Shopping for Health Care: Enrollees with Skin in the Game. *JAMA Intern Med.* March 2016; 176(3), 395–397. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2482348>.

⁸ Boynton A, and Robinson JC. Appropriate Use Of Reference Pricing Can Increase Value. *Health Affairs.* July 7, 2015. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20150707.049155/full/>.

⁹ Azar AM, Mnuchin ST, and Acosta A. "Reforming America's Healthcare System Through Choice and Competition." December 3, 2018. Available at: <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

¹⁰ Bresnick J. Verma: Price Transparency Rule a "First Step" for Consumerism. January 11, 2019. Available at: <https://healthpayerintelligence.com/news/verma-price-transparency-rule-a-first-step-for-consumerism>.

¹¹ Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector, July 24, 2007 (updated April 29, 2008). Available at: <https://crsreports.congress.gov/product/pdf/RL/RL34101>.

¹² *Ibid.*

¹³ *Ibid.*

¹⁴ GAO. Health Care Price Transparency: Meaningful Price Information Is Difficult for Consumers to Obtain Prior to Receiving Care. Publicly released October 24, 2011. Available at: <https://www.gao.gov/products/GAO-11-791>.

¹⁵ Desai S, et al. Association Between Availability of a Price Transparency Tool and Outpatient Spending. *JAMA.* 2016;315(17):1874–1881. Available at: <https://jamanetwork.com/journals/jama/fullarticle/2518264>.

¹⁶ Kullgren JT, et al. A census of state health care price transparency websites. *JAMA.* 2013;309(23):2437–2438. Available at: <https://jamanetwork.com/journals/jama/fullarticle/1679957>.

¹⁷ *Ibid.*

¹⁸ *Ibid.*

¹⁹ Available at: <https://oshpd.ca.gov/data-and-reports/cost-transparency/hospital-chargemasters/2018-chargemasters/>.

²⁰ Jenkins K. *CMS Price Transparency Push Trails State Initiatives.* The National Law Review. February 8, 2019. Available at: <https://www.natlawreview.com/article/cms-price-transparency-push-trails-state-initiatives>.

²¹ *Ibid.*

²² Available at: <http://oregonhospitalguide.org/> and <http://oregonhospitalguide.org/understanding-the-data/procedure-costs.html>.

procedure codes with a “plain-English description” of the service, which must be updated at least annually.²³

Not only have States taken an interest in price transparency, but insurers and self-funded employers have also moved in this direction. For example, some self-funded employers are using price transparency tools to incentivize their employees to make cost-conscious decisions when purchasing healthcare services. Most large insurers have embedded cost estimation tools into their member websites, and some provide their members with comparative cost and value information, which includes rates that the insurers have negotiated with in-network providers and suppliers.

Research suggests that making such consumer-friendly pricing information available to the public can reduce healthcare costs for consumers. Specifically, recent research evaluating the impact of New Hampshire’s price transparency efforts reveals that providing insured patients with information about prices can have an impact on the out-of-pocket costs consumers pay for medical imaging procedures, not only by helping users of New Hampshire’s website choose lower-cost options, but also by leading to lower prices that benefited all patients, including those in the State that did not use the website.^{24 25}

Despite the growing consumer demand and awareness of the need for healthcare pricing data, there continues to be a gap in easily accessible pricing information for consumers to use for healthcare shopping purposes. Specifically, there is inconsistent (and many times nonexistent) availability of provider charge information, among other limitations to understanding data made available or barriers to use of the data. We believe this information gap can, in part, be filled by the new requirements we are finalizing in this final rule, under section 2718(e) of the PHS Act, as described below. As we explained in the CY 2020 OPPI/ASC proposed rule, we believe that ensuring public access to hospital standard

charge data will promote and support current and future price transparency efforts. We believe that this, in turn, will enable healthcare consumers to make more informed decisions, increase market competition, and ultimately drive down the cost of healthcare services, making them more affordable for all patients.

2. Summary of Proposals and General Comments

In the CY 2020 OPPI/ASC proposed rule (84 FR 39398), we indicated that health care consumers continue to lack the meaningful pricing information they need to choose the healthcare services they want and need despite our prior requirements for hospitals to publicly post their chargemaster rates online. Based on feedback from hospitals and consumers following the January 1, 2019 implementation of the revised guidelines, and in accordance with President’s Executive Order on “Improving Price and Quality Transparency in American Healthcare to Put Patients First” (June 24, 2019), we proposed an expansion of hospital charge display requirements to include charges and information based on negotiated rates and for common shoppable items and services, in a manner that is consumer-friendly. We also proposed to establish a mechanism for monitoring and the application of penalties for noncompliance.

Specifically, we proposed to add a new Part 180—Hospital Price Transparency to title 45 CFR which would contain our regulations on price transparency for purposes of section 2718(e) of the PHS Act. We made proposals related to: (1) A definition of “hospital”; (2) different reporting requirements that would apply to certain hospitals; (3) definitions for two types of “standard charges” (specifically, gross charges and payer-specific negotiated charges) that hospitals would be required to make public, and a request for public comment on other types of standard charges that hospitals should be required to make public; (4) a definition of hospital “items and services” that would include all items and services (both individual and packaged) provided by the hospital to a patient in connection with an inpatient admission or an outpatient department visit; (5) requirements for making public a machine-readable file that contains a hospital’s gross charges and payer-specific negotiated charges for all items and services provided by the hospital; (6) requirements for making public payer-specific negotiated charges for select hospital-provided items and

services that are “shoppable” and that are displayed and packaged in a consumer-friendly manner; (7) monitoring for hospital noncompliance with requirements for publicly disclosing standard charges; (8) actions that would address hospital noncompliance, which include issuing a written warning notice, requesting a CAP, and imposing CMPs on noncompliant hospitals and publicizing these penalties on a CMS website; and (9) appeals of CMPs.

Comment: Commenters included individual consumers, patient advocates, hospitals and health systems, private insurers, employers, medical associations, health benefits consultants, health information technology (IT) organizations and organizations with price transparency expertise, and academic institutions, among others. The majority of commenters expressed broad support for our proposed policies (in whole or in part) or agreed with the objectives we seek to accomplish through these requirements. Many of these commenters stated that the disclosure of hospital standard charges would serve to increase competition, drive down healthcare prices, and allow consumers to compare healthcare costs across facilities and to have better control over their budgets and the financing of their healthcare needs.

Many commenters shared personal stories and examples of their experiences, illustrating their desire to shop and learn healthcare service prices in advance, and expressed frustration at their current inability to prospectively access medical costs. Commenters also provided specific examples of the ways that knowledge of healthcare pricing in advance would benefit consumers and empower them to make lower cost choices. Many commenters stated that consumers have a “right to know” or “right to understand” healthcare costs in advance of receiving treatment.

Individual consumers that submitted comments generally praised the proposals. One commenter stated it is the “best attempt [thus] far to provide price transparency to the American public.” But other commenters who supported hospital disclosure of charge information as a necessary first step also recognized that such disclosure would still fall, as one commenter stated, “far short of the full price and cost transparency we need in every part of our healthcare system.”

By contrast, many organizations, including those representing hospitals and insurers, that submitted comments expressed strong concerns with the proposals and generally questioned

²³ Jenkins K. *CMS Price Transparency Push Trails State Initiatives*. The National Law Review. February 8, 2019. Available at: <https://www.natlawreview.com/article/cms-price-transparency-push-trails-state-initiatives>.

²⁴ Brown ZY. What would happen if hospitals openly shared their prices? *The Conversation*. January 30, 2019. Available at: <https://theconversation.com/what-would-happen-if-hospitals-openly-shared-their-prices-110352>.

²⁵ Brown ZY. An Empirical Model of Price Transparency and Markups in Health Care. August 2019. Available at: http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf.

whether hospital charge disclosures would effectively reduce healthcare costs. Many of these entities commented on the practicalities and usefulness of displaying hospital standard charges and asserted that the proposal would not “directly” and “materially” serve the stated interest of improving consumer access to healthcare pricing information to help drive down healthcare costs.

Commenters that objected to the proposals also pointed out that disclosure of hospital charges would be insufficient to permit a consumer to obtain an out-of-pocket estimate in advance because consumers with insurance need additional information from payers. Some commenters generally indicated that the proposed disclosures would be of little benefit or use to consumers. Further, several commenters suggested that, for patients with health insurance, insurers, not hospitals, should be the primary source of price information, and that insurers should inform and educate their members on potential out-of-pocket costs in advance of elective services. Some expressed concerns that patients could be confused by hospital charge information and misinterpret the standard charge data the hospital is required to display.

Response: We thank the many commenters for their support of CMS’ price transparency initiative in general, and our proposals to require hospitals to make public their standard charge information in particular, which, for reasons articulated in the CY 2020 OPPTS/ASC proposed rule, we agree can improve consumer knowledge of the price of healthcare items and services in advance. For example, disclosure of payer-specific negotiated charges can help individuals with high deductible health plans (HDHPs) or those with co-insurance determine the portion of the negotiated charge for which they will be responsible for out-of-pocket. We believe that regulations we are finalizing in this final rule, implementing section 2718(e) of the PHS Act, requiring hospitals make public standard charges, are imperative for several reasons, including that consumers currently do not have the information they need in a readily usable way or in context to inform their healthcare decision-making. Further, we believe that greater transparency will increase competition throughout the market and address healthcare costs. For instance, disclosure of pricing information will allow providers, hospitals, insurers, employers and patients to begin to engage each other and better utilize market forces to address the high cost of

medical care in a more widespread fashion.

While we understand the commenters’ concerns that disclosure of hospital standard charges may not be used by all consumers, we disagree that the availability of such data would be of little benefit to consumers generally. We continue to believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs. We believe healthcare markets could work more efficiently and provide consumers with higher-value healthcare if we promote policies that encourage choice and competition. As we noted in the CY 2020 OPPTS/ASC proposed rule, and restated in section II.A.2 of this final rule, numerous studies suggest that consumers want greater transparency and price information so that they can make more informed decisions about where to seek care based on price (84 FR 39572).

We do, however, agree with commenters who indicated that disclosure of hospital charge information alone may be insufficient or does not go far enough for consumers to know their out-of-pocket costs in advance of receiving a healthcare service. As we indicated in the CY 2020 OPPTS/ASC proposed rule (84 FR 39574), there are many barriers to obtaining an out-of-pocket estimate in advance and to make price comparisons for healthcare services, including that the data necessary for such an analysis are not available to the general public for personal use. Necessary data to make out-of-pocket price comparisons depends on an individual’s circumstances. For example, a self-pay individual may simply want to know the amount a healthcare provider will accept in cash (or cash equivalent) as payment in full, while an individual with health insurance may want to know the charge negotiated between the healthcare provider and payer, along with additional individual benefit-specific information such as the amount of cost-sharing, the network status of the healthcare provider, how much of a deductible has been paid to date, and other information. We therefore agree with commenters who recognize that these policies to require hospitals to make public their standard charges are merely a necessary first step. We discuss the importance and necessity of specific types of hospital standard charges in section II.D of this final rule.

In response to commenters suggesting that insurers should be the primary source of price information, we disagree that insurers alone should bear the

complete burden or responsibility for price transparency. At least one key reason that insurers cannot alone bear the burden is that, in numerous instances, they are not participants in the transaction; for example, as discussed in section II.D of this final rule, self-pay patients and insured patients who are considering paying in cash have an interest in understanding hospitals’ cash prices, or for employers who want to contract directly with hospitals. We also note that the proposed rule entitled Transparency in Coverage (file code CMS–9915–P) would place complementary transparency requirements on most individual and group market health insurance issuers and group health plans.

Comment: A few commenters asked CMS not to move forward with the final rule, stating that price transparency should be done only at the state level. These commenters expressed concern that CMS moving forward in this area would either limit price transparency to a “one size fits all” approach or complicate or undercut efforts already ongoing in several states. These commenters suggested that instead of federal mandates, CMS could work with hospitals to provide meaningful information to patients about their out-of-pocket costs for their hospital care by improving financial counseling, or provide grant dollars for states to improve their own price transparency programs.

More generally, many commenters asserted that several hospitals already respond to consumer requests for actionable healthcare pricing information in advance of receiving care, such as through existing tools, publicizing how and from whom patients can obtain price estimates, providing individualized financial counseling, or a combination of these methods.

Response: We believe it is appropriate to promulgate regulations pursuant to section 2718(e) of the PHS Act.

We further believe that transparency in pricing is a national issue, which Congress has recognized by enacting hospital price transparency statutory requirements.

We appreciate the commenters’ concerns about the possible interactions between new federal requirements for hospitals to make public standard charges and existing State price transparency initiatives, or hospital initiatives. As we discussed in the CY 2020 OPPTS/ASC proposed rule, we have sought ways to ensure sufficient flexibility in the new requirements, particularly around the form and

manner of making public hospital price information, as well as the frequency of making public this information. As with the proposed requirements, we continue to believe that the requirements we are finalizing in this final rule will align with and enhance ongoing State and hospital efforts for the display of hospital charge information. We note that while many States have made progress in promoting price transparency, most State efforts continue to fall short. For example, a group that tracks State progress found in their most recent report that all but seven States scored an “F” on price transparency.²⁶ States that excel at promoting price transparency (for example, New Hampshire and Maine, the only two States to receive an “A” rating) are also States where the price of shoppable services has reportedly decreased²⁷ or fostered a more competitive market.²⁸ We believe these final rules will provide a national framework upon which States can either begin or continue to build.

We commend those hospitals that are already publicly releasing their standard charges and providing patients individualized assistance to help them understand their projected costs in advance of receiving care. However, not all hospitals are prioritizing providing such assistance. Moreover, we do not believe that such existing hospital initiatives diminish the need to, and benefits of, establishing consistent, nationwide requirements for hospitals to make public standard charges. We encourage efforts to provide consumers with additional price information (beyond the requirements established in this final rule) and for hospitals to continue to educate and provide prospective out-of-pocket information to patients. By doing so, hospitals can help consumers gain an understanding of hospital standard charge information and thereby support consumers in making cost conscious decisions regarding their care in advance.

Comment: Some commenters generally indicated that the proposals

for hospitals to disclose their standard charges would be very burdensome to implement. Several commenters also suggested that the proposed price transparency requirements are contrary to the Patients over Paperwork initiative, which is a CMS initiative that aims to remove regulatory obstacles that get in the way of providers spending time with patients.

Response: The Patients over Paperwork initiative is in accord with President Trump’s Executive Order that directs federal agencies to “cut the red tape” to reduce burdensome regulations. Through “Patients over Paperwork,” CMS established an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience.²⁹ Generally, we believe the final requirements will increase transparency in hospital charge information and will achieve one of our primary goals of putting patients first and empowering them to make the best decisions for themselves and their families.³⁰ Efficiencies could also be gained through implementation of these requirements for markets, providers and patients.^{31 32 33} To implement section 2718(e) of the PHS Act and to achieve these goals, some burden on hospitals is necessary. However, we have sought through rulemaking to minimize the burden wherever possible.

We acknowledge commenters’ concerns related to burden. However, we believe that the burdens placed on hospitals to make public their standard charge data is outweighed by the benefit that the availability of these data will have in informing patients regarding healthcare costs and choices and improving overall market competition. Since we believe that transparency is necessary to improve healthcare value

and empower patients, we believe the need justifies the additional burden. While the burdens hospitals may incur to implement these requirements might be administrative in nature, we believe that the benefits to consumers, and to the public as a whole, justify this regulatory action and that we are thereby prioritizing patients through this regulatory action.

Comment: A few commenters offered suggestions for how to improve hospital price transparency in general, including the following:

- Presenting pricing data with quality, health outcomes, and other relevant data.
- Encouraging shared decision-making and cost of care conversations between patients and clinicians at the point of care.
- Addressing unexpected costs of care and providing consumer protections from unexpected and unnecessary out-of-pocket spending, such as those resulting from incidents where the patient is billed at rates that are inconsistent with publicly posted prices for their payer (referred to by a few commenters as “price surprise”), or billed by out-of-network providers that provided treatment at an in-network facility, or the practice where the provider bills the patient for the balance between the amount the patient’s health insurance plan covers and the amount that the provider charges (“balance billing”).

Response: We acknowledge that additional barriers have to be overcome to allow consumers to identify appropriate sites of care for needed healthcare services, determine out-of-pocket costs in advance, and utilize indicators of quality of care to make value-based decisions. As we have previously described, we believe the policies we are finalizing in this final rule requiring hospitals to make public standard charges are a necessary and important first step in ensuring transparency in healthcare prices for consumers, but that the release of hospital standard charge information is not sufficient by itself to achieve our ultimate goals for price transparency. We also note that our final policies do not preclude hospitals from undertaking additional transparency efforts beyond making public their standard charges. HHS continues to explore other authorities to further advance the Administration’s goal of enhancing consumers’ ability to choose the healthcare that is best for them, to make fully informed decisions about their healthcare, and to access both useful price and quality information and

²⁹ CMS.gov website, Patients Over Paperwork, at <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html>.

³⁰ CMS.gov, Patients Over Paperwork webpage, available at <https://www.cms.gov/About-CMS/story-page/patients-over-paperwork.html>; see also 84 FR 27021 (RFI describing CMS’ top priority as putting patients first and empowering them to make the best decisions for themselves and their families).

³¹ Kim M. The Effect of Hospital Price Transparency in Health Care Markets. 2011. Available at: <https://repository.upenn.edu/dissertations/AAI3475926/>.

³² CRS Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector. July 24, 2007. Available at: <https://fas.org/sgp/crs/secretary/RL34101.pdf>.

³³ Santa J. The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary. 2010. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK53921/>.

²⁶ de Brantes F, et al. Price Transparency & Physician Quality Report Card 2017. Catalyst for Payment Reform. Available at: https://www.catalyze.org/wp-content/uploads/2017/11/Price-Transparency-and-Physician-Quality-Report-Card-2017_0-1.pdf.

²⁷ Brown ZY. Equilibrium Effects of Health Care Price Information. *The Review of Economics and Statistics*. Published October 2019; 101:4, 699–712. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.

²⁸ Gudiksen KL, et al. The Secret of Health Care Prices: Why Transparency Is in the Public Interest. California Health Care Foundation. July 2019. Available at: <https://www.chcf.org/wp-content/uploads/2019/06/SecretHealthCarePrices.pdf>.

provide incentives to find low-cost, high-quality care.

We agree that cost-of-care conversations at the point of care are important. National surveys show that a majority of patients and physicians want to have these conversations, but often the information necessary for actionable conversations is unavailable.³⁴ A recent supplemental issue of the *Annals of Internal Medicine*³⁵ highlighted this issue and identified best practices for integrating cost-of-care conversations at the point of care. We believe that disclosure of hospital standard charges along with the disclosure of payer information is the first step to ensuring patients and practitioners have actionable data to support meaningful cost-of-care conversations. We encourage these conversations and the disclosure of additional relevant information to support patient decisions about their care.

We also agree that “surprise billing” is an issue of great concern to consumers and of great interest to both federal and state lawmakers. The policies finalized in this final rule will not resolve that issue entirely, although it is possible that disclosure of hospital standard charges could help mitigate some surprise billing experienced by consumers.

Comment: One commenter suggested that Medicare and Medicaid beneficiaries need an easy way to report fraud and balance billings by providers.

Response: There already exist multiple avenues by which anyone suspecting healthcare fraud, waste, or abuse in Medicare and/or Medicaid may readily report it to oversight authorities. For example, the HHS Office of Inspector General (OIG) Hotline accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS’ programs (see <https://oig.hhs.gov/FRAUD/REPORT-FRAUD/INDEX.ASP> for instructions). Additionally, anyone wishing to report instances of potential Medicare fraud may contact Medicare’s toll-free customer service operations at 1-800-MEDICARE (1-800-633-4227), and obtain additional information at www.medicare.gov/fraud. Anyone suspecting Medicaid fraud, waste, or abuse is encouraged to report it to the Program Integrity contact of the

respective State Medicaid Agency (see <https://www.medicaid.gov/about-us/contact-us/contact-state-page.html> for the 50 United States, the District of Columbia, the US Virgin Islands, and Puerto Rico).

B. Definition of “Hospital” and Hospitals Regarded as Having Met Requirements

1. Definition of “Hospital”

Section 2718(e) of the PHS Act does not define “hospital.” Initially, we considered proposing to adopt a definition of “hospital” that is used either in other sections of the PHS Act or in the SSA, but we found that no single or combined definition was suitable because those other definitions were applicable to specific programs or Medicare participation and therefore had program-specific requirements that made them too narrow for our purposes. For example, we considered referencing the definition of “hospital” at section 1861(e) of the SSA because that definition is well understood by institutions that participate as hospitals for purposes of Medicare. However, we were concerned that doing so could have had the unintentional effect of limiting the institutions we believe should be covered by section 2718(e) of the PHS Act. Even so, we believe that the licensing requirement described at section 1861(e)(7) of the SSA captures the institutions that we believe should be characterized as hospitals for purposes of this section.

Accordingly, we proposed to define a “hospital” as an institution in any State in which State or applicable local law provides for the licensing of hospitals and that is: (1) Licensed as a hospital pursuant to such law; or (2) approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing (which we proposed to codify in new 45 CFR 180.20).

We believe this proposed definition is the best way to ensure that section 2718(e) of the PHS Act applies to each hospital operating within the United States. First, in addition to applying to all Medicare-enrolled hospitals (that, by definition, must be licensed by a State as a hospital, or otherwise approved by the State or local licensing agency as meeting hospital licensing standards), the proposed definition would also capture any institutions that are, in fact, operating as hospitals under State or local law, but might not be considered hospitals for purposes of Medicare participation. As discussed in section XVI.A.2. of the CY 2020 OPPI/ASC proposed rule (84 FR 39572 through

39573), many States have promoted price transparency initiatives, and some require institutions they license as hospitals to make certain charges public as a part of those initiatives. Therefore, defining a hospital by its licensure (or by its approval by the State or locality as meeting licensing standards) may carry the advantage of aligning the application of Federal and State price transparency initiatives to the same institutions.

We also proposed that, for purposes of the definition of “hospital,” a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. We stated that this proposed definition of State would be consistent with how that term is defined under section 2791(d)(14) of the PHS Act. We further stated that we believed that adopting this definition of “State” for purposes of section 2718(e) of the PHS Act is appropriate because, unlike the other provisions in section 2718 which apply to health insurance issuers, section 2718(e) applies to hospitals. Therefore, it is distinguishable from the approach outlined in the July 2014 letters³⁶ to the Territories regarding the PHS Act health insurance requirements established or amended by Public Law 111-148 and Public Law 111-152.

Our proposed definition focused on whether or not the institution is licensed by the State or under applicable local law as a hospital, or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. As such, a “hospital” under our proposed definition includes each institution that satisfies the definition, regardless of whether that institution is enrolled in Medicare or, if enrolled, regardless of how Medicare designates the institution for its purposes. Thus, we noted that the proposed definition includes critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals (SCHs), and inpatient rehabilitation facilities (IRFs), which we previously identified in our guidelines as being hospitals for the purposes of section 2718(e) of the PHS Act,³⁷ as well as any other type of institution, so long as it is licensed as

³⁴ University of Utah Health website, Let’s Talk About Money, <https://uofuhealth.utah.edu/value/lets-talk-about-money.php>.

³⁵ *Fostering Productive Health Care Cost Conversations: Sharing Lessons Learned and Best Practices*. May 2019 Vol: 170, Issue 9_Supplement. *Annals of Internal Medicine*. Available at: <https://annals.org/aim/issue/937992>.

³⁶ The July 2014 letters are available at: <https://www.cms.gov/CCIIO/Resources/Letters/index.html#Health%20Market%20Reforms>.

³⁷ Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PropMedicareFeeSvcPmtGen/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-internet.pdf>.

a hospital (or otherwise approved) as meeting hospital licensing standards.

Finally, we noted that the proposed definition of “hospital” did not include entities such as ambulatory surgical centers (ASCs) or other non-hospital sites-of-care from which consumers may seek healthcare items and services. We discussed that, for example, non-hospital sites may offer ambulatory surgical services, laboratory or imaging services, or other services that are similar or identical to the services offered by hospital outpatient departments. In the interest of increasing opportunities for healthcare consumers to compare prices for similar services and promoting widespread transparency in healthcare prices, we encouraged non-hospital sites-of-care to make public their lists of standard charges in alignment with the proposed requirements so that consumers could make effective pricing comparisons.

We invited public comments on our proposed definition of “hospital,” which we proposed to codify at 45 CFR 180.20.

Comment: A few commenters requested that CMS finalize the definition of hospital as proposed and applauded the agency’s effort to provide a standard definition of hospital for the purposes of making standard charges public. One commenter agreed that the definition of hospital should not be limited to only those hospitals that participate in Medicare.

Several commenters suggested that the proposed definition of hospital is too limited, and suggested that CMS expand the definition to include other providers, such as physicians, ASCs, clinics, community health centers, and skilled nursing facilities, in order to better educate consumers on prices for services furnished by all provider types. A few commenters generally suggested that CMS extend price transparency policies to all service providers and all places of service, not just hospitals or hospital settings. One commenter suggested that CMS expand the definition of hospital to include any facility that conducts surgery with anesthesia.

In particular, a few commenters explained the need for ASCs to be transparent with their prices. One commenter noted that federally mandated payment and other policies continue to emphasize patients obtaining care in an outpatient setting instead of an inpatient acute care hospital and therefore the definition of hospital should reflect the greater role ASCs are taking in the healthcare system. Commenters also noted that ASCs provide similar services to

hospitals and may therefore compete with hospitals. On the other hand, one commenter urged CMS to apply price transparency standards to ASCs to minimize incentives for hospitals to defer surgeries to new ASCs formed for the purpose of circumventing disclosure of the hospital’s charges.

Commenters took diverging positions on whether IRFs should be required to make public standard charges. A few commenters urged that IRFs be included among the entities required to make public standard charges. On the other hand, as described and addressed in Section II.B.2 of this final rule, a few commenters suggested that IRFs be exempt from the reporting requirements.

Response: We thank the commenters that supported our proposed definition of hospital. We believe that our proposed definition of hospital, which we are finalizing, is a broad definition that will encompass all institutions recognized by a State as a hospital. Because section 2718(e) of the PHS Act applies to each hospital operating within the United States, we do not believe we have the authority to apply the price transparency requirements to non-hospital sites of care. For this reason, we decline to adopt commenters’ suggestions that we expand the definition of hospital to include all service providers and places of service, including to all places of service that provide surgical services requiring anesthesia. We also decline the commenters’ suggestions to narrow the scope of the definition of hospital, for instance to exclude IRFs where the IRFs otherwise meet the definition of hospital we are finalizing. We believe such an approach would not be consistent with section 2718(e) of the Act, which applies to each hospital operating in the United States. Given the importance of making public standard charge data to inform consumer healthcare decision-making, we believe it is important to not overly constrict the definition of hospital, which might permit subsets of hospitals that meet the definition we are finalizing to avoid public disclosure of their standard charges.

We defer to States’ or localities’ hospital licensing standards for the determination of whether an entity falls within the definition of hospital for the purposes of new 45 CFR part 180. Any facility licensed by a State or locality as a hospital, or that is approved by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing, would be considered a “hospital” for the purposes of section 2718(e) of the Act and therefore

required to comply with the requirements to make public their standard charges in the form and manner required by this final rule. For this reason, we cannot provide an exhaustive list of institution types encompassed within State or locality hospital licensing laws.

Regarding specific types of entities, however, we note that healthcare providers such as ASCs, physicians, or community health centers would not likely satisfy our specified definition of “hospital” since they are not likely to be licensed by a State or locality as a hospital or to be approved by the agency of such State or locality responsible for licensing hospitals as meeting the standards established for such licensing. We recognize that ASCs provide many of the same services as hospitals and note that many ASCs already engage in price transparency efforts of their own. We have no knowledge that existing price transparency initiatives (those in states that already require hospitals to make public standard charges and our existing guidance that hospitals make public standard charges pursuant to section 2718(e) of the PHS Act) have engendered any shifts in business between hospitals and ASCs. However, we believe it is reasonable to assume that shifts to the most appropriate care setting may occur as referring providers and their patients seek out the highest value setting for their care.

Comment: A few commenters requested clarification on how the requirements to make standard charges public and CMS compliance actions would apply to hospital outpatient services that are provided off-campus, or in hospital-affiliated or hospital-owned clinics. One commenter asked whether all hospital locations under one CMS Certification Number (CCN) are a single hospital for the purpose of the proposal or whether they are considered separate locations. The commenter expressed concern that there is an absence of any connection between the CY 2020 OPPI/ASC proposed rule’s definition of “hospital” and the CCN. The commenter expressed concern that this lack of clarity would hinder compliance with the proposal if finalized and lessen the impact of the proposed penalty.

Response: We did not propose to define the term “hospital” with reference to the CCN, which is the hospital identification system we use for purposes of Medicare and Medicaid. As we discussed in the CY 2020 OPPI/ASC proposed rule, we declined to base the definition of hospital on Medicare participation, as the statute states all hospitals operating within the United

States must make available a list of their standard charges.

As discussed in section II.E.6 of this final rule, each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location, as stated in 45 CFR 180.50. All hospital location(s) operating under the same hospital license (or approval), such as a hospital's outpatient department located at an off-campus location (from the main hospital location) operating under the hospital's license, are subject to the requirements in this rule.

Final Action: We are finalizing our proposal to define "hospital" to mean an institution in any State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law, or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. For purposes of this definition, a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. We are finalizing our proposal to set forth the definition of "hospital" in the regulations at new 45 CFR 180.20.

2. Special Requirements That Apply to Certain Hospitals

In the CY 2020 OPPI/ASC proposed rule (84 FR 39575 through 39576), we proposed that hospital standard charge disclosure requirements would not apply to federally-owned or operated hospitals, including Indian Health Service (IHS) facilities (including Tribally-owned and operated facilities), Veterans Affairs (VA) facilities, and Department of Defense (DOD) Military Treatment Facilities (MTFs), because, with the exception of some emergency services, these facilities do not provide services to the general public and the established payment rates for services are not subject to negotiation. Instead, each of these facility types is authorized to provide services only to patients who meet specific eligibility criteria. For example, individuals must meet the requirements enumerated at 42 CFR 136.22 through 136.23 to be eligible to receive services from IHS and Tribal facilities. Similarly, under 38 CFR 17.43 through 17.46, VA hospitals provide hospital, domiciliary, and nursing home services to individuals with prior authorization who are discharged or retiring members of the Armed Forces

and, upon authorization, beneficiaries of the PHS, Office of Workers' Compensation Programs, and other Federal agencies (38 CFR 17.43). In addition, federally-owned or operated hospitals such as IHS and Tribal facilities³⁸ impose no cost-sharing, or, in the case of VA hospitals³⁹ and DOD MTFs,⁴⁰ little cost-sharing. With respect to such facilities where there is cost-sharing, the charges are publicized through the **Federal Register**, Federal websites, or direct communication and therefore known to the populations served by such facilities in advance of receiving healthcare services. Only emergency services at federally-owned or operated facilities are available to non-eligible individuals. Because these hospitals do not treat the general public, their rates are not subject to negotiation, and the cost sharing obligations for hospital provided services are known to their patients in advance, we believe it is appropriate to establish different requirements that apply to these hospitals.

Specifically, we proposed to deem federally owned or operated hospitals that do not treat the general public (except for emergency services) and whose rates are not subject to negotiation, to be in compliance with the requirements of section 2718(e) of the PHS Act because their charges for hospital provided services are publicized to their patients (for example, through the **Federal Register**) (proposed new 45 CFR 180.30(b)). We also requested public comments on whether exceptions to our proposed requirements might be warranted for hospitals (for example, hospitals located in rural areas, CAHs, or hospitals that treat special populations) that are not federally owned or operated, while also ensuring that charges for the services provided by such hospitals are available to the public.

Comment: Commenters diverged as to whether additional exceptions should be made for providers that meet the proposed definition of "hospital," such that these providers would not be required to make standard charges public. One commenter strongly recommended that CMS not allow any exceptions to requirements for entities that meet the proposed definition of "hospital."

³⁸ Section 1680r(b) of the Indian Health Care Improvement Act (25 U.S.C. 1680r).

³⁹ VA cost-sharing information available at: <https://www.va.gov/HEALTHBENEFITS/cost/copays.asp>.

⁴⁰ MTF cost-sharing information available at: <https://tricare.mil/Costs/Compare> and https://comptroller.defense.gov/Portals/45/documents/rates/fy2019/2019_ia.pdf.

Other commenters requested that CMS exempt CAHs, rural hospitals, and SCHs from part or all requirements to make standard charges public. The commenters stated that the requirements would be challenging for small facilities and cited several justifications for this possible exemption, including that CAHs are already at a disadvantage when negotiating rates with third-party payers; they lack the implementation resources due to their size and reimbursement structure; and the likelihood of their experiencing operational disruptions as a result of diverting staff time and other resources to comply with the proposed requirements. On the other hand, one commenter specified that patients receiving care in CAHs and rural hospitals deserve to know how much services cost in advance.

A few commenters argued that LTCHs and IRFs ought to be excluded or exempted from the requirement of having to make public their standard charges for a variety of reasons, including: (1) Commenters' belief that patients are unable to schedule LTCH and IRF services in advance; (2) patients treated in LTCHs and IRFs are there for follow-up care after a short-term acute stay in a hospital and the critical nature of the patients' condition, and the need for tailored treatment plans for complex conditions, would not lend itself to being shoppable; (3) imposing price transparency requirements on LTCHs will not serve the objectives of increased market competition or quality improvement since sometimes there is only one LTCH in a single market and there are fewer than 400 total LTCHs nationwide.

One commenter requested that CMS exempt institutions and hospitals that are not enrolled in Medicare and which are not reimbursed under a prospective payment system.

Response: Our definition of "hospital" is any institution in any State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. As we explained in section II.B.1 of this final rule, we defer to States' or localities' hospital licensing standards for the determination of whether an entity falls within the definition of hospital for the purposes of new 45 CFR part 180. We continue to believe this definition provides the best way to ensure that section 2718(e) of the PHS Act applies to each hospital operating

within the United States. It also may help align the application of these requirements with State price transparency initiatives to the same institutions.

We appreciate the operational, resource, and other concerns raised by commenters, however, to the extent that IRFs, CAHs, LTCHs, rural hospitals, and SCHs (among others) fall within our proposed definition of hospital, we believe this is appropriate because patients, or their caregivers, should have the opportunity to know in advance (as their circumstances permit) standard charges for these entities' items and services, to inform their healthcare decision-making. We decline to either exempt such hospitals from making public standard charges, or deem such hospitals as having met requirements for making public their standard charges.

We recognize that some small hospitals, and rural hospitals, including CAHs and SCHs may face challenges in implementing these requirements, but we do not believe that such challenges are insurmountable.

We also disagree with the commenters that suggest that services provided by LTCHs and IRFs are not shoppable. Patients, and their caregivers, seeking long term care or rehabilitation services may have the opportunity to shop for these services in advance, and we believe patients and caregivers should have access to consumer-friendly charge information for such facilities. We believe that such information could be used by patients or their caregivers to better inform their decision-making when a patient transfers from an acute care facility (that falls within our definition of "hospital") to a post-acute care facility (that also falls within our definition of "hospital").

Further, we believe that patients with complex conditions, their caregivers, or both, may have a particular interest in using price data to inform healthcare decision-making. We believe that the data we are requiring hospitals to make public could inform healthcare decision-making by patients with complex conditions, their caregivers, or both, even though they may require additional, or specialized treatment.

We do not believe that the absence of competition for items or services in a market should excuse hospitals from making public standard charges that consumers may need to inform the cost of their care. We believe transparency in hospital prices is important to consumers' healthcare decision-making, regardless of the number of facilities in a particular market or nationwide.

We also decline the commenter's suggestion to exempt institutions and

hospitals from the requirements to make public standard charges if they are not enrolled in Medicare. As we explained in the CY 2020 OPPI/ASC proposed rule, we believe that such an approach would unduly limit the applicability of the policies for hospitals to make public standard charges under section 2718(e) of the PHS Act (84 FR 39575).

Final Action: We are finalizing as proposed to specify at 45 CFR 180.30 provisions on the applicability of the requirements for making public standard charges. We are finalizing as proposed to specify in 45 CFR 180.30(a) that the requirements to make public standard charges apply to hospitals as defined at 45 CFR 180.20.

We received no comments on our proposal to deem federally owned or operated hospitals to be in compliance with the requirements to make public standard charges. Therefore, we are finalizing, as proposed, to specify in 45 CFR 180.30(b) that federally owned or operated hospitals are deemed by CMS to be in compliance with the requirements for making public standard charges, including but not limited to:

- Federally owned hospital facilities, including facilities operated by the U.S. Department of VA and MTF operated by the U.S. Department of Defense.
- Hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act.

We received no comments on our proposal that hospital charge information must be made public electronically via the internet. We are finalizing this requirement as proposed at 45 CFR 180.30(c).

C. Definition of "Items and Services" Provided by Hospitals

Section 2718(e) of the PHS Act requires that hospitals make public a list of the hospital's standard charges for items and services provided by the hospital, including for DRGs. We proposed that, for purposes of section 2718(e) of the PHS Act, "items and services" provided by the hospital are all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples of these items and services include, but are not limited to, supplies, procedures, room and board, use of the facility and other items (generally described as facility fees), services of employed physicians and non-physician practitioners (generally

reflected as professional charges), and any other items or services for which a hospital has established a charge.

Our proposed definition included both individual items and services as well as "service packages" for which a hospital has established a charge. Every hospital maintains a file system known as a chargemaster, which contains all billable procedure codes performed at the hospital, along with descriptions of those codes and the hospitals' own list prices. The format and contents of the chargemaster vary among hospitals, but the source codes are derived from common billing code systems (such as the AMA's CPT system). Chargemasters can include tens of thousands of line items, depending on the type of facility, and can be maintained in spreadsheet or database formats.⁴¹ For purposes of section 2718(e) of the PHS Act, we proposed to define "chargemaster" to mean the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge (at proposed new 45 CFR 180.20). Each individual item or service found on the hospital chargemaster has a corresponding "gross" charge (84 FR 39578 through 39579). Each individual item or service may also have a corresponding negotiated discount, because some hospitals negotiate with third party payers to establish a flat percent discounted rate off the gross charge for each individual item and service listed on the chargemaster; for example, a hospital may negotiate a 50 percent discount off all chargemaster gross rates with a third party payer.

In contrast to the chargemaster, or so-called "fee-for-service" (FFS) price list, hospitals also routinely negotiate rates with third party payers for bundles of services, or "service packages," in lieu of charging for each and every imaging study, laboratory test, or alcohol swab found on the chargemaster.⁴² Such service packages may have charges established on, for example, the basis of a common procedure or patient characteristic, or may have an established per diem rate that includes all individual items and services furnished during an inpatient stay. Some hospitals present "self-pay package pricing" for prompt same-day payment from healthcare consumers.

⁴¹ Tompkins C, et al. The Precarious Pricing System For Hospital Services. *Health Affairs*. January/February 2006; 25(1). Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.25.1.45>.

⁴² Nichols LM, and O'Malley AS. Hospital Payment Systems: Will Payers Like The Future Better Than The Past? *Health Affairs*. January/February 2006; 25(1). Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.25.1.81>.

The hospital's billing and accounting systems maintain the negotiated charges for service packages which are commonly identified in the hospital's billing system by recognized industry standards and codes. For example, a DRG system may be used to define a hospital product based on the characteristics of patients receiving similar sets of [itemized] services.⁴³ Medicare and some commercial insurers have adopted DRG classifications as a method of inpatient hospital payment. Other codes (for example, payer-specific codes, CPT or Healthcare Common Procedure Coding System (HCPCS) codes) are used by hospitals and payers to identify service packages based on procedures.

For purposes of section 2718(e) of the PHS Act, we proposed to define a "service package" to mean an aggregation of individual items and services into a single service with a single charge (proposed new 45 CFR 180.20). In the CY 2020 OPPI/ASC proposed rule, we explained our belief that this was appropriate and consistent with section 2718(e) of the PHS Act because we believe the inclusion of DRGs as an item or service in section 2718(e) recognizes that hospital services can be provided, and charges billed, based on the service's individual component parts or as a more inclusive service package. While section 2718(e) of the PHS Act specifically includes items and services grouped into DRGs as an example of the items and services for which hospitals must list their standard charges, we explained that our proposed definition of "items and services" should include not just all DRGs (as established under 1886(d)(4) of the SSA) but also all other service packages provided by the hospital, including, for example, service packages the hospital provides in an outpatient setting for which a hospital may have established a standard charge. Therefore, our proposed definition of "items and services" includes both individual items and services and service packages.

We also included in our proposed definition of "items and services" provided by the hospital the services furnished by physicians and non-physician practitioners who are employed by the hospital. We explained our belief that the services the hospital provides through its employed physicians and non-physician practitioners are items and services provided by the hospital because such

clinicians are employed by the hospital specifically so it can offer such services to its patients. In addition, the hospital establishes and negotiates the charges for the employed physician and non-physician services and then bills and retains the payment for the professional services of employed physicians and non-physician practitioners. We therefore proposed to include these services in our proposed definition of items and services provided by the hospital under section 2718(e) of the PHS Act, and for hospitals to make public the charges for the services of their employed physicians and non-physician practitioners.

We also considered including in our proposed definition of items and services the services provided by physicians and non-physician practitioners who are not employed by the hospitals, but who provide services at a hospital location. For example, a procedure performed in a hospital setting may involve anesthesiology services provided by a non-employed physician who has established his or her own charge for the service provided at a hospital location. These physicians and non-physician practitioners may send a bill that is separate from the hospital bill, or they may elect to reassign their billing rights to the hospital that will send a single bill that includes both hospital charges and professional service charges. Often, healthcare consumers are not expecting an additional charge or are otherwise surprised when they receive bills from entities other than the hospital, or when charges for non-employed physicians and non-physician practitioners are higher than expected (for example, when a non-employed physician is out-of-network and the consumer's third party payer declines payment for those services for that reason). We explained our belief that the provision of such additional charge information would be exceptionally valuable to give consumers a more complete picture of the total amount they might be charged in connection with an inpatient admission or an outpatient department visit at a hospital location, potentially helping to address the widely recognized "surprise billing" issue. However, because physicians and non-physician practitioners who are not employed by the hospital are practicing independently, establish their own charges for services, and receive the payment for their services, we indicated we did not believe their charges for their services would fall within the scope of section 2718(e) of the PHS Act as they

are not services "provided by the hospital."

We welcomed comments on these proposals.

Comment: A few commenters agreed with the proposed definition of "items and services" including service packages. Many commenters, however, questioned the feasibility of providing standard charges for service packages, as they believe that it is neither feasible, nor technically possible, for a hospital to report data from its chargemaster as service packages. A few commenters also expressed concern that pricing for service packages as proposed presents a challenge because service packages are often unique to each payer, and the reimbursements negotiated with payers are not necessarily associated with a HCPCS code, DRG, National Drug Code (NDC), or Ambulatory Payment Classification (APC) as the proposed regulation anticipates.

A few commenters stated that they believe CMS needs to provide guidance or a framework to help hospitals define outpatient service packages and attribute ancillary services to specific primary services. Another commenter asked if the definition of "items and services" was flexible enough to allow for different payment models ranging from episodic care that has a guarantee of follow-up care being included if a complication happens, to care models that include subscription-based contracts.

Response: We thank commenters for their input on the proposal. We are finalizing the definition of "items and services" as proposed.

As we explained in the CY 2020 OPPI/ASC proposed rule, some hospitals routinely negotiate rates with third party payers for bundles of services or "service packages." We agree with commenters that the standard charge for a service package is not typically found on the hospital's chargemaster, which simply lists out all the individual items and services. Standard charges for service packages are negotiated between the hospital and payer and are identified by common billing codes (for example, DRGs or APCs) or other payer-specific identifiers that provide context to the type and scope of individualized items and services that may be included in the package. As explained in more detail in section II.D.3 of this final rule, the payer-specific charge the hospital has negotiated for a service package (also referred to as the 'base rate') can be found in other parts of the hospital billing and accounting systems than the chargemaster, or in rate tables or the rate sheets found in hospital in-network

⁴³ Mistichelli J. Diagnosis Related Groups (DRGs). Georgetown University. June, 1984. Available at: <https://repository.library.georgetown.edu/handle/10822/556896>.

contracts with third party payers indicating the agreed upon rates for the provision of various hospital services.

We decline to define outpatient service packages and attributed ancillary services because we believe this would be too prescriptive and each hospital may provide different outpatient service packages and ancillary services. We note, however, that we provide some additional guidance for how hospitals should display of payer-specific negotiated charges for hospital items and services (including service packages) and their ancillary services, as applicable, in sections II.F of this final rule.

We also note that the definition of items and services that we are finalizing gives hospitals flexibility to display their standard charges for service packages that are unique to each of their payer-specific contracts. Thus, a service package that has been negotiated with a third party payer to include treatment for complications or follow up care is included in our definition of hospital items and services.

Comment: One commenter sought clarification on whether CMS is retaining the requirement in current CMS guidelines that PPS hospitals post a list of their standard charges for each Medicare Severity (MS)–DRG.

Response: We are finalizing policies that would supersede the current guidance, and require hospitals to make public their payer-specific charges for items and services, including service packages as identified by DRG, APC, or other common billing code. CMS previously issued guidelines specifying that only hospitals paid under the Medicare IPPS (referred to as subsection (d) hospitals) would be required to establish (and update) and make public a list of their standard charges for each DRG established under section 1886(d)(4) of the SSA.⁴⁴ In retrospect, we recognize that this guidance unnecessarily limited the reporting of DRGs by hospitals according to section 2718(e) of the PHS Act, which specifies that a hospital make public a list of the hospital’s standard charges for items and services provided by the hospital, including for DRGs established under section 1886(d)(4) of the SSA. As indicated in our proposed definition of “items and services,” we interpret the statute to apply to not just individualized items and services, but also to service packages. We believe

such service packages are identified by common billing codes (for example, DRG or APCs), not just MS–DRGs. We are therefore implementing new policies in these regulations. Additionally, as discussed in more detail in section II.D.3, we clarify that the standard charge associated with the DRG would be the base rate the hospital has negotiated with third party payers.

Comment: A few commenters supported a definition of items and services that would include services of employed physicians and non-physician practitioners (generally reflected as professional charges). A few commenters supported a more expansive definition of items and services that would require hospitals to post charges for all practitioners who affiliate with a hospital. Commenters who favored this approach typically stated that CMS should place hospitals in a position to be fully responsible for transparency around the entire bill, citing concerns about surprise billing where patients received a separate bill from medical practitioners not employed by the hospital.

Response: We appreciate commenters support for the proposed definition of items and services which would include services of employed physicians and non-physician practitioners (generally reflected as professional charges). We also appreciate comments encouraging the adoption of an even broader definition of items and services that includes services for physicians and non-physician practitioners who are affiliated with the hospital. As stated in the CY 2020 OPPI/ASC proposed rule, because physicians and non-physician practitioners who are not employed by the hospital are practicing independently, establish their own charges for services, and receive the payment for their services, we do not believe the charges for their services fall within the scope of section 2718(e) of the PHS Act as they are not services “provided by the hospital.” We note that in section II.F.2 of this final rule, we require hospitals to display their standard charges for shoppable services in a consumer-friendly manner, and we provided an example template for the format hospitals could use for this purpose. In section II.F of this final rule, we require hospitals to group the primary shoppable service with the ancillary services customarily provided by the hospital. We also strongly encourage and recommend that hospitals, for the sake of consumer-friendly presentation, indicate any additional ancillary services that are not provided by the hospital but that the patient is likely to experience as part of

the primary shoppable service. We recommend and encourage hospitals to indicate that such services may be billed separately by other entities involved in the patient’s care. We believe such disclosure may be helpful to enable consumers to identify when services of physicians or non-physician practitioners not employed by the hospital may be separately charged.

Comment: Several commenters sought clarification on the term “employment,” noting there are various relationships and employment arrangements (including, for example, full time employment by a hospital, or independent contractor arrangements). A few commenters described these arrangements. For example, one commenter stated that large academic medical centers may have faculty who are housed in a business entity affiliated with the hospital, but not necessarily employed by that hospital. The commenter also stated there may be instances where independent practices assign billing rights to the hospitals entity, but those practitioners are not considered employed by the hospital. A few commenters explained that in many instances, the employment of physicians and non-physician practitioners represent complicated legal organizational structures. Another commenter explained that it could be difficult to understand in what scenarios physicians are employed based on looking at the billing entity for professional services.

Response: We appreciate the commenters’ suggestions identifying examples of the variation and complexity in employment models and possible contracting relationships that may exist between hospitals and physicians, or entities employing physicians. Given such variation and complexity, we believe it is important to preserve flexibility for hospitals to identify employed physicians or non-physician practitioners under their organizational structure, and we decline at this time to codify a definition of “employment.”

Comment: Several commenters disagreed that services provided by physicians and non-physician practitioners employed by hospitals should be included in the definition of items and services. These commenters suggested that, under the proposed approach, hospitals that employ physicians and non-physician practitioners would be providing displaying prices that would not be comparable with prices of hospitals that do not employ, and therefore need not disclose, physician and non-physician practitioner prices, and expressed

⁴⁴ Available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProposedMedicareFeeSvcPmtGen/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-internet.pdf>.

concern that this would result in consumer confusion. A few commenters believed hospitals that employ physicians and non-physician practitioners would be at a disadvantage under the proposed definition of “items and services,” as their standard charges would appear higher than hospitals that do not. One comment suggested that an unanticipated consequence of requiring price transparency only for employed providers could be hospitals moving capital and services into “partnerships” in order to take advantage of the hidden pricing that such a partnership would enable.

Response: We disagree with commenters who suggest that services for employed physicians should be excluded from the definition of items and services as we believe this information will be valuable to give consumers a complete picture of the total amount they might be charged by a hospital.

We disagree with comments suggesting that hospital price transparency requirements would disadvantage those hospitals that employ physicians and non-physician practitioners as compared to hospitals that do not. As further discussed in section II.F. of this final rule, with respect to the requirement to make public certain standard charges for shoppable services in a consumer-friendly format, hospital employed physicians’ and non-physician practitioners’ services may be charged as ancillary services to a primary shoppable service. Under such circumstances, hospitals would list such ancillary services separately from the primary shoppable service. In Table 2, in section II.F. of this final rule, we include an example for how hospitals could format and display their shoppable services. We also note that our final policies require that the standard charges for each shoppable service (including ancillary services) be listed separately, not summed (see section II.F. of this final rule). We therefore believe consumers, comparing shoppable services for multiple hospitals, will be able to distinguish whether or not the hospital standard charges include charges for services of physicians and non-physician practitioners.

We also do not have sufficient information to conclude that a requirement for hospitals to disclose standard charges for services of employed physicians and non-physician practitioners is likely to result in a systematic change from the practice of employing physicians and non-physician practitioners to favoring other

types of partnerships and employment arrangements. In developing our proposals for hospital price transparency, we drew from similar requirements of States and we are not aware that such price transparency requirements altered the mode by which hospitals employ physicians and non-physician practitioners.

Comment: A few commenters suggested that CMS lacked the legal basis to establish a definition of hospital items and services that includes services of employed physicians and non-physician practitioners.

Response: Section 2718(e) of the PHS Act requires hospitals to make public the hospital’s standard charges for items and services provided by the hospital, including for DRGs. The term “standard charges for items and services” is not defined in section 2718. We believe the Secretary has the authority to define “items and services.” Since hospitals charge patients for the services of their employed physicians and non-physician practitioners, we believe it is reasonable for the Secretary to define items and services as including their services.

Comment: One commenter expressed concern with requiring hospitals to make public standard charges for services of employed emergency room physicians, urging a cautious approach so as to not undermine the patient protections in place under the Emergency Medical Treatment and Labor Act (EMTALA). The commenter explained that EMTALA stipulates that a hospital may not place any signs in the emergency department regarding the prepayment of fees or payment of co-pays and deductibles that may have the chilling effect of dissuading patients from coming to the emergency department. That, the commenter said, could lead patients to leave prior to receiving a medical screening examination and stabilizing treatment without regard to financial means or insurance status. The commenter expressed concern that if the hospital attempts to provide pricing information to patients prior to stabilizing them, it would not only constitute an EMTALA violation, but it could also potentially cause the patient’s health to deteriorate since it could delay the patient from receiving critical care. While the commenter noted that the penalties for violating EMTALA are steep, their larger concern was that if price transparency for emergency care is not approached carefully, a hospital could inadvertently put patients in the position of making life-or-death healthcare decisions based on costs.

Several other commenters stressed how important it is that consumers

know the cost of emergency services in non-life threatening circumstances. One commenter explained that he or she might have used price data (if available) to determine which hospital emergency room to go to for treatment of a non-life threatening condition. One commenter noted that in the case of an emergency, people would not have time for comparison of shoppable healthcare services.

Response: We appreciate the comment expressing concern about potential interaction between EMTALA, or section 1867 of the SSA (42 U.S.C. 1395dd), and the requirements for hospitals to make public standard charges under section 2718(e) of the PHS Act. However, we believe that the policies we finalize here that require hospitals to make public standard charges online are distinct from EMTALA’s requirements and prohibitions and that the two bodies of law are not inconsistent and can harmoniously co-exist. To be clear, the price transparency provisions that we are finalizing do not require that hospitals post any signage or make any statement at the emergency department regarding the cost of emergency care or any hospital policies regarding prepayment of fees or payment of co-pays and deductibles. But we do believe that the policies we are finalizing, for hospitals to make public standard charges, offer consumers opportunities for informed decision-making by providing them with information about the cost of care which, for example, they might consider prior to visiting a hospital emergency department for treatment of a non-life threatening condition.

Comment: One commenter believed that there should be better patient education to go along with the requirements for listing standard charges related to items and services and service packages.

Response: We note that this rule does not preclude hospitals from taking additional measures to educate their patient populations on the data they make publicly available.

Final Action: We are finalizing, as proposed, the meaning of “items and services” at new 45 CFR 180.20. In the CY 2020 OPPI/ASC proposed rule, we had included several examples of items and services within the definition; for clarity, we are finalizing a technical change to enumerate these examples at 45 CFR part 180.20.

Accordingly, items and services means all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection

with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples include, but are not limited to the following:

- (1) Supplies and procedures.
- (2) Room and board.
- (3) Use of the facility and other items (generally described as facility fees).
- (4) Services of employed physicians and non-physician practitioners (generally reflected as professional charges).
- (5) Any other items or services for which a hospital has established a standard charge.

D. Definitions for Types of “Standard Charges”

1. Overview and Background

Under our current guidelines related to section 2718(e) of the PHS Act (as discussed in the FY 2019 IPPS/LTCH PPS proposed rule and final rule (83 FR 20164 and 41144, respectively)), a hospital may choose the format it uses to make public a list of its standard charges, so long as the information represents the hospital’s current standard charges as reflected in its chargemaster.

As we explained in the CY 2020 OP/ASC proposed rule, we received feedback from several commenters in response to the 2018 requests for information (RFIs), including hospitals and patient advocacy organizations, who indicated that gross charges as reflected in hospital chargemasters may only apply to a small subset of consumers; for example, those who are self-pay or who are being asked to pay the chargemaster rate because the hospital is not included in the patient’s insurance network. We explained that stakeholders also noted that the charges listed in a hospital’s chargemaster are typically not the amounts that hospitals actually charge to consumers who have health insurance because, for the insured population, hospitals charge amounts reflect discounts to the chargemaster rates that the hospital has negotiated with third party payers. Further, with respect to patients who qualify for financial assistance or who pay in cash, commenters on the RFIs pointed out that some hospitals will charge lower amounts than the rates that appear on the chargemaster. Adding to the complexity, a few commenters noted that hospitals often package items and services and charge a single discounted negotiated amount for the packaged service. For example, as discussed in I.C. of this final rule, instead of itemizing and charging for each individual hospital item or service

found on the chargemaster, a hospital may identify a primary common condition or procedure and charge a single negotiated or “cash” amount for the primary common condition or procedure that includes all associated items and services that are necessary for treatment of the common condition or to perform the procedures. We stated that we believed these comments illustrated a fundamental challenge of making healthcare prices transparent in general, and specifically with respect to the issue of how we should best implement section 2718(e) of the PHS Act; simply put, hospitals do not offer all consumers a single “standard charge” for the items and services they furnish. Rather, the “standard charge” for an item or service (including service packages) varies depending on the circumstances particular to the consumer (84FR 39577 through 39578).

As discussed in the CY 2020 OP/ASC proposed rule, in developing our proposals in this rulemaking we took into account the comments we received from the 2018 RFIs responding to our question about how “standard charges” should be defined. We indicated in the CY 2020 OP/ASC proposed rule that we believed the variety of suggested definitions reflected and supported our assessment that hospitals can have different standard charges for various groups of individuals. We stated that, in general, for purposes of 2718(e) of the PHS Act, we believed a standard charge could be identified as a charge that is the regular rate established by the hospital for the items and services provided to a specific group of paying patients. Therefore, we considered what types of standard charges may reflect certain common and identifiable groups of paying patients and we proposed to define standard charges to mean “gross charges” and “payer-specific negotiated charges,” and to codify this definition in proposed new 45 CFR 180.20. As explained in the CY 2020 OP/ASC proposed rule, our proposal to define standard charges as gross charges and payer-specific negotiated charges reflects the fact that a hospital’s standard charge for an item or service is not typically a single fixed amount, but, rather, depends on factors such as who is being charged for the item or service, and particular circumstances that apply to an identifiable group of people, including, for example, healthcare consumers that are insured members of third party insurance products and plans that have negotiated a rate on its members’ behalf.

Further, in the CY 2020 OP/ASC proposed rule, we acknowledged that the proposed definition of hospital

“standard charges” would be limited to only two of the many possibilities that exist for defining types of hospital “standard charges,” and we discussed other potential definitions that we considered, and sought public input and comment on the alternatives and additional types of standard charges that may be useful to consumers.

Comment: Many commenters, in particular, individuals and those representing independent medical practices, expressed frustration related to the opacity of healthcare prices, stating that hospital charges are often unreasonable. Commenters described hospital billing practices as a “shell game” and asserted that the use of overly inflated chargemaster rates to negotiate with payers is an unfair practice that leads patients to get “gouged.” One commenter noted that the “lack of price transparency circumvents market forces that seek to keep prices within reasonable limits [which has] resulted in the creation of a dysfunctional market with rapidly increasing and excessive charges for which the consumer is ultimately responsible.” Others similarly asserted that the lack of availability of healthcare costs leads to “predatory pricing” on the part of hospitals and insurance companies, and noted that millions of Americans have gone bankrupt because they get “stuck with bills that are beyond reasonable.”

Many commenters asserted that hospital disclosure of standard charges would be critical to bring accountability and increased value to the healthcare industry; however, many other commenters stated that they believed the movement toward value-based care could or would be harmed by hospital disclosure of standard charges, specifically, as a result of disclosure of payer-specific negotiated charges.

Many commenters were highly supportive of our proposals and, in particular, of the proposals to require hospitals to make public both gross and payer-specific negotiated charges. Many commenters asserted that such disclosure is informative and necessary for consumers and will improve the value of healthcare for consumers. For example, commenters indicated that knowing the rate the insurer had negotiated on their behalf would be essential for patients with co-insurance and HDHPs to help determine their out-of-pocket cost estimates in advance. Other commenters indicated that the gross charge or cash rate was important for self-pay patients (with or without insurance) to compare facility prices.

Many other commenters, however, disagreed with our proposals,

questioning the legal authority for requiring disclosure of more than one type of hospital standard charge as proposed, with objections focused mainly on the proposed definition and requirement to disclose payer-specific negotiated charges.

Many commenters supported the addition of, or offered alternative suggestions for, necessary types of standard charges such as the discounted cash price and variations of the de-identified minimum, median, or maximum negotiated charge.

Response: Hospital bills can be mystifying, even to those who have been in healthcare-related professions for years; some hospital charges are market-based, while others are not. There are three broad types of hospital rates, depending on the patient and payer: (1) Medicaid and Medicare FFS rates; (2) Negotiated rates with private insurers or health plans; and (3) Uninsured or self-pay.

Medicaid FFS rates are dictated by each State and tend to be at the lower end of market rates. Medicare FFS rates are determined by CMS and those rates tend to be higher than Medicaid rates within a state. Privately negotiated rates vary with the competitive structure of the geographic market and usually tend to be somewhat higher than Medicare rates, but in some areas of the country the two sets of rates tend to converge.

Chargemaster (gross) rates charged to self-pay individuals bear little relationship to market rates, are usually highly inflated,⁴⁵ and tend to be an artifact of the way in which Medicare used to reimburse hospitals. Under the old system, the more services a hospital provided and longer a patient's stay, the greater the reimbursement. Congress, recognizing that the reimbursement system created disincentives to provide efficient care, enacted in 1983 a prospective payment system. The primary objective of the prospective payment system is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries.

To partly compensate hospitals for certain overly costly hospitalizations, hospitals may receive an "outlier"

payment which is based on the hospital's billed charges, adjusted to cost, in comparison to the payment that would otherwise be received and an outlier threshold. See 42 CFR 412.84. To determine whether an individual case would qualify for an outlier payment, the hospital's cost-to-charge ratio is applied to the covered charges to estimate the costs of the case. In the late 1990s, many hospitals began manipulating or gaming that ratio to make it easier to qualify for outlier payments. The larger the charges, the smaller the ratio, but it takes time for the ratio to be updated. Thus, by way of example, if a hospital had a cost-to-charge ratio 1 to 5, or 20 percent, then a pill which cost the hospital \$1 to purchase might be billed to a patient at \$5. However if the hospital doubled the charge to the patient to \$10, the corresponding change in its ratio would take time to be updated. Its costs might look like \$2 instead of \$1 in the interim. Rule changes have reduced such manipulation. Nevertheless, some hospitals' charges do not reflect market rates, and these can come into play when a hospital bills a self-pay patient. Hospital bills that are generated off these chargemaster rates can be inherently unreasonable when judged against prevailing market rates.

As premiums under the ACA have become less affordable,⁴⁶ many individuals, both with and without insurance, have large unpaid hospital bills. Some hospitals, including some that are categorized as charitable, have responded by instituting collection actions against those patients. As the number of these suits have proliferated, many states courts have had to grapple with hospital charging systems in order to judge whether a given set of charges was reasonable. There are several potential metrics for assessing reasonableness of a hospital's charge in a given case as an alternative to the chargemaster (gross) rates described above. These include the rate Medicare would have paid for those same services, the amount hospitals are supposed to charge needy patients who lack insurance "not more than the amounts generally billed to individuals who have insurance covering such care" (see IRC 501(r)(5)(A) or the amounts billed consistent with the financial assistance policy each non-profit hospital is required to have (see IRC 501(r)(4)).

We continue to believe that the public posting of hospital standard charge

information will be useful to the public, including consumers who need to obtain items and services from a hospital, consumers who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making referrals, and other members of the public who may develop consumer-friendly price transparency tools or perform analyses and make policy to drive value-based care. In the CY 2020 OPPI/ASC proposed rule, we stated that we believed these proposed requirements would represent an important step towards putting healthcare consumers at the center of their healthcare and ensuring they have access to the hospital standard charge information they need. Additionally, as stated in the CY 2020 OPPI/ASC proposed rule, we believe that requiring transparency of hospital charges will drive competition, which, in turn, may have the effect of not only lowering hospital charges for the most vulnerable consumers and those with the least market power to negotiate prices, but also for consumers who have access to charges negotiated on their behalf by a third party payer.

We also continue to believe that price transparency will lead to lower costs for consumers and better quality of care. As stated in the CY 2020 OPPI/ASC proposed rule, many empirical studies have investigated the impact of price transparency on markets, with most research showing that price transparency leads to lower and more uniform prices, consistent with predictions of standard economic theory. Further, evidence shows that healthcare quality is not often correlated with price.⁴⁷ Traditional economic analysis suggests that if consumers have better pricing information for healthcare services, providers would face pressure to either lower prices or to provide better quality of care for the prices they charge.⁴⁸ Much of the research evidence we considered in the development of these requirements and in the CY 2020 OPPI/ASC proposed rule are reprised in sections II.A, II.D.3, and in our Regulatory Impact Analysis (RIA) (section V). Because the drive towards value depends on access to both quality and cost information, we believe that disclosure of hospital standard charges fully aligns with and supports our drive

⁴⁵ Richman BD, et al. Battling the Chargemaster: A Simple Remedy to Balance Billing for Unavoidable Out-of-Network Care. *Am J Manag Care*. 2017;23(4):e100–e105. Available at: <https://www.ajmc.com/journals/issue/2017/2017-vol23-n4/battling-the-chargemaster-a-simple-remedy-to-balance-billing-for-unavoidable-out-of-network-care>.

⁴⁶ NCSL website, Health Insurance: Premiums and Increases, at <http://www.ncsl.org/research/health/health-insurance-premiums.aspx>.

⁴⁷ Hussey P, et al. The Association Between Health Care Quality and Cost A Systematic Review. *Ann Intern Med*. January 2013; 158(1): 27–34. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4863949/>.

⁴⁸ Ginsburg P. Shopping For Price In Medical Care. *Health Affairs*. 2007. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.26.2.w208>.

toward value care as one half of the value proposition. In other words, whereas hospital quality information is readily available to the public,^{49 50} hospital standard charge information is not. Disclosure of hospital standard charge information will therefore complement quality information so that consumers can make high value decisions about their care.

Section 2718 of the PHS Act provides authority to require disclosure of hospital standard charges. Specifically, section 2718(e) of the PHS Act requires each hospital operating within the United States for each year to establish (and update) and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the SSA. In addition to section 2718(e) and section 2718(b)(3) (regarding enforcement), section 1102 of the SSA supports the requirements in this rule. Section 1102(a) of the SSA requires the Secretary to "make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he or she] is charged" under the SSA. By its terms, this provision authorizes regulations that the Secretary determines are necessary to administer these programs. In our view, as discussed further below, there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs. In addition, these requirements also promote the efficient administration of the Medicare and Medicaid programs.

Since the PHS Act does not define "standard charges" for purposes of implementation of section 2718(e) of the PHS Act, we proposed to define standard charges by the regular rate established by the hospital for an item or service provided to a specific group of paying patients. The term "rate" is defined in the Oxford dictionary as "a fixed price paid or charged for something, especially goods or services." We therefore use the terms "rate" and "charge" interchangeably throughout this final rule. We believe that reading the statute to permit disclosure of several types of charges (or "rates") that are standard for different identifiable groups of people is reasonable for several reasons. First, while there is a definition of "charge"

in the SSA that is used for purposes of Medicare (as commenters noted and as discussed in more detail in II.D.2), there is not a definition of 'standard charges' in either the PHS Act or the SSA. We believe that had Congress intended us to use the SSA definition of "charges," Congress would have referenced that definition of "charges" and included this provision in the SSA, as opposed to the PHS Act. Alternatively, Congress could have indicated that hospitals make public their "charges" and not qualified the term by inserting "standard" in front of it. Moreover, we believe the statute contemplates disclosure of charges other than the hospital chargemaster rates because the statute requires hospitals to disclose their "standard charges" for items and services, *including for diagnosis related groups* (italicized for emphasis). This suggests that the statute contemplates disclosure of charges other than the list prices as found in the hospital chargemaster because the hospital chargemaster contains only list prices for individual items and services. Hospital chargemasters do not include list prices for service packages represented by common billing codes such as DRGs. Instead, "standard charges" for service packages are determined as a result of negotiations with third party payers.⁵¹ For these reasons and others articulated in the CY 2020 OPPI/ASC proposed rule, we believe the term "standard charges" for purposes of implementing section 2718(e) of the PHS Act may be defined to mean the standard charges as they relate to different identifiable groups of people and to include charges other than those found in the hospital chargemaster.

As there are many different identifiable groups of paying patients (some that are self-pay and others that are members of third party payer insurance plans), in the CY 2020 OPPI/ASC proposed rule, we defined two types of standard charges, specifically, the gross (chargemaster) charges and the payer-specific negotiated charges. As explained in section II.A. of this final rule, we continue to believe that gross charges found in the chargemaster as well as negotiated charges are both informative and necessary for consumers to understand their potential out-of-pocket cost obligations, but such information is not readily available to consumers. These two specific types of

standard charges have the potential to inform two large identifiable groups of healthcare consumers who do not currently have ready access to hospital charge information, specifically those who have limited power to negotiate charges (for example, self-pay individuals) and those who rely on third party payers to negotiate charges on their behalf. We also continue to believe that hospital face only a limited burden to make publicly available these types of standard charges because good business practices necessitate that these charges be available, maintained, and in use in hospital billing and accounting systems.

Section 2719 of the PHS Act requires non-grandfathered plans and issuers to provide a notice of adverse benefit determination⁵² (commonly referred to as an explanation of benefits (EOB)) to participants, beneficiaries, and enrollees after healthcare items or services are furnished and claims for benefits are adjudicated. We note that presentation of both gross charges and payer-specific negotiated charges is consistent with the standard charges found in a patient's EOB that health insurance plans are required to provide to patients following a healthcare service. EOBs include such data points as: The type of service provided; the amount the hospital billed for the service (which we define as the gross charge for purposes of implementing section 2718(e) of the PHS Act); any discount the patient received for using an in-network provider (which we define as the payer-specific negotiated charge for purposes of implementing section 2718(e) of the PHS Act) or the allowed amount for out-of-network providers; the portion or amount the plan paid the hospital; and the remaining amount owed out-of-pocket and any portion of that amount applied toward the deductible. It is evident that while the first two sets of charge data are necessary for a consumer to understand their out-of-pocket obligations, that data are insufficient as the consumer must obtain additional information from his or her third party payer related to the circumstances of their particular insurance plan (for example, what portion of the payer-specific negotiated charges would be paid by the plan and

⁴⁹ <https://www.medicare.gov/hospitalcompare/search.html>.

⁵⁰ AHRQ website, Comparative Reports on Hospitals, at <https://www.ahrq.gov/talkingquality/resources/comparative-reports/hospitals.html>.

⁵¹ Office of Attorney General, Commonwealth of Massachusetts. *Examination of Health Care Cost Trends and Cost Drivers Pursuant to G.L. c. 12C, § 17*. (October 11, 2018). Available at: <https://www.mass.gov/files/documents/2018/10/11/AGO%20Cost%20Trends%20Report%202018.pdf>.

⁵² An adverse benefit determination means an adverse benefit determination as defined in 29 CFR 2560.503-1, as well as any rescission of coverage, as described in 29 CFR 2590.715-2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time). See 26 CFR 54.9815-2719, 29 CFR 2590.715-2719 and 45 CFR 147.136. Plans subject to the requirements of ERISA (including grandfathered health plans) are also subject to a requirement to provide an adverse benefit determination under 29 CFR 2560.503-1.

other plan dependencies such as the patient's co-insurance obligations or where the patient is in their deductible for the year). Both gross charges and payer-specific negotiated charges are therefore necessary starting points for patients with third party payer insurance to understand their out-of-pocket cost obligations, and hospitals have ready access to both. By making these two important types of standard charges public, consumers could have the information necessary to create what could be considered an EOB in advance of a service, rather than having to wait for months after services were rendered to understand the extent of their healthcare costs. We address the gross charges as a type of standard charge in section II.D.2 of this final rule. We address the payer-specific negotiated charge in section II.D.3 of this final rule.

Finally, we appreciate commenter support and suggestions for alternative types of standard charges and are finalizing three additional types of standard charges in response to comments. Specifically, we are finalizing the discounted cash price (as discussed in section II.D.4.c of this final rule), as well as the de-identified minimum negotiated charge and the de-identified maximum negotiated charge which are discussed in section II.D.4.d of this final rule.

Final Action: After considering the public comments, we are finalizing as proposed our definition of standard charges at 45 CFR 180.20 to mean the regular rate established by the hospital for an item or service provided to a specific group of paying patients. We are also finalizing two types of standard charges, gross charges and payer-specific negotiated charges (as discussed in more detail in sections II.D.2 and II.D.3 of this final rule). Further, as a result of broad stakeholder support for the discounted cash price as an alternative type of standard charge because of its greater applicability to self-pay individuals, we are adding the discounted cash price as a third type of standard charge (as discussed in more detail in section II.D.4.c of this final rule). In response to the many commenters who supported variations of the de-identified minimum, median and maximum negotiated charges, we are finalizing modifications to define the de-identified minimum negotiated charge, and de-identified maximum negotiated charge as a fourth and fifth type of standard charge (as discussed in more detail in section II.D.4.d of this final rule). Each of these types of standard charges (the gross charge, the payer-specific negotiated charge, the discounted cash price, the de-identified

minimum negotiated charge, and the de-identified maximum negotiated charge) and the comments received are discussed in more detail in sections II.D.2, II.D.3, and II.D.4.c and II.D.4.d of this final rule, respectively.

2. Definition of "Gross Charges" as a Type of Standard Charge

We proposed that, for purposes of the first type of "standard charge," a "gross charge" would be defined as the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts (at new 45 CFR 180.20). As we explained in the CY 2020 OPPI/ASC proposed rule (84 FR 39576 through 39577), the hospital chargemaster contains a list of all individual items and services the hospital provides. The gross charges reflected in the chargemaster often apply to a specific group of individuals who are self-pay, but do not reflect charges negotiated by third party payers. We also noted that the chargemaster does not include charges that the hospital may have negotiated for service packages, such as per diem rates, DRGs or other common payer service packages, and therefore this type of standard charge would not include standard charges for service packages.

We proposed to require hospitals to make public their gross charges because, in addition to applying to a specific group of individuals, based on research and stakeholder input, we believe gross charges are useful to the general public, necessary to promote price transparency, and necessary to drive down premium and out-of-pocket costs for consumers of healthcare services. For example, studies suggest that the gross charge plays an important role in the negotiation of prices with third party insurance products that are subsequently sold to consumers.⁵³ Specifically, as hospital executives and others familiar with hospital billing cycles often note, hospitals routinely use gross charges as a starting point for negotiating discounted rates with third party payers, and higher gross charges have been found to be associated with both higher negotiated rates and, in turn, higher premiums and out-of-pocket costs for insured individuals.^{54 55}

⁵³ Bai G and Anderson GF. Market Power: Price Variation Among Commercial Insurers for Hospital Services. *Health Affairs*. Oct 2018; 37(10): 1615–1622. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0567>.

⁵⁴ Bai G and Anderson GF. Extreme Markup: The Fifty US Hospitals With The Highest Charge-To-Cost Ratios. *Health Affairs*. Jun 2015; 34(6): 922–928. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1414>.

⁵⁵ Batty M and Ippolito B. Mystery of The Chargemaster: Examining The Role Of Hospital List

As such, gross charges are relevant to all consumers, including those with insurance coverage. We stated in the CY 2020 OPPI/ASC proposed rule that we believe that requiring transparency of hospital gross charges may drive competition, which, in turn, might have the effect of not only lowering hospital charges for the most vulnerable consumers and those with the least market power to negotiate prices, but also for consumers who have access to charges negotiated on their behalf by a third party payer.

Additionally, we indicated in the CY 2020 OPPI/ASC proposed rule that third party developers of consumer price transparency tools can use gross charges in conjunction with additional information (such as an individual's specific insurance and benefit information and quality data) to develop and make available consumer-friendly out-of-pocket cost estimates that allow consumers to compare healthcare service prices across hospitals and other nonhospital settings of care. Moreover, we noted in the CY 2020 OPPI/ASC proposed rule (84 FR 39572 through 39573) that research suggests that making such consumer-friendly information available to the public has been demonstrated to reduce consumer healthcare costs. As such, we concluded that public access to hospital gross charges is critical to inform all patients (both self-pay and insured) of their choices and drive transparency in prices and proposed to codify the proposed definition of "gross charges" at new 45 CFR 180.20. We invited public comment on our proposal to define a type of "standard charge" as a "gross charge" and on our proposed definition of "gross charge."

Comment: Several commenters specifically agreed with our proposal to include gross charges as a type of standard charges. A few commenters also stated that they believed gross charges should be the only definition of "standard charge." Several commenters, however, disagreed with the proposed inclusion of gross charges as a type of standard charge due to their belief that the definition conflicts with the definition of "charges" used in CMS's Provider Reimbursement Manual Part 1 (PRM1). Several commenters emphasized the importance of CMS remaining consistent with its definitions of "charges" due to their belief that deviating from these definitions would undermine the accuracy of hospital cost

Prices in What Patients Actually Pay. *Health Affairs*. April 2017; 36(4): 689–696. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0986>.

reports which is fundamental to the Medicare rate-setting process.

Response: We thank commenters for their support of a definition of the first type of standard charge to be the “gross charge” and disagree with commenters who state that the gross charge should be the only standard charge. As further explained in section II.D.1 of this final rule, we believe the statute contemplates standard charges other than those found in the hospital chagemaster. Additionally, we sought comment last year on a definition of “standard charges” and, as a result of comments, we were persuaded a singular “standard” that applies to all identifiable groups of patients is not possible because groups of patients with third party payer insurance have different standard charges that apply to them than do patients without third party payer coverage. We therefore decline to adopt the several commenters’ suggestions that we finalize the gross charge as the only type of hospital standard charge.

Further, we do not believe our proposed definition of “gross charges” for purposes of implementing section 2718(e) of the PHS Act conflicts with definitions of “charges” found in the PRM1, which states “Charges refer to the regular rates established by the provider for services rendered to both beneficiaries and to other paying patients. Charges should be related consistently to the cost of the services and uniformly applied to all patients whether inpatient or outpatient. All patients’ charges used in the development of apportionment ratios should be recorded at the gross value; *i.e.*, charges before the application of allowances and discounts deductions.”⁵⁶ In fact, we believe our definition of “gross charge” as the charge for an individual item or service that is reflected on a hospital’s chagemaster, absent any discounts, is the same as the charges referenced in the PRM1 and that hospitals use to create cost reports for Medicare purposes. We further do not believe that the term “charges” as used in the PRM is in conflict because the term is defined for a specific purpose and use, that is, for purposes of Medicare cost reporting. For this reason, we disagree with commenters that our definition of “gross charges” as a type of standard charge in any way undermines the accuracy of hospital Medicare cost reports.

Additionally, gross charges may also sometimes be referred to as “billed charges” or “billed amounts” and appear on a patient’s EOB as the first charge listed, and are the first step in explaining the patient’s out-of-pocket obligations. When the consumer has no insurance and is self-pay, there is no EOB and the hospital often applies the gross charges to the consumer if no other pre-arrangement has been worked out (for example, if the consumer has not taken advantage of a discounted cash price offered by the hospitals).

Comment: Regarding the need for and usefulness of gross charges as a type of standard charge, several commenters asserted that gross charge data would be meaningful to the public and necessary for full price transparency. A few commenters emphasized the positive difference this information would make if people had the ability to see information, for example one commenter stated that they would like to see the different levels of room charges on a list, stating that it would make a big difference for most people. A few commenters added that by seeing costs up front they could make an informed decision before receiving care, in order to both anticipate their bill and potentially shop around. A few commenters also expressed that by seeing all charges up front, consumers could determine whether “self-pay” would be a better deal for them than paying the insurance copay and deductible. By contrast, several commenters disagreed that gross charges would be applicable or useful to the public, because they believe that they do not represent what most consumers would actually pay (particularly those with third party payer coverage) and would not be meaningful to the public. One commenter stated that even in the hands of app developers, this data may have little relevance to insured individuals because the data wouldn’t be presented in the context of the individual’s health plan. One commenter disagreed with hospitals posting gross charges because they believe that in rural areas, the appearance of high prices may deter a consumer from seeking care.

Response: We thank the commenters for their input. We agree with stakeholders who suggested that while the gross charge may be applicable to some self-paying patients, it is not the standard charge that applies to groups of insured patients. Even some self-paying patients may find that some hospitals offer a cash discounted price off their chagemaster rates (as discussed in more detail in section II.D.4.c of this final rule). Because of this, we are finalizing

definitions for several types of standard charges that would be applicable to both self-pay patients as well as consumers with third party payer coverage. As we outlined in more detail in the CY 2020 OPPI/ASC proposed rule (84 FR 39578 through 39579), research suggests that gross charges appear to play an important role in prices paid by consumers with third-party insurance products because higher gross charges are associated with higher negotiated rates, premiums, and consumer out-of-pocket costs. For consumers who are self-pay or who lack insurance, such information can be useful in advance of selecting a provider of healthcare services to help patients determine potential out-of-pocket cost obligations. This information may also have high value for researchers and other academics who can assess regional and national cost trends to determine the effectiveness of price transparency efforts, and for lawmakers to determine policy improvements that are necessary to drive toward value in healthcare. As noted in II.D.1 in this final rule, the presentation of gross charges is the starting point for insured patient’s EOBs, which contain multiple charge and other data points necessary for patients to understand their out-of-pocket cost obligations. We therefore believe that disclosure of gross charges are useful to the general public and necessary to promote price transparency and reduce premiums and out-of-pocket costs for consumers of healthcare.

We recognize the unique challenges that rural hospitals face, but disagree that rural hospitals making standard charges public would deter patients from seeking necessary care, especially where there is already minimal competition with a CAH or sole community hospital. We believe instead that this information would allow consumers to include price considerations in their treatment plan for elective procedures, which may result in selecting the most appropriate setting for their care and increased patient satisfaction.

Final Action: At new 45 CFR 180.20, we are finalizing as proposed a definition of gross charge, as a type of standard charge, to mean the charge for an individual item or service that is reflected on a hospital’s chagemaster, absent any discounts.

3. Definition of “Payer-Specific Negotiated Charge” as a Type of Standard Charge

As noted in section II.D.1. of this final rule, in general, for purposes of 2718(e), we believe a standard charge can be identified as a regular rate established

⁵⁶ Part I, Chapter 22, Section 2202.4 of the Medicare Provider Reimbursement Manual <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html>.

by the hospital for the items and services provided to a specific group of paying patients. We proposed that, for purposes of the second type of “standard charge,” the “payer-specific negotiated charge” would be defined as the charge that the hospital has negotiated with a third party payer for an item or service. We further proposed to define “third party payer” for purposes of section 2718(e) of the PHS Act as an entity that, by statute, contract, or agreement, is legally responsible for payment of a claim for a healthcare item or service, and to codify this definition at new 45 CFR 180.20. As the reference to “third party” suggests, this definition excludes an individual who pays for a healthcare item or service that he or she receives (such as self-pay patients).

We proposed to focus on a second type of “standard charge” related to negotiated rates because most consumers (over 90 percent⁵⁷) rely on a third party payer to cover a portion or all of the cost of healthcare items and services, including a portion or all of the cost of items and services provided by hospitals (in accordance with the terms and conditions of the third party payer’s contract agreement with that consumer). Some third party payers (for example, FFS Medicare and Medicaid) currently make public the maximum rate they pay for a hospital item or service. However, many third party payers do not reveal their negotiated rates, even to individuals on behalf of whom they pay. Additionally, many contracts between third party payers and hospitals contain so-called “gag clauses” that prohibit hospitals from disclosing the rates they have negotiated with third party payers.⁵⁸ Because consumers are not generally part of the negotiations or privy to the resulting negotiated rates, consumers often find it difficult to learn in advance of receiving a healthcare service the rate their third party payers may pay and subsequently what the individual’s portion of the cost will be. Having insight into the charges negotiated on one’s behalf is necessary for insured healthcare consumers to determine and compare their potential out-of-pocket obligations prior to receipt of a healthcare service. For example, if a healthcare consumer knows that he or

she will be responsible for a co-pay of 20 percent of the charges for a hospital service, he or she can compare the charges that the third party negotiated with hospital A and hospital B and, from that, the consumer can determine his or her expected out-of-pocket costs at hospital A versus hospital B.

In the CY 2020 OPPS/ASC proposed rule, we explained that knowing a negotiated charge is also important because a growing number of insured healthcare consumers are finding that some services are more affordable if the consumer chooses to forego utilizing their insurance product and simply pays out-of-pocket. For example, stakeholders and reports indicate that an increasing number of consumers are discovering that sometimes providers’ cash discounts can mean paying lower out-of-pocket costs than paying the out-of-pocket costs calculated after taking into account a third party payer’s higher negotiated rate.^{59 60 61 62} However, consumers cannot make such determinations without knowing the rate their third party payer has negotiated.

For the reasons discussed above, we indicated that we agreed with 2018 RFI commenters that gross charges (as a type of standard charge) could be applicable to one identifiable group of consumers (for example, self-pay) but are not enough for another large and identifiable group of consumers (for example, those with third party insurance) to know their charges for hospital items. Thus, we proposed that a type of “standard charge” is the “payer-specific negotiated charge” that would be defined as the charge (or rate) that a hospital has negotiated with a third party payer for an item or service. We stated that we decided to focus on negotiated rates rather than all payer rates because charges that are not negotiated (for example, FFS Medicare or Medicaid rates) are often already publicly available.

In the CY 2020 OPPS/ASC proposed rule, we stated that it is clear that such data is necessary for consumers to be able to determine their potential out-of-pocket costs in advance, and that we believe the release of such data would help drive down healthcare costs (as discussed above and supported by recent price transparency research). However, we also stated we recognized that the impact resulting from the release of negotiated rates is largely unknown and that some stakeholders had expressed concern that the public display of negotiated rates, at least without additional legislative or regulatory efforts, may have the unintended consequence of increasing healthcare costs of hospital services in highly concentrated markets or as a result of anticompetitive behaviors.⁶³

Moreover, we recognized in the CY 2020 OPPS/ASC proposed rule that requiring release of all payer-specific negotiated charges for all hospital items and services (both individual items and services as well as service packages) would mean releasing a large amount of data. To get a sense for the number of potential negotiated rates a hospital may have, we conducted an internal analysis of plans in the regulated individual and small group insurance markets under the ACA. Our analysis indicated that the number of products or lines of service per rating area ranges from approximately 1 to 200 in the individual market (averaging nearly 20 products or lines of service in each rating area), while in the small market group, the number ranges from 1 to 400 (averaging nearly 40 products or lines of service in each rating area). We further noted our belief that most, if not all, hospitals maintain such data electronically because these data are used routinely for billing, and concluded that disclosure of such large amounts of charge information would present little burden for a hospital to electronically pull and display online in a machine-readable format (as discussed in more detail in the CY 2020 OPPS/ASC proposed rule at 84 FR 39581 through 39585). We went on to explain that ensuring display of such a large amount of data in a consumer-friendly manner may pose greater challenges.

In the CY 2020 OPPS/ASC proposed rule, we noted that, in displaying the payer-specific negotiated charges, hospitals would display all negotiated charges, including, for example, charges

⁵⁷ Berchick E, et al. Health Insurance Coverage in the United States: 2017. United States Census Bureau, September 2018. Available at: <https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf>.

⁵⁸ King JS, Muir MA, Alessi SA. Clarifying Costs Can Increased Price Transparency Reduce Healthcare Spending? 4 William & Mary Policy Review 319 (2013). Available at: <https://pdfs.semanticscholar.org/f604/1a0484c65c593525d0c07e040cf655697f2d.pdf>.

⁵⁹ Beck M. How to Cut Your Health-Care Bill: Pay Cash. *The Wall Street Journal*. February 15, 2016. Available at: <https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277>.

⁶⁰ Rosato D. How Paying Your Doctor in Cash Could Save You Money. *Consumer Reports*. May 4, 2018. Available at: <https://www.consumerreports.org/healthcare-costs/how-paying-your-doctor-in-cash-could-save-you-money/>.

⁶¹ Terhune C. Many hospitals, doctors offer cash discount for medical bills. *Los Angeles Times*. March 27, 2012. Available at: <https://www.latimes.com/business/healthcare/la-fi-medical-prices-20120527-story.html>.

⁶² Weissmann D. ‘An Arm And A Leg’: Can You Shop Around For A Lower-Priced MRI? *Kaiser Health News*. June 19, 2019. Available at: <https://khn.org/news/an-arm-and-a-leg-can-you-shop-around-for-a-lower-priced-mri/>.

⁶³ King JS, Muir MA, Alessi SA. Clarifying Costs Can Increased Price Transparency Reduce Healthcare Spending? 4 William & Mary Policy Review 319 (2013). Available at: <https://pdfs.semanticscholar.org/f604/1a0484c65c593525d0c07e040cf655697f2d.pdf>.

negotiated with Medicare Advantage plans because such rates are negotiated. Conversely, hospitals would not include payment rates that are not negotiated, such as rates set by certain healthcare programs that are directly government-financed, for example, those set by CMS for FFS Medicare. We indicated, however, that we believed the display of a non-negotiated rate (for example, display of a Medicare and Medicaid FFS rate for an item or service) in conjunction with the gross charge and the payer-specific negotiated charges for the same item or service could be informative for the public and that the proposals would not preclude hospitals from displaying them.

Finally, we proposed to codify the definition of “payer-specific negotiated charge” and “third party payer” at new 45 CFR 180.20. We invited public comment on our proposal to define a type of “standard charge” as a “payer-specific negotiated charge.” We also sought public comment on whether and how the release of such specific charge information could result in unintended consequences and on whether and how there may be different methods for making such information available to individuals who seek to understand what their out-of-pocket cost obligations may be in advance of receiving a healthcare service.

Comment: Many individual commenters and organizations, including patient/consumer advocates, IT and tool developers, medical associations, and small business plan entities, were strongly in favor of the release of payer-specific negotiated charges, indicating that such information is essential for individual decision-making. One commenter stated that the Administration’s goal to improve the value of care relies on the disclosure of negotiated rates.

By contrast, many commenters, including commenters from hospitals and large insurers, indicated that the release of gross charges or payer-specific negotiated charges would not be helpful or meaningful to consumers who want to know their individual out-of-pocket estimates. Many commenters noted that the release of gross and payer-negotiated charges is not sufficient by itself, highlighting consumers’ need for additional information (such as co-pay, deductible, etc.) to get an individualized out-of-pocket estimate. Several commenters stated their belief that identification of the payer was not necessary for negotiated charges to be useful to the public. Several commenters raised concern related to the potential for patient confusion over the posting of negotiated charges,

including if they try to determine how it impacts their financial obligation or over potential discrepancies between the amount the hospital makes public and the amount the insurer indicates to the patient in EOBs sent after the fact. Many commenters stated that they do not believe consumers will use this information.

Response: We appreciate the response from stakeholders who expressed support for our proposed definition of a type of standard charge as the payer-specific negotiated charge. We agree for the policy reasons indicated in the CY 2020 OPPTS/ASC proposed rule (84 FR 39579 through 39580) and by commenters that public disclosure of payer-specific negotiated charge (also known as negotiated rates) is essential for insured individuals’ decision-making. For the reasons we have indicated, we disagree with commenters who indicated that payer-specific negotiated charges are meaningless to consumers, but we do agree that a payer-specific negotiated charge does not, in isolation, provide a patient with an individualized out-of-pocket estimate. As explained in the GAO report we describe in section II.A. of this final rule, payer-specific negotiated charges are a critical piece of information necessary for patients to determine their potential out-of-pocket cost estimates in advance of a service. As explained in section II.D.1 of this final rule, EOBs are designed to communicate provider charges and resulting patient cost obligations, taking third party payer insurance into account, and the payer-specific negotiated charge is a standard and critical data point found on patient’s EOB. When a consumer has access to payer-specific negotiated charge information prior to receiving a healthcare service (instead of sometimes weeks or months after the fact when the EOB arrives), in combination with additional information from payers, it can help him or her determine potential out-of-pocket cost. Knowing a negotiated charge is also important because a growing number of insured healthcare consumers are finding that some services are more affordable when they elect to forego utilizing their health insurance product and, instead, pay out-of-pocket. We further agree that consumers may be able to get a general sense of the cost of healthcare services by viewing de-identified negotiated rates, and we address this issue in more detail in section II.D.4.d of this final rule. However, we believe that having hospitals disclose payer-specific negotiated charges would provide

consumers with more specific information for their particular circumstance and insurance plan.

We disagree that there will be confusing discrepancies between the posted hospital charges and the patient’s EOB because payer-specific negotiated rates are agreed upon, and, therefore, known in advance by both hospitals and third party payers. We suggest that hospitals access and review the rate sheets (also referred to as rate tables or fee schedules) that are typically included in the contracts hospitals have with third party payers in order to ensure the information they make public is consistent with their contracted rates.

Finally, based on the multitude of comments we received from patient advocates and individual consumers, we believe that patients will use the charge information that hospitals make public. Additionally, hospital charge information can inform shared decision-making and patient-centric referrals at the point of care. Recent research suggests that an increasing number of patients are seeking information from their providers about the anticipated costs of healthcare services. For example, in a recent national survey, a majority of patients, physicians, and employers are ready, or feel a responsibility, to have cost of healthcare conversations.⁶⁴ Such conversations depend on the availability of standard charge information.

Comment: Many commenters, including hospital associations and large insurers, questioned CMS’ legal authority to require disclosure of payer-specific negotiated charges. For example, many commenters believed that payer-specific negotiated rates are proprietary and requiring their disclosure would infringe upon intellectual property rights recognized by Congress through the Defend Trade Secrets Act of 2016 (DTSA).⁶⁵ A few commenters indicated that disclosure of payer-specific negotiated charges was likely limited under the Freedom of Information Act (FOIA). Commenters argued that the FOIA protects trade secrets and confidential commercial or financial information against broad public disclosure. These commenters further asserted that the requirement to disclose payer-specific negotiated charges would violate the First Amendment, and, therefore, compelling disclosure would be unconstitutional. Several commenters pointed out that

⁶⁴ University of Utah Health website, Let’s Talk About Money, <https://uofuhealth.utah.edu/value/lets-talk-about-money.php>.

⁶⁵ 18 U.S.C. 1836.

some contracts between hospitals and payers include non-disclosure clauses, prohibiting the hospital from disclosing the rates they negotiated with third party payers.

Response: We believe that we have authority to define “standard charges” to mean the regular rate established by the hospital for an item or service provided to a specific group of paying patients, and that one type of standard charges is payer-specific negotiated charges. As explained in section II.D.2 of this final rule, the term “standard charges” is not defined in either the SSA or the PHS Act. We are also not aware of any historical usage of the term by the industry, and note that its association with the rates in a hospital chargemaster appears to have originated with our guidelines that took effect on January 1, 2019. Additionally, we note that many stakeholders (including hospitals) have provided feedback that our current guidelines are neither sufficient to inform consumers (particularly those with insurance) what their charges for a hospital item or service will be, nor reflective of the financial liability that they will actually incur. We therefore concluded it would be reasonable to define payer-specific negotiated charges as a type of “standard charge.”

We do not believe that the payer-specific negotiated charges hospitals would be required to disclose are proprietary or would constitute trade secrets. To the contrary, this information is already generally disclosed to the public in a variety of ways, for example, through State databases and patient EOBs. For example, New Hampshire has released payer and provider specific negotiated rates in its state operated HealthCost database. Maine has also been releasing negotiated rate information for over a decade. Additionally, the rates are routinely available to patients through EOBs. As noted elsewhere, that presentation of both gross charges and payer-specific negotiated charges is consistent with the standard charges found in a patient’s EOBs that health insurance plans are required to provide to patients following a healthcare service. EOBs include such data points as: The type of service provided; the amount the hospital billed for the service (which we define as the gross charge for purposes of these requirements); any in-network discount an insured patient received (which we define as the payer-specific negotiated charge for purposes of these requirements); and the remaining amount owed out-of-pocket and any portion of that amount applied toward

the patient’s deductible. Additionally, negotiated rates are relatively easy to access, for example, by competitors in a local market, by price transparency vendors who use reverse engineering to determine negotiated rates for their tools, and by private entities that use crowdsourcing efforts to collect the standard charge information found on EOBs and display them online to assist the public in price shopping.⁶⁶

With respect to the Defend Trade Secrets Act of 2016, we do not believe it is applicable here, as it applies only to trade secrets that are “misappropriated,” which is defined by reference to, among other things, “improper means,” where there was a “duty to maintain the secrecy,” or “accident or mistake.” We do not believe any of the meanings of the term “misappropriation” under the Defend Trade Secrets Act apply to a circumstance where an agency rule requires disclosure of certain information. 18 U.S.C. 1836 *et seq.*

Finally, to the extent commenters intended to cite the Trade Secrets Act, we note that it applies only to disclosures “not authorized by law,” in contrast to the circumstance here, where this final rule requires disclosure of certain information. 18 U.S.C. 1905. We would also note that, as a threshold matter, the Trade Secrets Act contemplates disclosure by a federal actor (“an officer or employee of the United States or of any department or agency thereof . . .”), and not disclosures by private entities, as contemplated by this final rule.

Consistent with price transparency and economics research (discussed in section II.D.1 and elsewhere in this final rule), we believe that the disclosure of payer-specific negotiated charges would serve a greater public interest and that “concealing negotiated price information serves little purpose other than protecting dominant providers’ ability to charge above-market prices and insurers’ ability to avoid paying other providers those same elevated rates.”⁶⁷ For Maine, one State official indicated that “to date, there is no evidence that the release of [Maine Health Data Organization] claims data has resulted in an anticompetitive market. In fact, quite the opposite. Transparency is what fosters a

competitive market.”⁶⁸ Similarly, disclosure of claims data in New Hampshire has resulted in increased competition and reduced prices for healthcare services.⁶⁹ Additionally, even if a contract between a hospital and a payer contained a provision prohibiting the public disclosure of its terms, it is our understanding that such contracts typically include exceptions where a particular disclosure is required by Federal law.

With respect to FOIA, while Exemption 4 does protect confidential trade secrets or confidential commercial information, it does not apply to disclosures by private entities such as hospitals as contemplated by this rule.

Finally, requiring hospitals to make public standard charges is consistent with First Amendment jurisprudence. Rules, such as this one, that require certain factual commercial disclosures pass muster under the First Amendment where the disclosure advances a government interest and does not unduly burden speech. When the government requires accurate disclosures in the marketing of regulated products under appropriate circumstances, it does not infringe on protected First Amendment interests. As the United States Supreme Court recognized in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) and recently confirmed in *Nat’l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372, 2376 (2018) (“NIFLA”), required disclosures of factual, noncontroversial information in commercial speech may be subject to more deferential First Amendment scrutiny. Under the approach articulated in *Zauderer*, courts have upheld required disclosures of factual information in the realm of commercial speech where the disclosure requirement reasonably relates to a government interest and is not unjustified or unduly burdensome such that it would chill protected speech.⁷⁰ As further discussed below, and cited elsewhere in this final rule, the required disclosures here advance the

⁶⁶ Gudiksen KL, et al. *The Secret of Health Care Prices: Why Transparency Is in the Public Interest*. California Health Care Foundation. July 2019. Available at: <https://www.chcf.org/wp-content/uploads/2019/06/SecretHealthCarePrices.pdf>.

⁶⁹ Brown ZY. *Equilibrium Effects of Health Care Price Information*. *The Review of Economics and Statistics*. Published October 2019; 101:4, 699–712. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.

⁷⁰ See *Zauderer*, 471 U.S. at 651; *Milavetz v. United States*, 559 U.S. 229, 250, 252–53 (2010); *NIFLA*, 138 S. Ct. at 2376 (“[W]e do not question the legality of . . . purely factual and uncontroversial disclosures about commercial products.”).

⁶⁶ <https://clearhealthcosts.com/pricecheck-share-form/>.

⁶⁷ Catalyst for Payment Reform. “Report Card on State Price Transparency Laws,” July 2015. Available at: https://www.catalyze.org/wp-content/uploads/woocomerce_uploads/2017/04/2015-Report-Card-on-State-Price-Transparency-Laws.pdf.

government's substantial interest in providing consumers with factual price information to facilitate more informed health care decisions, as well as the government's substantial interest in lowering healthcare costs, as further discussed below.⁷¹ As discussed elsewhere in this final rule, each of the standard charges we have chosen specifically because they are relevant to a specific group of consumers. For example, the negotiated charges are directly relevant to patients covered by a payer's specific insurance product. We note that hospitals regularly use their payer-specific negotiated charges to determine insured patient out-of-pocket costs, and payer-specific negotiated charges are also regularly supplied to consumers on EOBs.

Furthermore, these disclosures would neither "drown[] out the [speaker's] own message" or "effectively rule[] out" a mode of communication.⁷² Indeed, the requirement to provide standard charge information is not unduly burdensome where, as here, the hospital has the ability to convey other information of its choosing in the remainder of the website and other interactions with the public.

Some comments assert that the rule should be evaluated under the intermediate scrutiny test for commercial speech articulated in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980). Under that test, agencies can regulate speech where the regulation advances a substantial government interest and the regulation is no more extensive than necessary to serve that interest. Although many of these comments failed to offer any explanation as to why the more deferential review under *Zauderer* would not apply, one comment asserted that the *Zauderer* test is limited to disclosures that appear in advertising. We disagree. "Although the Court in *Zauderer* may have referred repeatedly to advertising . . . , these references were contextual and not the sine qua non of *Zauderer's* reasoning. *Zauderer* did not base its holding on any notion of estoppel or equity, but on the lack of a significant constitutional interest in not disclosing factual and noncontroversial information to consumers." *CTIA—Wireless Ass'n v.*

⁷¹ See generally, *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 310 (1st Cir. 2005) (recognizing that the government interest in cost-effective health care justified disclosure of financial interests of pharmacy benefit managers); *N.Y. State Rest. Ass'n v. N.Y. City Bd. Of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (recognizing that the government interest in "promot[ing] informed consumer decision-making" justified posting of calories on menus in chain restaurants).

⁷² *NIFLA*, 138 S. Ct. at 2378.

City of Berkeley, 158 F. Supp. 3d 897, 903 (N.D. Cal. 2016), *aff'd*, 928 F.3d 832, 842 (9th Cir. 2019).

In any event, although we believe that *Zauderer* provides the appropriate framework for review, the rule also satisfies the elements of the *Central Hudson* test. The government interest here is clear. As discussed above, the required disclosures here advance the government's substantial interest in providing consumers with factual price information to facilitate more informed health care decisions. In addition, these disclosures advance the government's substantial interest in lowering healthcare costs. Healthcare costs continue to rise, and healthcare spending is projected to consume almost 20 percent of the economy by 2027.⁷³ Hospital spending accounts for a substantial share of overall healthcare spending, and hospital charges for similar procedures can vary significantly from hospital to hospital. It is well-documented that the lack of transparency in hospital prices is a barrier that prevents consumers from understanding what their financial liability will be for hospital items and services, and that lack of knowledge not only affects their ability to shop for value, but also gives them no ability to proactively make decisions that could impact that financial liability. Additionally, as discussed in section II.D.1, these rising costs impact the Medicare Trust Funds and the amount paid to hospitals by Medicare.

We note further that public comments received for this rule, healthcare consumers resoundingly expressed support for having access to hospital pricing information. This public sentiment is echoed in numerous studies and surveys show that consumers are concerned about the high cost of healthcare, want to be able to know prices prior to purchasing a healthcare service, and are frustrated by the lack of access to information on medical costs before receiving medical services.^{74 75 76 77 78} Employers are also

⁷³ CMS. National Health Expenditures Projections, 2018–2027: Forecast Summary. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf>.

⁷⁴ Sinha SL, et al. "The Demographics of Healthcare Price Transparency." Accenture Consulting, 2017. Available at: https://www.accenture.com/_acnmedia/pdf-69/accenture-health-the-demographics-of-healthcare-price-transparency-infographic.pdf.

⁷⁵ Foundation for Government Accountability. "Poll: Voters Want The Right To Shop For Health Care." January 29, 2018. Available at: <https://thefga.org/poll/right-to-shop-poll/>.

⁷⁶ Schleifer D, et al. "Still Searching: How People Use Health Care Price Information in the United

States." Public Agenda, April 2017. Available at: https://www.publicagenda.org/wp-content/uploads/2019/09/PublicAgenda_StillSearching_Brief_2017.pdf.

actively seeking healthcare pricing information for initiatives that drive reductions in healthcare costs^{79 80 81} and once they have access, they are able to drive healthcare value.⁸²

The rule is also narrowly tailored to achieve the government's interest because there is a direct connection between the disclosure of hospital standard charge information and reduced healthcare costs and increased patient satisfaction. As we have described elsewhere in this final rule, we believe the regulations we are establishing are an important first step in providing information to consumers to support their healthcare decision-making. Although some States have made progress in promoting price transparency, most State efforts fall short. Further, existing hospital initiatives to make public their gross charges are not sufficient to provide insured consumers with the information applicable to them. Specifically, insured consumers need to understand the rates third party payers have negotiated (payer-specific negotiated charges) on their behalf for hospital items and services. There is emerging evidence that when healthcare consumers use healthcare pricing information, cost savings results for both inpatient and outpatient care without sacrificing

States." Public Agenda, April 2017. Available at: https://www.publicagenda.org/wp-content/uploads/2019/09/PublicAgenda_StillSearching_Brief_2017.pdf.

⁷⁷ "News Reports about a Weakening Economy Impacting How Some Patients Seek Medical Treatment." TransUnion. September 17, 2019. Available at: <https://newsroom.transunion.com/news-reports-about-a-weakening-economy-impacting-how-some-patients-seek-medical-treatment/>.

⁷⁸ Shih YT, and Chien C. A review of cost communication in oncology: Patient attitude, provider acceptance, and outcome assessment. *Cancer*, 123: 928–39. Available at: <https://online.library.wiley.com/doi/full/10.1002/cncr.30423>.

⁷⁹ Livingston S. Setting the bar for hospital prices: NC aims to tie reimbursement to Medicare for state employees. *Modern Healthcare*. March 2, 2019. Available at: <https://www.modernhealthcare.com/hospitals/setting-bar-hospital-prices>.

⁸⁰ Prager E. Consumer Responsiveness to Simple Health Care Prices: Evidence from Tiered Hospital Networks. September 21, 2017. Available at: https://pdfs.semanticscholar.org/053e/218f13dcd7f21002c623268151918a708f0.pdf?_ga=2.190709035.1212076034.1563994376-1742025875.1563994376.

⁸¹ Wu S, et al. Price Transparency for MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition. *Health Affairs*. August 2014; 33(8). Available at: <https://doi.org/10.1377/hlthaff.2014.0168>.

⁸² Sachdev G, et al. Self-Insured Employers Are Using Price Transparency To Improve Contracting With Health Care Providers: The Indiana Experience. *Health Affairs*. October 7, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20191003.778513/full/>.

quality.^{83 84 85 86 87} Moreover, cost savings drive competition^{88 89} and create a ‘spillover’ effect benefitting all regional consumers.^{90 91 92} Additionally, providers are discovering that providing price estimates ahead of a healthcare service results in fewer billing-related complaints, decreased revenue losses for the provider, and overall increased patient satisfaction.^{93 94} Finally, we are not aware of any alternatives to the

⁸³ Robinson JC and Brown TT. Increases In Consumer Cost Sharing Redirect Patient Volumes And Reduce Hospital Prices For Orthopedic Surgery. *Health Affairs*. August 2013; 32(8). Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.0188>.

⁸⁴ Blase B. “How Price Transparency Would Revolutionize Healthcare.” *New York Post*. October 12, 2019. Available at: <https://nypost.com/2019/10/12/how-price-transparency-would-revolutionize-healthcare/>.

⁸⁵ Rhoads J. Right to Shop for Public Employees: How Health Care Incentives are Saving Money in Kentucky. Foundation for Government Accountability. March 8, 2019. Available at: <https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf>

⁸⁶ Lieber EMJ. “Does It Pay to Know Prices in Health Care?” *American Economic Journal*. 2017, 9(1): 154–179. Available at: <https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.20150124>.

⁸⁷ Whaley C, et al. “Association Between Availability of Health Service Prices and Payments for These Services.” *JAMA*. 2014; 312(16):1670–1676. Available at <https://jamanetwork.com/journals/jama/fullarticle/1917438>.

⁸⁸ Boynton A, and Robinson JC. Appropriate Use Of Reference Pricing Can Increase Value. *Health Affairs*. July 7, 2015. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20150707.049155/full/>.

⁸⁹ Wu S, et al. Price Transparency for MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition. *Health Affairs*. August 2014; 33(8). Available at: <https://doi.org/10.1377/hlthaff.2014.0168>.

⁹⁰ Brown ZY. Equilibrium Effects of Health Care Price Information. *The Review of Economics and Statistics*. Published October 2019; 101:4, 699–712. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.

⁹¹ Wu S, et al. Price Transparency for MRIs Increased Use Of Less Costly Providers And Triggered Provider Competition. *Health Affairs*. August 2014; 33(8). Available at: <https://doi.org/10.1377/hlthaff.2014.0168>.

⁹² Blase B. “How Price Transparency Would Revolutionize Healthcare.” *New York Post*. October 12, 2019. Available at: <https://nypost.com/2019/10/12/how-price-transparency-would-revolutionize-healthcare/>.

⁹³ Otero HJ, et al. The Cost-Estimation Department: A Step Toward Cost Transparency in Radiology. *JACR*. February 2019; 16(2): 194–95. Available at: [https://www.jacr.org/article/S1546-1440\(18\)30981-5/fulltext](https://www.jacr.org/article/S1546-1440(18)30981-5/fulltext).

⁹⁴ Hammer DC. “Adapting customer service to consumer-directed health care: by implementing new tools that provide greater transparency in billing, hospitals can decrease collection costs while improving consumer satisfaction.” *Healthcare Financial Management*. September 2006; 60(9). Available at: <https://go.galegroup.com/ps/anonymous?id=GALE%7CA151440927&sid=googleScholar&v=2.1&it=r&linkaccess=abs&issn=07350732&p=AONE&sw=w>.

policies in this final rule that would be as effective in achieving these results. As discussed above and elsewhere in this final rule, hospital chargemaster disclosures do not include the charges applicable to insured consumers; and relying on individual hospitals for voluntary disclosures may not allow consumers to make comparisons between hospitals or sufficiently drive competition or create “spillover” effects. Similarly, relying on state-by-state initiatives would only benefit consumers in some states.

Comment: Many commenters expressed confusion related to the term payer-specific negotiated charge, indicating that such a hospital charge does not exist, or that the term is in conflict with terminology used within the healthcare industry, such as “negotiated rates” or the “allowed amount.” Several commenters asserted that hospitals do not negotiate “payment rates,” “methodologies” or “allowed amounts” with third party payers. Additionally, many commenters suggested in general usage (and according to one commenter, as defined by *dictionary.com*), the definition of “standard” means “usual, common, or customary” and asserted that payer-specific negotiated charges are not usual, common, or customary because they vary from payer to payer.

Other commenters seemed to suggest that payer-specific charges could not be identified because, as one commenter noted, rates associated with DRGs can have three levels of payments based on the types of co-morbidities and can change based on change in a patient’s condition or treatment plan.

Response: As explained in the CY 2020 OPPTS/ASC proposed rule, we could not identify an existing definition of “standard charges,” nor do we believe that a single “standard charge” can be identified for purposes of implementing section 2718(e) of the PHS Act, since factors such as insured status and the particular third-party payer plan drive the hospital charges borne by consumers. Therefore, we proposed a new definition for “standard charges” (which can also be called “rates”) that could apply to certain identifiable groups of individuals—specifically, individuals that are self-pay and individuals that have third party payer coverage. Thus, the charges the hospital has negotiated with a specific payer for a hospital item or service are the standard charges that apply to consumers with a specific plan through a specific insurer—in other words, the rate is the usual or common rate for the members of that plan. Therefore, one type of “standard

charge” is the gross rate or charge found in the hospital chargemaster (which aligns with the PRM1’s definition of “charges”) while another “standard charge” is the charge or rate that the hospital has negotiated with a third party payer for an item or service.

When hospitals contract with a third party payer to be included in the plan’s network, the hospital and insurer agree to specific, often discounted, prices that will apply to items or services furnished by the hospital. Best practice according to healthcare financial management experts and revenue cycle managers dictates that these payer-specific negotiated charges should be included in hospital contracts and listed in associated rate sheets (also called rate tables or fee schedules). Rate sheets include a list of all hospital items and services for which the hospital and payer have established regular rates (for example, the payer-specific negotiated charges that apply to hospital items and services). Hospitals also routinely keep and maintain such rate sheets to police and validate their reimbursements from payers as part of their revenue management cycle, holding payers accountable for the rates they have negotiated with the hospital. Such rates tables are also used by hospitals to compare against benchmarks (such as Medicare FFS rates) to determine where it is advantageous to renegotiate for higher amounts at the next opportunity. The contracted rate, sometimes called the “negotiated rate,” “in-network amount,” “allowed charges” or “negotiated discount” can be significantly lower than what the hospital would charge an individual who did not have an insurance company negotiating discounts on his or her behalf, and this contracted rate is reflected in the patient’s EOB after the healthcare service has been provided. As such, we do not believe the term “payer-specific negotiated charges” conflicts with any particular defined industry term or with the term “charges” as defined by Medicare. We further clarify that the payer-specific negotiated charge is the charge the hospital has negotiated with a third party for an item or service and does not refer to the amount the hospital is ultimately paid by the insurer or patient for an item or service. We believe that it is unlikely such amounts could be considered hospital standard charges and that it would prove very difficult for a hospital to make such amounts public in advance, given that, as commenters point out, the actual paid amounts are dependent on information that the hospital does not have without

contacting the insurer to determine the specifics of the patient's obligations under the patient's contract with the insurer.

We note that the payer-specific negotiated charge for a DRG is the rate the hospital has negotiated for the DRG as a service package. We clarify that the requirement to make public the payer-specific negotiated charge for a DRG would mean the base rate that is negotiated by the hospital with the third party payer, and not the adjusted or final payment received by the hospital for a packaged service.

Comment: In response to CMS' request for comment on the potential unintended consequences of releasing payer-specific charge information, many commenters asserted such disclosure would be confusing or even harmful to patients. For example, many commenters raised patient-specific concerns that the policy would impact patients negatively by creating reliance on published rates when they could potentially be required to pay a higher out-of-pocket amount after the service, or could impact their health by confusing them or causing them to seek out cheaper care rather than the most effective or best quality care. One commenter expressed concern that display of payer-specific negotiated charges would shift the burden of understanding the costs of care from the hospitals/payers to consumers.

Response: We thank the commenters for their input. We continue to believe that the public posting of hospital standard charge information will be beneficial to healthcare consumers who need to obtain items and services from a hospital, healthcare consumers who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making referrals, and other members of the public who may develop consumer-friendly price transparency tools. This belief is supported by the many commenters who asserted the desire to have better access to, and understanding of, hospital charges. While we cannot discount the possibility that some consumers may find required hospital data disclosures confusing, we believe that the vast majority will find the increased availability of data, especially as it may be reformatted in consumer-friendly price transparency tools, overwhelmingly beneficial. Additionally as noted in section II.D.1 of this final rule, patients already receive this information in the form of EOBs, so we do not believe that advance notice of such standard charges would cause confusion beyond the confusion and frustration that currently exists for

lack of such knowledge as expressed by commenters who feel they are "flying blind." We also note that nothing in this final rule would prevent a hospital from engaging in patient education or otherwise assisting patients in understanding potential hospital charges in advance of receiving a hospital service, including articulating factors that may influence ultimate patient out-of-pocket costs or displaying quality information along with hospital charge information.

Moreover, we strongly disagree that the display of payer-specific negotiated charges would effect some shift from hospitals/payers to consumers of the burden of understanding the costs of care, and we pointedly note that research,⁹⁵ vast amounts of media reports,⁹⁶ as well as many commenters to the CY 2020 OPPS/ASC proposed rule make clear that consumers already bear, and are exceptionally frustrated at the lack of publicly available data to help ease, that burden. We believe that requiring disclosure of hospital standard charges is a necessary first step to begin to alleviate consumers' frustration in understanding their potential cost of care in advance of the receipt of services.

Finally, as noted by commenters, knowing the payer-specific negotiated charges can be highly beneficial for consumers in HDHPs and in plans where the consumer is responsible for a percentage (that is, co-insurance) of the negotiated rate. The most common coinsurance arrangement is 20/80 where the consumer is responsible for 20 percent of the payer-negotiated charges and the insurer covers the remaining 80 percent. Both HDHPs and co-pays are becoming more common^{97 98} and create a great deal of uncertainty for consumers who can't access the rates hospitals and insurers have negotiated.

⁹⁵ Aliferis L. Variation in Prices for Common Medical Tests and Procedures. *JAMA Intern Med.* 2015; 175(1):11–12. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/1935935>.

⁹⁶ CBS News, Medical Price Roulette: CBS News investigates the lack of transparency in America's health care system. September 20, 2019. Available at: <https://www.cbsnews.com/news/medical-price-roulette-cbs-news-investigates-the-lack-of-transparency-in-americas-health-care-system/>.

⁹⁷ Cohen RA, et al. Health Insurance Coverage: Early Release of Estimates From the National Health Interview Survey, January–March 2018. National Center For Health Statistics. Available at: <https://www.cdc.gov/nchs/data/nhis/earlyrelease/Insur201808.pdf>.

⁹⁸ Miller EG, et al. High-Deductible Health Plan Enrollment Increased From 2006 To 2016, Employer-Funded Accounts Grew In Largest Firms. *Health Affairs.* August 2018. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.0188>.

Comment: Many commenters cautioned that disclosure of payer-specific negotiated charges would increase, not decrease, healthcare costs in certain markets due to anticompetitive behaviors or increases in prices as a result of hospital knowledge of better rates negotiated by neighboring hospitals. Specifically, many commenters stated that disclosure of payer-specific negotiated charges could encourage price fixing and facilitate hospital collusion, causing prices to rise and thus harming consumers. Others raised concerns that publicly displaying insurer contract information would make it easier for insurers to circumvent antitrust safeguards, negatively affecting competition. Several commenters also argued that the inclusion of payer-specific negotiated charges as a standard charge would result in adverse market impacts on published rates and hamper hospitals' ability to negotiate fair and competitive payment rates with payers. One commenter more specifically argued that if all payer rates are disclosed, then every payer paying above the lowest rate would renegotiate to the lowest rate for every service, leaving hospitals with very little power to object. One commenter specifically suggested that CMS conduct a pilot study in only a few markets to determine the impact of the policy on negotiated prices before finalizing.

Response: As indicated in our literature review and Economic Analyses (84 FR 39630 through 84 FR 39634), we concluded that implementing our proposals, most of which we are finalizing in this final rule, would yield many benefits with particular benefits for consumers who we believe have a right to know the cost of hospital services before committing to them and to be able to shop for the best value care and for employers who purchase healthcare for their employees.

In general, our belief that accessible pricing information would reduce healthcare costs by encouraging providers to offer more competitive rates is consistent with predictions of standard economic theory.⁹⁹ Economists have long concluded that markets work best when consumer prices reflect the actual cost to create and deliver the product.¹⁰⁰ And a number of empirical

⁹⁹ CRS Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector. July 24, 2007. Available at: <https://fas.org/spp/crs/secretary/RL34101.pdf>.

¹⁰⁰ Murray R. Setting Hospital Rates to Control Costs and Boost Quality: The Maryland Experience.

studies on price transparency in other markets shows that transparency initiatives tend to lead to more consistent, lower prices.^{101 102} However, some economists do not believe that healthcare price transparency will prevent rising costs due to the unique characteristics of the healthcare market.¹⁰³

In our discussion of available research and market impacts (84 FR 39579 through 84 FR 39580), we took into account the potential for unintended consequences. Specifically, we noted that at minimum, our policy to require disclosure of payer-specific negotiated charges would release data necessary to better understand how the level of price dispersion in various healthcare markets impacts healthcare spending and consumer out-of-pocket costs. As noted in the CY 2020 OPPI/ASC proposed rule, negotiated charges for various procedures varies widely within and across geographic regions on the United States.¹⁰⁴ Some factors associated with the level of hospital price dispersion in a geographic area are the hospital's size, healthcare demand, labor costs, and technology, although it was the hospital's market power (level of competition) that was most positively associated with high price dispersion.^{105 106} One researcher found that variation in prices across hospital referral regions is the primary driver of variation in spending per enrollee for those privately insured, while the

quantity of care provided across hospital referral regions is the primary driver of variation in spending per beneficiary for Medicare.¹⁰⁷ One major barrier to fully understanding healthcare price variation (and understanding the impact of transparency of healthcare pricing in general) is the lack of availability of negotiated charges to researchers and the public.¹⁰⁸ We noted that our proposals would make hospital charge information available, which would generate a better understanding of (1) hospital price dispersion, and (2) the relationship between hospital price dispersion and healthcare spending. Understanding these relationships through release of pricing data could lead to downward price pressure on healthcare prices and reductions in overall spending system-wide, particularly in markets where there is insurer and hospital competition,¹⁰⁹ or to considerable spending reductions and reduction of price dispersion.¹¹⁰

In their comprehensive analysis of the impact of regulations across more than 30 States requiring public access to the prices of hospital procedures, some researchers found that regulations lowered the price of shoppable procedures such as hip replacements by approximately five percent overall compared to prices for non-shoppable procedures such as appendectomies. They further found that half of the observed price reduction in charges was due to hospitals lowering their prices to remain competitive. This was particularly true for high priced hospitals and for hospitals in competitive urban areas.¹¹¹ Research has also indicated that price transparency initiatives can decrease prices paid by consumers and insurers. One study found that following the introduction of a State-run website providing out-of-pocket costs for a subset of shoppable outpatient services reduced the charges for these

procedures by approximately 5 percent for consumers, in part by shifting demand to lower cost providers.¹¹² In addition, the study found that, following the introduction of the website, insurers over time experienced a 4-percent reduction in administrative costs for imaging services.

Another possibility we considered was that transparency in payer-specific negotiated charges could narrow the dispersion of prices in a market, meaning that knowledge of payer-specific charges may not only result in lowering prices for payers currently paying rates above the median, but could also increase prices for payers that are currently paying rates below the median. We considered whether making payer-specific negotiated prices public could risk disrupting the ability for certain payers to extract aggressive discounts in the future, especially from providers in markets with limited competition. For example, a hospital providing an aggressive discount to a particular payer may become motivated to withdraw such discount to avoid divulging such information to other payers with whom they contract.

Several studies of mandated price transparency in non-healthcare commodity markets have shown suppliers can use the information to their advantage in maximizing the prices they can charge in markets with limited competition or where commodities are not easily transferable across geographies.¹¹³ We noted that although there are no definitive conclusions on the effects of price transparency on markets, one study found that it can either increase or decrease prices depending on the strength of the bargainers and the size of the market.¹¹⁴ While price transparency gives buyers and sellers important information about the value of items and services, the effect may result in price increases by changing the incentives for buyers and sellers may also enable traders to observe deviations

Health Affairs. September/October 2009; 28(5). Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.28.5.1395>.

¹⁰¹ CRS Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector. July 24, 2007. Available at: <https://fas.org/spp/crs/secretary/RL34101.pdf>.

¹⁰² Kim M. The Effect of Hospital Price Transparency in Health Care Markets. 2011. Available at: <https://repository.upenn.edu/dissertations/AAI3475926/>.

¹⁰³ King JS, Muir MA, Alessi SA. Clarifying Costs Can Increase Price Transparency Reduce Healthcare Spending? 4 William & Mary Policy Review 319 (2013). Available at: <https://pdfs.semanticscholar.org/f604/1a0484c65c593525d0c07e040cf655697f2d.pdf>.

¹⁰⁴ Kennedy K, et al. Health Care Cost Institute. Past the Price Index: Exploring Actual Prices Paid for Specific Services by Metro Area. Healthy Marketplace Index. April 30, 2019. Available at: <https://www.healthcostinstitute.org/blog/entry/hmi-2019-service-prices>.

¹⁰⁵ Cooper Z, et al. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. *The Quarterly Journal of Economics*. December 2015. Available at: <https://pdfs.semanticscholar.org/cb9c/f90786cc39ddac6d88f3ba1074a7c2d5f0a5.pdf>.

¹⁰⁶ Bai G and Anderson GF. Market Power: Price Variation Among Commercial Insurers For Hospital Services. *Health Affairs*. Oct 2018; 37(10): 1615–1622. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0567>.

¹⁰⁷ Cooper Z, et al. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. *The Quarterly Journal of Economics*. December 2015. Available at: <https://pdfs.semanticscholar.org/cb9c/f90786cc39ddac6d88f3ba1074a7c2d5f0a5.pdf>.

¹⁰⁸ *Ibid*.

¹⁰⁹ Ho K and Lee RS. Insurer Competition and Negotiated Hospital Prices. August 2013. Available at: <https://pdfs.semanticscholar.org/b6e9/11d7e171d3074b473439f93d377f4a4202bf.pdf>.

¹¹⁰ Brown ZY. An Empirical Model of Price Transparency and Markups in Health Care. August 2019. Available at: http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf.

¹¹¹ Christensen HB, Floyd E, and Maffett M. "The Effects of Price Transparency Regulation on Prices in the Healthcare Industry." Available at: <https://www.bakerinstitute.org/media/files/event/01ce2e80/HPP-paper-AHEC-Floyd.pdf>.

¹¹² Brown ZY. Equilibrium Effects of Health Care Price Information. *The Review of Economics and Statistics*. Published October 2019; 101:4, 699–712. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.

¹¹³ See for example, Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector. July 24, 2007. Available at: <https://fas.org/spp/crs/secretary/RL34101.pdf>.

¹¹⁴ Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector. July 24, 2007. Available at: <https://fas.org/spp/crs/secretary/RL34101.pdf>.

from collusive practices. Allowing weaker bargainers to see prices negotiated by stronger bargainers will change incentives facing buyers and sellers, and can lead to price increases.

In the absence of a national model, we looked to two States that previously enacted price transparency laws, California and New Hampshire. California enacted a requirement for hospitals to post their CDM in 2004, and in 2003, New Hampshire created an all-payer claims database, later publishing the data in 2007 in a statewide, web-based price transparency comparison tool. Studies assessing the impact of the New Hampshire State law have found that the efforts focused on the wide variation of provider prices, which in turn created opportunities for new benefit design that incentivized consumer choice of lower costs providers and sites of service.¹¹⁵ In California, the link between hospital chargemaster data and patient cost was validated through a 10-year study of the chargemaster data which found that each dollar in a hospital's list price was associated with an additional 15 cents in payment to a hospital for privately insured patients (versus publicly insured patients).¹¹⁶ We indicated that this effort to improve the availability of charge data could open up the possibility to States to further regulate hospital charges—examples seen in both California and New Hampshire that took further legislative action to reduce price dispersion, reduce surprise billing and to place limits on charges for the uninsured and for out-of-network providers.

In addition to economic effects described above, we analyzed consumer impact and concluded that consumers may feel more satisfied with their care when they are empowered to make decisions about their treatment. A recent survey¹¹⁷ indicated a strong desire for price transparency and openness. Eighty-eight percent of the population polled, demanded improved

transparency with respect to their total financial responsibility, including co-pays and deductibles. Another study suggests that improving a patient's financial experience served as the biggest area to improve overall customer satisfaction.¹¹⁸ According to a 2011 GAO report, transparent healthcare price information may help consumers anticipate their healthcare costs, reduce the possibility of unexpected expenses, and make more informed choices about their care, including for both shoppable services as defined in this rule and other hospital items and services in both outpatient and inpatient settings.¹¹⁹

A large part of the literature on consumer use of price information comes from studies of price transparency tools, particularly those offered by third party payers and for shoppable services. Some studies of consumer use of price information through web-based tools, such as those offered by self-insured employers or plans, indicate that they may help consumers save money on shoppable services. One study examined consumer use of an employer-sponsored, private price transparency tool and its impact on claims payments for three common medical services: Laboratory tests; advanced imaging services; and clinician office visits.¹²⁰ That study found that those who used the tool had lower claims payments by approximately 14 percent for laboratory tests; 13 percent for advanced imaging services; and approximately 1 percent for office visits compared to those who did not use the tool. Another study found that those employed by a large corporation who used a healthcare price transparency tool were able to reduce their costs by 10 to 17 percent compared to nonusers.¹²¹ Those using the tool mainly searched for information on shoppable services and also tended to have more limited insurance coverage. However, one study of the use of price transparency tools by consumers with

an employer-based, high deductible health plan found that consumers' likely perception that higher price is a proxy for higher quality care may lead them to select higher-cost options.¹²² This study found a spending drop between 11.8 and 13.8 percent occurring across the spectrum of healthcare service categories at the health plan level; the majority of spending reductions were due to consumer quantity reductions across a broad range of services, including both high and low value care. Another study of the use of price transparency tools by consumers found that only 10 percent of consumers who were offered a tool with price information utilized it, and that there was a slight relative increase in their out-of-pocket health spending on outpatient services compared to the patient group that was not offered the tool.¹²³

Although we are not requiring that hospitals develop a price comparison tool, we encourage innovation in this area by making standard charges available in a machine-readable format to third-party tool developers as well as the general public. We continue to believe that the use of a third-party tool would enhance public access to pricing data, but we do not believe the absence of one would cause confusion among consumers on how to use the available standard charge data made public by the hospital because we are also proposing requirements for hospitals to make public their payer-specific charges for a set of shoppable services in a consumer-friendly manner. A large part of consumer buy-in and understanding may depend on providers' willingness and ability to make public, and to have conversations with consumers about, their standard charge data to allow for price comparison and decisions about upcoming medical treatment. As consumers' healthcare costs continue to rise, clinicians are in a unique position to discuss the financial impacts of healthcare decisions with their patients. One study found that patients will often choose services based on clinician referral rather than consideration of

¹¹⁵ Tu H, and Gourevitch R. California HealthCare Foundation and Robert Wood Johnson Foundation. Moving Markets, Lessons from the New Hampshire Price Transparency Experiment. April 2014. Available at: <https://www.chcf.org/wp-content/uploads/2017/12/PDF-MovingMarketsNewHampshire.pdf>.

¹¹⁶ Batty M and Ippolito B. Mystery Of The Chargemaster: Examining The Role Of Hospital List Prices In What Patients Actually Pay. *Health Affairs*. April, 2017; 36(4): 689–696. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0986>.

¹¹⁷ See Gruessner V. Consumer Satisfaction Dips When Payers Lack Price Transparency. *Private Payers News* (October 3, 2016). Available at: <https://healthpayerintelligence.com/news/consumer-satisfaction-dips-when-payers-lack-price-transparency>.

¹¹⁸ Experian Health, Improve the healthcare financial journey. *Patient Engagement* (June 21, 2018). Available at: <https://www.experian.com/blogs/healthcare/2018/06/healthcare-financial-journey/>.

¹¹⁹ Government Accountability Office. September 2011. Health Care Price Transparency: Meaningful Price Information Is Difficult for Consumers to Obtain Prior to Receiving Care. Available at: <https://www.gao.gov/assets/590/585400.pdf>.

¹²⁰ Whaley C, et al. "Association Between Availability of Health Service Prices and Payments for These Services." *JAMA*. 2014; 312(16):1670–1676. Available at <https://jamanetwork.com/journals/jama/fullarticle/1917438>.

¹²¹ Lieber EMJ. "Does It Pay to Know Prices in Health Care?" *American Economic Journal*. 2017, 9(1): 154–179. Available at: <https://pubs.aeaweb.org/doi/pdfplus/10.1257/pol.20150124>.

¹²² Brot-Goldberg ZC, et al. What Does a Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics. Cambridge, MA: National Bureau of Economic Research; Working Paper, October 2015. Available at: <https://www.nber.org/papers/w21632.pdf>.

¹²³ Desai S, et al. Association between availability of a price transparency tool and outpatient spending. *JAMA*. 2016;315(17):1874–1881. doi:10.1001/jama.2016.4288. Available at: <https://jamanetwork.com/journals/jama/fullarticle/2518264>.

cost.¹²⁴ We believe that the pricing information made available as a result of this final rule will help ensure that clinicians have relevant pricing data to counsel patients on financial options. A systematic review found that clinicians and their patients believe communication about healthcare costs is important and that they have the potential to influence health and financial outcomes, but that discussions between clinicians and patients about costs are not common,¹²⁵ even though a majority of patients and physicians express a desire to have such cost-of-care conversations.¹²⁶ In our review, we found evidence that physicians were open to having these conversations, and that they were occurring more frequently, but providers have also identified the need for price information as a barrier to discussing costs with patients.¹²⁷ ¹²⁸ In addition, a literature review of 18 studies measuring the effects of charge display on cost and practice patterns found that having prospective access to prices for radiology and laboratory services changed physician's ordering behavior, and in 7 of the 9 studies on cost reported statistically significant cost reduction when charges were displayed.¹²⁹

Employers can also benefit from transparency in provider pricing and disclosure of payer-specific negotiated charges in particular. Some employers are seeking and implementing innovative ways using transparency in healthcare pricing to reduce healthcare costs and are using healthcare pricing

information effectively to do so.¹³⁰ Some employers, particularly self-insured employers, are using knowledge of payer-specific negotiated charges in their discussions with providers and health plans to drive referrals to high value care settings which is driving down the cost of healthcare for both employer and employee. For example, self-insured employers in Indiana are effectively using knowledge of hospital charges to improve contracting with providers.¹³¹ ¹³² Additionally, based on our review of economics research, we believe the healthcare market will become more effective and efficient as a result of transparency in healthcare pricing. For example, one study found that when the State of California adopted a reference pricing model for their employees, usage of lower priced facilities increased by 9 to 14 percent and facilities in California responded by reducing their prices by 17 to 21 percent.¹³³ The California and the New Hampshire initiatives (described earlier) were both demonstrated to produce "spillover" effects, meaning that changing market prices as a result of consumer shopping benefited even those who were not actively shopping.¹³⁴

In summary, we concluded that transparency in pricing is necessary and can be effective to help bring down the cost of healthcare services, reduce price dispersion, and benefit consumers of healthcare services, including patients and employers. In light of this, we do not believe additional testing needs to be done prior to finalizing this rule. We further note that the federal government has laws and processes to investigate and act when entities engage in collusive or other anticompetitive practices.

Comment: Many commenters indicated that it would be a challenge and burden for hospitals to access and display their payer-specific negotiated charges. For example, many commenters asserted that such information is either "non-existent" (specifically that it does not exist in hospital accounting systems) or is not available to be reported by hospitals without significant manual effort, while several others indicated that consumers should pursue information on out-of-pocket obligations from insurers as opposed to hospitals. Several others indicated that the data is not available electronically and would require manual entry or require hospitals to purchase prohibitively expensive software. Several commenters stated that charges on the chargemaster are not always associated with negotiated charges due to billing complexities such as per diem rates and bundled payment arrangements and that the CY 2020 OPPI/ASC proposed rule relied on the mistaken assumption that payer-specific rates can be expressed in a static matrix. One commenter explained that hospital managed care agreements do not typically set forth simple dollar amounts for each service; instead, they specify payment methodologies, which are in essence negotiated payment algorithms rather than static matrices. The commenter also noted that the appropriate payment amount for a particular service package cannot be calculated until the delivery of care, and the assignment of any dollar amount prior to the delivery of care would risk overstating or understating the applicable payment amount for that case.

Response: As noted above, hospital payer-specific negotiated charges or rates can be found within the in-network contracts that hospitals have signed with third party payers. Such contracts often include rates sheets that contain a list of hospital items and services (including service packages) and the corresponding negotiated rates. If the rate sheets are not in electronic form, we suggest that the hospital request an electronic copy of their contract and corresponding rate sheet from the third party payer. Additionally, we note that we are concurrently issuing a proposed rule entitled Transparency in Coverage (file code CMS-9915-P) that would require most issuers of individual and group market health insurance and group health plans to make public, in an electronic machine-readable format, negotiated rate and unique out-of-network allowed amount information that hospitals, including

¹²⁴ Chernew M, et al. "Are Health Care Services Shoppable? Evidence from the Consumption of Lower-Limb MRI Scans." National Bureau of Economic Research, Working Paper No. 24869. Issued July 2018, revised January 2019. Available at: <https://www.nber.org/papers/w24869>.

¹²⁵ Meluch AL, and Oglesby WH. (2015). Physician-patient communication regarding patients' healthcare costs in the US: A systematic review of the literature. *Journal of Communication in Healthcare*, 8(2), 151-160. Available at: <https://www.tandfonline.com/doi/full/10.1179/1753807615Y.0000000010?scroll=top&needAccess=true>.

¹²⁶ University of Utah: The State of Value in U.S. Healthcare. Available at: <https://uofuhealth.utah.edu/value/>.

¹²⁷ Schiavoni KH, et al. How Primary Care Physicians Integrate Price Information into Clinical Decision-Making. *J Gen Intern Medicine*. 2017 January; 32(1): 81-87. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5215149/>.

¹²⁸ Alexander GC, et al. Barriers to Patient-physician Communication About Out-of-pocket Costs. *J Gen Intern Med*. 2004 August; 19(8): 856-860. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1492500/>.

¹²⁹ Goetz C, et al. The effect of charge display on cost of care and physician practice behaviors: a systematic review. *Journal Gen Intern Med*. 2015 Jun; 30(6):835-42. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25691240>.

¹³⁰ Woods L, et al. Employers are fixing health care. *Harvard Business Review*. March 2019. Available at: <https://hbr.org/cover-story/2019/03/how-employers-are-fixing-health-care>.

¹³¹ Sachdev G. Using RAND 2.0 Hospital Pricing Report to Achieve High Value. Employers' Forum of Indiana. July 31, 2019. Available at: <https://employersforumindiana.org/media/2019/07/Using-RAND-2.0-Hospital-Prices-to-Achieve-Value-presented-by-Gloria-Sachdev-7-31-19.pdf>.

¹³² Sachdev G, et al. Self-Insured Employers Are Using Price Transparency To Improve Contracting With Health Care Providers: The Indiana Experience. *Health Affairs*. October 7, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20191003.778513/full>

¹³³ Robinson JC and Brown TT. Increases In Consumer Cost Sharing Redirect Patient Volumes And Reduce Hospital Prices For Orthopedic Surgery. *Health Affairs*. August 2013; 32(8). Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.0188>.

¹³⁴ Blase B. Transparent Prices Will Help Consumers and Employers Reduce Health Spending. Galen Institute. September 27, 2019. Available at: https://galen.org/assets/Blase_Transparency_Paper_092719.pdf.

CAHs, and others could use. Access to these data may be a benefit to less resourced hospitals which indicated that payers may take advantage of small hospitals that don't diligently maintain their contracts or contracted rates.

We agree that payer-specific negotiated charges are not found in a hospital's chargemaster because such charges are typically found in other parts of the hospital's billing and accounting systems or in their payer contracts. We also agree that such charges are often negotiated for service packages rather than for individualized items and services as listed in the hospital chargemaster, and that negotiated contracts often include methodologies that would apply to payment rates, often leading to payments to hospitals that are different than the base rates negotiated with insurers for hospital items and services. However, we do not agree that these issues represent barriers to making public payer-specific negotiated charges because as clarified above, the negotiated rates we are requiring to be made public are the base rates, not the payment received. Additionally, we offer suggestions for developing the comprehensive machine-readable file in section II.E of this final rule and the display of payer-specific charges for the set of shoppable services in a low-cost consumer-friendly format in section II.F of this final rule.

Finally, we recognize that some hospitals may have negotiated charges with many payers representing hundreds of plans. We believe the burden to hospitals for making public all payer-specific negotiated charges is outweighed by the public's need for access to such information. However, after consideration of the comments received, we are responding to concerns about burden by finalizing a policy to delay the effective date of these final rules to January 1, 2021 (see section II.G.3 of this final rule for more details). We believe that by extending this final rule effective date, hospitals will have sufficient time to collect and display the standard charge information as required under this rule. Additionally, we are finalizing a policy to regard hospitals that offer internet-based price estimator tools as having met the requirements for making public their consumer-friendly list of shoppable services (section II.F.5 of this final rule) which will relieve some burden for hospitals that are already displaying consumer-friendly charge information.

Comment: Several commenters specifically noted that although the CY 2020 OPPS/ASC proposed rule exempts the publication of Medicaid FFS

arrangements, payer-specific negotiated charges would include Medicaid managed care organizations (MCOs) and the information published would have little value to Medicaid beneficiaries since their out-of-pocket obligations are limited by federal and state cost-sharing requirements and the information may intimidate families from seeking necessary care due to the confusion caused by the charges.

Response: Under this final rule, hospitals would be required to make public their standard charges for payer-specific negotiated charges. As noted by commenters and as we explained in the proposed rule, such payer-specific negotiated charges would not include non-negotiated payment rates (such as those payment rates for FFS Medicare or Medicaid). However, hospitals will be required to make public the payer-specific negotiated charges that they have negotiated with third party payers, including charges negotiated by third party payer managed care plans such as Medicare Advantage plans, Medicaid MCOs, and other Medicaid managed care plans. Based on research cited previously, as well as patient and patient advocate comments, we disagree that the display of payer-specific negotiated rates will have little value to individuals enrolled in Medicaid MCOs or other Medicaid managed care plans in which third parties negotiate charges with hospitals. We believe that all consumers, including, for example, beneficiaries enrolled in Medicaid MCOs, should have the advantage of a full line of sight into their healthcare pricing. We are therefore finalizing as proposed our definition of payer-specific negotiated charges which would include Medicare and Medicaid plans managed by third party payers who negotiate charges with providers.

Final Action: We are finalizing as proposed a definition of payer-specific negotiated charge as a type of standard charge at new 45 CFR 180.20 to mean the charge that a hospital has negotiated with a third party payer for an item or service. We are also finalizing as proposed a definition of "third party payer" for purposes of section 2718(e) of the PHS Act as an entity that, by statute, contract, or agreement, is legally responsible for payment of a claim for a healthcare item or service.

4. Alternative Definitions for Types of Standard Charges That We Considered

In addition to the two types of standard charges (gross charges and payer-specific negotiated charges) that we proposed and are finalizing for purposes of section 2718(e) of the PHS Act, we sought public comment on

whether we should instead, or additionally, require the disclosure of other types of charges as standard charges. We considered several alternatives for types of standard charges related to groups of individuals with third party payer coverage and also for types of standard charges that could be useful to groups of individuals who are self-pay.

a. Volume-Driven Negotiated Charge

As a variant of the definition of the "payer-specific negotiated charge," we considered defining a type of "standard charge" based on the volume of patients to whom the hospital applies the standard charge. Specifically, we considered defining a type of "standard charge" as the "modal negotiated charge." The mode of a distribution represents the number that occurs most frequently in a set of numbers. Here, we considered defining "modal negotiated charge" as the most frequently charged rate across all rates the hospital has negotiated with third party payers for an item or service. We indicated that we believed that this definition could provide a useful and reasonable proxy for payer-specific negotiated charges and decrease burden for the amount of data the hospital would have to make public and display in a consumer-friendly format. We sought public comment on whether the modal negotiated charge would be as informative to consumers with insurance and whether it should be required as an alternative or in addition to the payer-specific negotiated charges.

Comment: A few commenters supported volume-driven negotiated charges, such as the modal-negotiated charge, or a similar variation of such a charge based on volume, as a type of standard charge, stating that hospitals should publish chargemaster and negotiated amounts based on the billing volume. One commenter noted that developing and communicating a volume-driven average charge could be challenging, given that hospitals and insurers often negotiate charges for non-standardized bundled services and service packages. A few commenters disagreed with further defining negotiated charges based on volume, stating that they believe the information would be both incorrect and confusing to consumers and onerous for hospitals required to report the information. Additionally, one commenter strongly objected to use of a volume-driven charge, stating that they believe such an alternative standard charge would perpetuate the idea that insurers have been able to drive prices lower based on volume-driven negotiations.

Response: After consideration of the comments received, we agree with the commenters who stated that volume-driven charge information could be confusing to consumers, and we believe it is less useful than the types of standard charges we are finalizing. Because the modal negotiated rate, or similar volume-driven variations, would combine rates the hospital has negotiated with all third party payers for all items or services and weigh that number based on the volume of patients (a number unknown to the public), we agree it could be misleading for consumers who are trying to combine the volume-driven rate with their specific benefit information to determine their potential out-of-pocket obligations in advance, as it does not represent what their specific payer has negotiated. This type of standard charge may have utility in certain circumstances, however, after consideration of the public comments we received, we are not defining “modal negotiated charges” as a type of volume-driven “standard charge” at this time.

b. All Allowed Charges

We also considered defining a type of “standard charge” as the charges for all items and services for all third party payer plans and products, including charges that are non-negotiated (such as FFS Medicare rates), which we would call “all allowed charges.” As we explained in the CY 2020 OPPTS/ASC proposed rule, this option would have required hospitals to provide the broadest set of charge information for all individuals with health insurance coverage because it would have the advantage of including all identified third party payer charges (including third party payer rates that are not negotiated). Additionally, every consumer would have access to charge information specific to his or her insurance plan. We considered, but did not propose, this alternative because we stated we believed consumers with non-negotiated healthcare coverage already have adequate and centralized access to non-negotiated charges for hospital items and services and are largely protected from out-of-pocket costs which may make them less sensitive to price shopping. However, we sought public comment on whether increasing the data hospital would be required to make public would pose a burden, particularly for smaller or rural hospitals that may not keep such data electronically available.

Comment: We received a few comments related to all allowed charges. One commenter supported the inclusion of the “Medicare allowable”

charge in particular as a type of standard charge in order to provide a meaningful benchmark using existing data. One commenter objected to including all allowed charges as a type of standard charges due to their belief that consumers whose insurance plans are non-negotiated already have access to the information that would be required.

Response: We agree with commenters who indicated there is no need to include all allowed charges because the allowed amounts of plans that are not negotiated (for example, FFS Medicare and Medicaid) are already publicly disclosed. Moreover, such publicly disclosed allowed amounts make a benchmark available to those who wish to use it; nothing in this final rule would prevent a hospital or third party payer from displaying a Medicare FFS rate as a benchmark. However, we believe it would be redundant to require hospitals to re-disclose already public rates and create an unnecessary burden. After consideration of the public comments we received, we are not finalizing a requirement for hospitals to re-disclose “all allowed charges” at this time.

c. Definition of Discounted Cash Price as a Type of “Standard Charge”

As discussed in the CY 2020 OPPTS/ASC proposed rule (84 FR 39577 through 39579), hospital gross charge information may be most directly relevant to a group of self-pay consumers who do not have third party payer insurance coverage or who seek care out-of-network. Such consumers would not need information in addition to hospital gross charges in order to determine their potential out-of-pocket cost obligations because the gross charge would represent the totality of their out-of-pocket cost estimate. However, stakeholders have indicated that hospitals often offer discounts off the gross charge or make other concessions to individuals who are self-pay. Thus, we considered defining a type of “standard charge” as the “discounted cash price,” defined as the price the hospital would charge individuals who pay cash (or cash equivalent) for an individual item or service or service package. We considered this alternative definition because there are many consumers who pay in cash (or cash equivalent) for hospital items and services.

As we explained in the CY 2020 OPPTS/ASC proposed rule, the first subgroup of self-pay consumers that we believed could benefit from knowing the discount cash price would be those who are uninsured. The number of

uninsured individuals in the United States rose to 27.4 million in 2017.¹³⁵ These individuals’ need for hospital price transparency differs from patients with insurance who generally are otherwise shielded from the full cost of hospitalization and hospital items and services. Uninsured individuals do not have the advantage of having access to a discounted group rate that has been negotiated by a third party payer. Therefore, individuals without insurance may face higher out-of-pocket costs for healthcare services.

The second subgroup of self-pay consumers we indicated may benefit from knowing the discounted cash price are those who may have some healthcare coverage but who still bear the full cost of at least certain healthcare services. For example, these may be individuals who: Have insurance but who go out of network; have exceeded their insurance coverage limits; have high deductible plans but have not yet met their deductible; prefer to pay through a health savings account or similar vehicle; or seek non-covered and/or elective items or services. We noted that many hospitals offer discounts to these groups of individuals, either as a flat percentage discount off the chargemaster rate or at the insurer’s negotiated rate, while some hospitals offer consumers a cash discount if they pay in full on the day of the service.¹³⁶ Other hospitals have developed and offer standardized cash prices for service packages for certain segments of the population that traditionally pay in cash for healthcare services.¹³⁷ We recognized that currently, it is difficult for most consumers to determine in advance of receiving a service what discount(s) the hospital may offer an individual because cash and financial need discounts and policies can vary widely among hospitals.

We therefore specifically considered an option that would require hospitals to make public the cash discount that would apply for shoppable services and service packages that would include all ancillary services, similar to our proposals for consumer-friendly display

¹³⁵ Kaiser Family Foundation. The Number of Uninsured People Rose in 2017, Reversing Some of the Coverage Gains Under the Affordable Care Act. December 2018. Available at: <https://www.kff.org/uninsured/press-release/the-number-of-uninsured-people-rose-in-2017-reversing-some-of-the-coverage-gains-under-the-affordable-care-act/>.

¹³⁶ Beck M. How to Cut Your Health-Care Bill: Pay Cash. *The Wall Street Journal*. February 15, 2016. Available at: <https://www.wsj.com/articles/how-to-cut-your-health-care-bill-pay-cash-1455592277>.

¹³⁷ Hempstead K and White C. Plain Talk about Price Transparency. *Health Affairs*. March 25, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20190319.99794/full/>.

of payer-specific negotiated charges (84 FR 39585 through 39591). In this case, the discounted cash price would represent the amount a hospital would accept as payment in full for the shoppable service package from an individual. Such charges could be lower than the rate the hospital negotiates with third party payers because it would not require many of the administrative functions that exist for hospitals to seek payment from third party payers (for example, prior authorization and billing functions). However, we recognized that many hospitals have not determined or maintain, a standard cash discount that would apply uniformly to all self-pay consumers for each of the items and services provided by the hospital or for service packages, unlike they do for negotiated charges. We sought comment on this option, specifically, how many shoppable services for which it would be reasonable to require hospitals to develop and maintain, and make public a discounted cash price.

In addition, in the CY 2020 OPPI/ASC proposed rule we noted that many hospitals offer cash discounts on a sliding scale according to financial need. In such instances, we acknowledged that it may be difficult for a hospital to establish and make public a single standardized cash rate for such groups of consumers. For this reason, we also considered a different definition that would take sliding scale cash discounts into account by defining a standard charge as the median cash price. The median cash price would be the midpoint of all cash discounts offered to consumers, including prices for self-pay patients and those qualifying for financial assistance. We indicated that for uninsured patients who may qualify for financial assistance, the value of making a median cash price public could raise awareness of their available options, including the ability to apply for financial assistance, however, we also stated that we believed such a rate would be less useful to the public than a single standard cash price that the hospital would accept as payment in full as discussed above.

Comment: Many commenters, including individual consumers, patient advocates, clinicians, and insurers, strongly supported including a definition of standard charges to reflect the discounted cash price that would be offered to a self-pay consumer because they believe this information would be beneficial and relevant to consumers, including consumers with third party payer coverage. A few commenters suggested that CMS redefine this type of “standard charge” as hospital walk-in

rates, meaning the rates a hospital will typically charge to a patient without insurance, and one commenter suggested that hospitals post the “Amounts Generally Billed,” an IRS-defined term for the maximum amount individuals under a hospital’s financial assistance plan would pay.

By contrast, several commenters, mostly hospital representatives, disagreed with defining standard charges as the discounted cash price due to their belief that the cash price is often reflective of after-the-fact charity discounts due to the patient’s inability to pay or as a result of lack of insurance. One commenter disagreed with defining a cash rate as a type of standard charge because they believe CMS cannot require or force hospitals to have discounted cash prices, and therefore cannot require their disclosure.

Response: We thank the commenters for their strong support and their input on the utility of the discounted cash price for all consumers. We considered this alternative definition because there are many consumers who may wish to pay in cash (or cash equivalent) for hospital items and services, whether insured or uninsured, for a variety of reasons. We agree with commenters who indicated that the discounted cash price is important for many self-pay consumers. Many hospitals have already developed and offer standardized cash prices for service packages for certain segments of the population who traditionally pay in cash for healthcare services and who pay cash (or cash equivalent) in advance of receiving a healthcare service.¹³⁸ Such prices and services are typically offered as a consumer-friendly packaged service that negates the need for hospitals to expend administrative time and resources billing third party payers and resubmitting charges when payment is denied.¹³⁹ Moreover, we agree with commenters who indicated that up-front knowledge of pricing can increase patient satisfaction and reduce bad debt and could help mitigate “surprise billing.”

As discussed in the CY 2020 OPPI/ASC proposed rule, we made a distinction between the discounted cash price (the price a hospital agrees to accept from a self-pay consumer as payment in full) versus a median cash

price that would take into account any and all cash prices accepted by hospitals, including cash payments accepted following sliding scale discounts as a result of charity care. We clarify that the “discounted cash price” would reflect the discounted rate published by the hospital, unrelated to any charity care or bill forgiveness that a hospital may choose or be required to apply to a particular individual’s bill. Thus, the discounted cash price is a standard charge offered by the hospital to a group of individuals who are self-pay. The discounted cash price may be generally analogous to the “walk-in” rate referred to by commenters, however, we do not want to take a position as to whether it is the same as the cash discount price because the cash discounted price would apply to all self-pay individuals, regardless of insurance status.

We are therefore finalizing a definition of discounted cash price as a type of standard charge. We note that we agree with commenters who indicate that some hospitals may not have determined a discounted cash price for self-pay consumers. For some hospitals, the cash price is the undiscounted gross charges as reflected in the hospital chargemaster as previously discussed. In that case, under our definition of discounted cash price, the hospital’s discounted cash price would simply be its gross charges as reflected in the chargemaster.

Final Action: We are finalizing the definition of discounted cash price that we discussed in the CY 2020 OPPI/ASC proposed rule. Specifically, we are finalizing a definition of cash discounted price to mean the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service. Hospitals that do not offer self-pay discounts may display the hospital’s undiscounted gross charges as found in the hospital chargemaster. We are finalizing this definition at 45 CFR 180.20.

d. Definitions of “De-Identified Minimum Negotiated Charge” and “De-Identified Maximum Negotiated Charge” as Two Types of Standard Charges

In the CY 2020 OPPI/ASC proposed rule, we also considered defining a type of “standard charge” as the de-identified minimum, median, and maximum negotiated charge. Under this definition, the hospital would be required to make public the lowest, median, and highest charges of the distribution of all negotiated charges across all third party payer plans and products. We indicated that this

¹³⁸ Hempstead K and White C. Plain Talk about Price Transparency. *Health Affairs*. March 25, 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20190319.99794/full/>.

¹³⁹ Bai G, et al. Providing Useful Hospital Pricing Information To Patients: Lessons From Voluntary Price Disclosure. *Health Affairs*. April 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20190416.853636/full/>.

information could provide healthcare consumers with an estimate of what a hospital may charge, because it conveys the range of charges negotiated by all third party payers. We also indicated that as a replacement for the payer-specific negotiated charge, this definition had the advantage of lowering reporting burden and could relieve some concerns by stakeholders related to the potential for increased healthcare costs in some markets as a result of the disclosure of third party payer negotiated charges. At the time, we did not propose to define the de-identified minimum, median, and maximum negotiated charges as types of standard charges because we believed the payer-specific negotiated charges would provide much more useful and specific information for consumers. However, we sought comment on this issue as an alternative type of standard charge.

Comment: Many commenters supported a definition of standard charges to require hospitals to post a de-identified range of negotiated rates, including the minimum, median, and maximum negotiated rates or all-inclusive range, quartiles or a median range (that is, the 25th and 75th percentile or the 25th through the 75th percentiles), another specific percentile within the range of negotiated charges, “usual and customary” (which are based on a regional percentile), or average rate. Commenters supported these alternatives in addition to payer-specific negotiated charges because they believe de-identified negotiated rate information would be relevant and beneficial to consumers. Commenters noted that many consumer-facing price transparency tools display the minimum and maximum negotiated charges for healthcare services already, or display regional average charges. One commenter stated that providing such alternative charges in addition to providing the payer-specific negotiated charges can be helpful as it provides a “meaningful anchor” for the patient when they are comparing options. Other commenters echoed this sentiment, indicating that such charges, in addition to payer-specific negotiated charges, are useful for consumers such as patients and employers.

Several commenters indicated they believed these types of standard charges could provide a suitable substitute for the payer-specific negotiated charges. A few commenters indicated that the substitution could protect the identification of individual payers in smaller markets which they said would reduce any legal or market risk that could be associated with compelling the release of negotiated rates, although one

commenter expressed concern that display of a de-identified maximum may have an adverse effect on the ability to negotiate lower rates. By contrast, patient advocates and consumers strongly opposed the substitution of any type of de-identified negotiated charge, stating such charges would provide a far less accurate indicator of a patient’s potential financial obligations compared to knowledge of the consumer’s own payer-specific negotiated charges. For example, one commenter said that substitution for payer-specific negotiated charges for a more general or informational charge may leave patients feeling misled and delays the country from moving closer to a patient-focused system. Another indicated that limiting standard charge information to a median or range would reduce utility of the information and serve to frustrate innovators who seek to provide consumers with an unbiased view of provider cost and quality.

Several commenters specifically indicated that a range (for example, the minimum and maximum negotiated charges) of de-identified charges would be useful to the public because it would make it easier for consumers to quickly understand the range of prices across all insurance plans that might apply. One commenter noted that requiring hospitals to make public a range instead of all payer-specific negotiated charges would not likely reduce burden.

Additionally, a few commenters recommended the use of regional or market averages or median rates, or the “usual and customary” which stated that displaying a market (not hospital) median, or the “usual and customary” which is defined by the National Council of Insurance Legislators (NCIL) as the 80th percentile of physician charges in a geographic region based on an independent unbiased benchmarking charge database. One commenter noted that such rates would serve as a basic benchmark for vendors and prevent the prices paid by insurers from being known.

A few commenters, however, disagreed with defining a standard charge based on the hospital’s minimum, median, and maximum negotiated rate (or a variation of these) due to their belief that this data would be of limited value or not be beneficial to consumers and may cause confusion. One commenter specifically requested that the median cash price not be finalized as a type of standard charge.

Response: We thank commenters for their support and innovative suggestions on variations of the potential definition of a type of

“standard charge” as the de-identified minimum, median, and maximum negotiated charge. We agree with commenters that information related to several types of de-identified negotiated rates could be useful and beneficial to consumers in conjunction with payer-specific negotiated charges, together as a range, or as separate types of standard charges.

First, we agree with commenters who suggested that the de-identified minimum negotiated charge and the de-identified maximum negotiated charge could each provide a benchmark for determining the value of a hospital item or service for referring providers or employers. For example, for a consumer with insurance who is obligated to pay a percentage of the negotiated charge, knowing the maximum would be more helpful and informative than not having any reference point at all and would relieve consumers of the fear and uncertainty due to the lack of knowledge. Disclosure of the minimum de-identified negotiated charge by itself could also provide a benchmark that could have an impact on market forces, as some commenters suggested. Therefore, we believe that each value, independent of the other, could be helpful in providing some standard hospital charge information to consumers.

We further agree with commenters who asserted that knowing both the minimum and the maximum (that is, the range) of negotiated rates could benefit consumers. As noted by commenters, many consumer facing pricing tools make use of ranges in their displays. For example, consumers without third party payer coverage could use the range to negotiate a charge with the hospital that is more reasonable than the gross charges a hospital might otherwise bill them. The range would also be useful for consumers with insurance, for example, someone obligated to pay a percentage of the negotiated rate would be able to determine both their minimum and maximum financial obligation for an item or service to compare across hospital settings.

Finally, however, we agree with commenters who indicated that the most beneficial hospital standard charge information for consumers (including patients and employers) would include requiring disclosure of payer-specific negotiated charges along with disclosure of the de-identified minimum negotiated charges and de-identified maximum negotiated charges. We agree with commenters who indicated that this set of information, taken together, can provide consumers with an even more complete picture of hospital

standard charges and drive value. For example, by knowing one's payer-specific negotiated charges in addition to the minimum and maximum negotiated charges for a hospital item or service, consumers with third party payer coverage could determine whether their insurer has negotiated well on their behalf by assessing where their payer-specific negotiated charge falls along the range. Such information would serve to promote value choices in obtaining a healthcare services, and may also promote value choices in obtaining a healthcare insurance product. Additionally, we agree with commenters that presenting such information aligns with current consumer-friendly tools and displays and supports innovation.

We are therefore finalizing with modification to define a fourth type of standard charge as the "de-identified minimum negotiated charge" to mean the lowest charge that a hospital has negotiated with all third party payers for an item or service. We are also finalizing with modification to define a fifth type of standard charge as the "de-identified maximum negotiated charge" to mean the highest charge that a hospital has negotiated with all third party payers for an item or service. To identify the minimum negotiated charge and the maximum negotiated charge, the hospital considers the distribution of all negotiated charges across all third party payer plans and products for each hospital item or service. We note that this distribution would not include non-negotiated charges with third party payers. The hospital must then select and display the lowest and highest de-identified negotiated charge for each item or service the hospital provides.

We appreciate the many additional innovative suggestions for how a range of de-identified negotiated charges could be displayed by a hospital. We note that we have interpreted section 2718(e) of the PHS Act to require each hospital to disclose its own standard charges, and not the charges that are standard in a particular region or market as some commenters suggested. However, if commenters believe such data to be valuable, nothing would prevent hospitals or other users of the information to include such ranges when presenting it to consumers.

Final Action: We are therefore finalizing with modification to define a fourth and fifth type of standard charge as the "de-identified minimum negotiated charge" to mean the lowest charge that a hospital has negotiated with all third party payers for an item or service. We are also finalizing with modification to define a fifth type of

standard charge as the "de-identified maximum negotiated charge" to mean the highest charge that a hospital has negotiated with all third party payers for an item or service. In response to comments and in the interest of minimizing hospital burden, we are not finalizing the inclusion of the median negotiated charge as a type of standard charge. We are finalizing these definitions at 45 CFR 180.20. As discussed above, we believe these additional types of standard charges could be useful and beneficial to consumers.

We intend for the de-identified minimum negotiated charge and de-identified maximum negotiated charge to be severable, one from the other, and from payer-specific negotiated charge, such that each of these three types of standard charges could stand-alone as a type of standard charge.

We believe it is reasonable to consider the de-identified minimum negotiated charge and the de-identified maximum negotiated charge as severable from payer-specific negotiated charge because these values represent the lowest or highest charge (along a distribution) that a hospital has negotiated across all third party payers for an item or service, and do not identify the third party payer with which these rates are negotiated. We also believe these types of standard charges are severable from each other because the de-identified minimum negotiated charge and the de-identified maximum negotiated charge are separate values in the distribution.

Further, we believe it is feasible for hospitals to separately identify each type of "standard charge", which according to the definition we are finalizing in 45 CFR 180.20 includes: Gross charge, payer-specific negotiated charge, de-identified minimum negotiated charge, de-identified maximum negotiated charge, and discounted cash price. As discussed elsewhere in section II.D of this final rule, we believe each type of standard charge is a reasonable, and necessary aspect of hospital price transparency, to ensure consumers have as complete information as possible to inform their healthcare decision-making. We therefore believe that all five charges (gross charge, payer-specific negotiated charge, de-identified minimum negotiated charge, de-identified maximum negotiated charge, and discounted cash price) provide value to consumers for the reasons discussed in this section. Accordingly, we intended for all five definitions to be severable, such that if a court were to invalidate the inclusion of an individual definition, the remaining definitions

would remain defined as types of standard charges.

We believe, when made public in combination (according to the requirements we are finalizing), these types of standard charges will be most effective in achieving meaningful transparency in prices of hospital items and services. We also recognize that each type of standard charge alone, if made public nationwide, could also further hospital price transparency in the United States.

E. Requirements for Public Disclosure of All Hospital Standard Charges for All Items and Services in a Comprehensive Machine-Readable File

1. Overview

Section 2718(e) of the PHS Act requires hospitals to make their standard charges public in accordance with guidelines developed by the Secretary. Therefore, we proposed that hospitals make public their standard charges in two ways: (1) A comprehensive machine-readable file that makes public all standard charge information for all hospital items and services (84 FR 39581 through 39585), and (2) a consumer-friendly display of common "shoppable" services derived from the machine-readable file (84 FR 39585 through 39591). In the CY 2020 OPPI/ASC proposed rule, we explained our belief that these two different methods of making hospital standard charges public are necessary to ensure that such data is available to consumers where and when it is needed (for example, via integration into price transparency tools, electronic health records (EHRs), and consumer apps), and also directly available and useful to consumers that search for hospital-specific charge information without use of a developed price transparency tool.

For purposes of displaying all standard charges for all items and services in a comprehensive machine-readable file, we proposed requirements for the file format, the content of the data in the file, and how to ensure the public could easily access and find the file. We agree with commenters who indicate that the machine-readable file would contain a large amount of data, however, we believe that a single data file would be highly useable by the public because all the data would be in one place. By ensuring accessibility to all hospital standard charge data for all items and services, these data will be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by

researchers and policy officials to help bring more value to healthcare.

Comment: A few commenters (particularly hospitals) noted concerns that the chargemaster data they already make public online appears to be accessed less by consumers and more by insurance brokers, competitors, and reporters. Additionally, many commenters believed that the proposed data to be made public would be too complex, voluminous, and time consuming for consumers to navigate and understand. Specifically, commenters expressed concern that: The data files would be comprised of thousands of lines of data that consumers would have to sift through; the volume of files could crash personal computers; the information could add to confusion for consumer who may not understand a chargemaster, coding, or the differences between ancillary services, gross charges, and payer-specific negotiated charges; providing large and complex datasets (even if standardized) would not achieve CMS's stated goal of transparency; and consumers may not be able to derive actual costs from standard charge information. Some commenters indicated that the machine-readable file should be made consumer-friendly and searchable.

Response: We believe that requiring hospitals to make public all standard charges for all items and services they provide is consistent with the mandate of section 2718(e) of the PHS Act. We agree with commenters who indicate that the machine-readable file would contain a large amount of data, however, we believe that a single data file would be highly useable by the public because all the data would be in one place. By ensuring accessibility to all hospital standard charge data for all items and services, these data will be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare. In order to ensure hospital standard charge data is more directly useful to the average patient, we proposed and are finalizing an additional requirement for hospitals to make a public standard charges for a set of shoppable services in a consumer-friendly manner (see section II.F of this final rule). We believe the shorter data set presented in a consumer-friendly manner is more likely to be directly useful to consumers who seek to compare costs for common shoppable services hospital-by-hospital.

We note that many machine-readable data sets that are made available for

public use can be quite large. For example, Medicare Provider Utilization and Payment Data files include information for common inpatient and outpatient services, all physician and other supplier procedures and services, and all Part D prescriptions.¹⁴⁰ These files are freely available to the public and contain hundreds of thousands of data points in .xlsx and .csv format. We therefore believe it is possible for hospitals to make public all their standard charges for all the items and services they provided in a similar manner. Additionally, we have not heard that large Medicare data files of data derived from claims causes any confusion for healthcare consumers, and healthcare consumers do not typically use the information in the data files directly. Instead, voluminous Medicare data is used by a variety of stakeholders, some of whom take the information and present it to users in a consumer-friendly manner.¹⁴¹ Similarly, we do not believe that making public a comprehensive machine-readable file with all standard charges for all items and services would create patient confusion. Finally, we note that by definition, machine-readable files are searchable.

2. Standardized Data Elements for the Comprehensive Machine-Readable File

In the CY 2020 OPPS/ASC proposed rule (84 FR 39582 through 39583), we proposed that hospitals disclose their list of standard charges for all items and services online in a single digital file that is machine-readable. Without specifying a minimum reporting standard for the machine-readable file, the standard charges data made publicly available by each hospital could vary, making it difficult for the users of the data to compare items and services. For example, some hospitals currently post a single column of gross charges without any associations to CPT or HCPCS codes or other identifying descriptions of the items and services to which the gross charge applies. A similar example would be a hospital that displays a list of gross charges that is correlated with a list of item numbers that are meaningful to the hospital billing personnel, but not understandable to the general public. By contrast, some hospitals list their gross charges along with a brief description of the item or

service to which each gross charge applies and the corresponding standardized identifying codes (typically HCPCS or CPT codes).

We expressed our concern that the lack of uniformity leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals. Therefore, for the comprehensive machine-readable file of all standard charges for all items and services, we made proposals to ensure uniformity of the data made publicly available by each hospital. To inform these proposals, we considered the data elements that are typically included in a hospital's billing system and which of those elements would result in hospital standard charge data being most transparent, identifiable, meaningful, and comparable. Specifically, we proposed that the list of hospital items and services include the following corresponding information, as applicable, for each item and service:

- Description of each item or service (including both individual items and services and service packages).
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding payer-specific negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each list of payer-specific charges must be clearly associated with the name of the third party payer.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the CPT code, HCPCS code, DRG, NDC, or other common payer identifier.
- Revenue code, as applicable.

We proposed to codify these requirements at proposed new 45 CFR 180.50(b). We stated that we believe that these elements would be necessary to ensure that the public would be able to compare standard charges for the same or similar items and services provided by different hospitals.

We proposed that hospitals associate each standard charge with a CPT or HCPCS code, DRG, NDC, or other common payer identifier, as applicable, because hospitals uniformly understand them and commonly use them for billing items and services (including both individual items and services and service packages). We also proposed

¹⁴⁰ CMS.gov website, Medicare Provider Utilization and Payment Data. Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html>.

¹⁴¹ Wei S, et al. Surgeon Scorecard. ProPublica. Updated July 15, 2015. Available at: <https://projects.propublica.org/surgeons/>.

that hospitals include item descriptions for each item or service. In the case of items and services that are associated with common billing codes (such as HCPCS codes), the hospital could use the code's associated short text description.

In addition, based on stakeholder feedback suggesting hospital charge information should include revenue codes to be comparable, we proposed to require that the hospital include a revenue code where applicable and appropriate. Hospitals use revenue codes to associate items and services to various hospital departments. When a hospital charges differently for the same item or service in a different department, we proposed that the hospital associate the charge with the department represented by the revenue code, providing the public some additional detail about the charges they may expect for hospital services provided in different hospital departments.

In developing this proposal, we also considered whether the following data elements, which are commonly included in hospital billing systems, might be useful to the public:

- Numeric designation for hospital department.
- General ledger number for accounting purposes.
- Long text description.
- Other identifying elements.

However, we determined that, for various reasons, these data elements may not be as useful as the data elements that we proposed to require hospitals to make public. For example, data elements such as general ledger numbers are generally relevant to the hospital for accounting purposes but may not add value for the public, while data elements such as alternative code sets (such as International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10)

codes) or long text descriptions associated with CPT codes, while useful, might be difficult to associate with a single item or service or be otherwise difficult to display in a file that is intended mainly for further computer processing. Because of this, we stated that while long text descriptions might benefit healthcare consumers and be appropriate for the consumer-friendly display of shoppable services (as discussed in the CY 2020 OPPTS/ASC proposed rule, 84 FR 39585 through 39591), we believe they may add unnecessary burden for hospitals when such descriptions are not readily electronically available, or when the display of such data is not easily formatted into a machine-readable file. Therefore, we did not propose to require these additional elements for the machine-readable data file that contains a list of all standard charges for all hospital items and services. We invited public comment on the proposed data elements for the comprehensive machine-readable file of all standard charges for all items and services that hospitals would be required to make public. We also sought public comment on the other data elements that, as we detail above, we considered but did not propose to require, and on any other standard charge data elements that CMS should consider requiring hospitals to make public.

Comment: A few commenters sought clarification on how to make public charges for various hospital items and services. For example, one commenter stated that gross charges are not established for several codes using surgical procedure codes, but rather are listed as unit of time. Others pointed out that charges for hospitals and physicians may be maintained separately, with some indicating that employed physician charges are not included in their hospital chargemaster.

Response: In its comprehensive machine-readable file, the hospital must include all standard charges for all items and services for which it has established a charge, which includes time-based gross charges. For items and services and associated gross charges found in the hospital chargemaster, the hospital could list, for example, the gross charge associated with supplies or amount charges per unit of time. An example of how a hospital could list its time-based gross charges for various items and services can be viewed in Table 1.

We understand that some hospitals may have several locations operating under a consolidated hospital license, and each location may have its own chargemaster. Some hospitals may have a chargemaster for hospital items and services (for example, supplies, procedures, or room and board charges) and one for hospital services provided by employed professionals, although more often all gross charges for all items and services provided by the hospital (including services of employed practitioners) are kept in a single hospital chargemaster. Moreover, we agree with commenters that often the charges for employed practitioners are not associated with specific CPT/HCPCS codes until after a service has been provided to a patient. However, the gross charge for the employed professional would still be present in the chargemaster. The last several rows of Table 1 illustrates one way a hospital could incorporate standard charges for professional services into their comprehensive machine-readable file. Additionally, we note that gross charges for some supplies, such as gauze pads, found in the hospital chargemaster may not have a corresponding common billing code. Therefore, we clarify that that common billing codes as a required data element be included as applicable.

TABLE 1—SAMPLE DISPLAY OF GROSS CHARGES ¹⁴²

Hospital XYZ Medical Center					
Prices Posted and Effective [month/day/year]					
Notes: [insert any clarifying notes]					
Description	CPT/HCPCS code	NDC	OP/Default gross charge	IP/ER gross charge	ERx Charge quantity
HB IV INFUS HYDRATION 31–60 MIN	96360	\$1,000.13	\$1,394.45	
HB IV INFUSION HYDRATION ADDL HR	96361	251.13	383.97	
HB IV INFUSION THERAPY 1ST HR	96365	1,061.85	1,681.80	
HB ROOM CHARGE 1:5 SEMI PRIV	2,534.00	
HB ROOM CHG 1:5 OB PRIV DELX	2,534.00	
HB ROOM CHG 1:5 OB DELX 1 ROOM	2,534.00	
HB ROOM CHG 1:5 OB DELX 2 ROOMS	2,534.00	
SURG LEVEL 1 1ST HR 04	Z7506	3,497.16	
SURG LEVEL 1 ADDL 30M 04	Z7508	1,325.20	
SURG LEVEL 2 1ST HR 04	Z7506	6,994.32	
PROMETHAZINE 50 MG PR SUPP	J8498	00713013212	251.13	383.97	12 Each.
PHENYLEPHRINE HCL 10% OP DROP	17478020605	926.40	1,264.33	5 mL.
MULTIVITAMIN PO TABS	10135011501	0.00	0.00	100 Each.
DIABETIC MGMT PROG, F/UP VISIT TO MD	S9141	185.00	
GENETIC COUNSEL 15 MINS	S0265	94.00	
DIALYSIS TRAINING/COMPLETE	90989	988.00	
ANESTH, PROCEDURE ON MOUTH	170	87.00	

Comment: One commenter provided a chart as an example of how to disclose price transparency information broken down by Medicare, Medicaid, commercial non-contracted in-network and commercial non-contracted out-of-network providers. Another commenter recommended that any publicly-available report of hospital negotiated prices be preceded by efforts to create standardized data definitions and formats across hospitals and ensure alignment with insurer reporting standards, which is critical to achieving consumer-friendly, useful, “apples-to-apples” information.

Response: We appreciate these comments and agree that standardization is important to ensure that hospital charge information can be compared across and between hospitals. Based on a review of state requirements and a sampling of hospitals that are currently making their charges public, we chose the specific data elements we are finalizing, which are included in hospital billing and accounting systems, as the ones that would result in hospital standard charge data being transparent, identifiable, meaningful, and comparable. For example, we believe that the billing codes present a common data element that provides an adequate

cross-walk between hospitals for their items and services. Such codes serve as a common language between providers and payers to describe the medical, surgical and diagnostic services provided by the healthcare community.

We agree that defining elements in a data dictionary or more specificity in data file formats could make it easier for IT personnel to use hospital charge data and will take it under consideration for future rulemaking.

For reasons we discussed earlier in section II.D.3. of this final rule, data on FFS Medicare and Medicaid is not included as a type of standard charge and would not be required to be included in the comprehensive machine-readable file. Because such data is publicly available, however, it could readily be included by a hospital that so chooses, or it could be added by those who use the hospital standard charge information. We further agree that additional data related to commercial non-contracted in-network and commercial non-contracted out-of-network providers could be useful for consumers and note that we are concurrently publishing a price transparency proposed rule entitled Transparency in Coverage (file code CMS–9915–P) focused on disclosure of negotiated rates and unique out-of-network allowed amounts from most individual and group market health insurance issuers and group health plans. We believe that by doing so we are aligning expectations and incentives across the healthcare system and helping to ensure alignment with

reporting standards applicable to issuers and group health plans.

Comment: A few commenters expressed concern that this proposal falls short of achieving its goal of informing patients about the cost of care in a meaningful way to choose among hospital providers. One commenter asserted that even when hospitals use the same or similar terminology to describe specific services, some services can be very specific in ways that patients may not understand and associated out-of-pocket costs can vary a great deal, and that unless patients are familiar with coding and standard descriptors, it is likely that many will compare cost estimates for services that are substantially different from what they will receive. Several commenters asserted that hospitals do not have adequate, timely health plan information related to patient benefit plans, bundled payments, and adjudication rules to provide patients with accurate out-of-pocket cost estimates prior to services. One commenter expressed concern with the ability for an accurate estimate to be “published in a file” due to the myriad ways that payers structure and adjudicate providers’ claims. The commenter noted that third-party payers have processing systems that determine “allowables”, adjustments, payments, patient responsibility, etc., and that address unique plan design constructs (at the employer’s discretion) based on each unique contract. Another commenter asserted that there is significant complexity in negotiated contracts and many other nuances in

¹⁴²Note that this example shows only one type of standard charge (specifically the gross charges) that a hospital would be required to make public in the comprehensive machine-readable file. Hospitals must also make public the payer-specific negotiated charges, the de-identified minimum negotiated charges, the de-identified maximum negotiated charges, and the discounted cash prices for all items and services.

contract arrangements that would mean that each hospital would need to provide data on literally thousands of service bundle combinations.

Response: We are clarifying the requirements for making public all standard charges for all items and services in a comprehensive machine-readable file and have included an example of the format and structure the list of gross charges could take (see Table 1). We agree that standardization in some form is important to ensure high utility for users of the hospital standard charge information, and we have proposed and are finalizing certain requirements (such as the data elements and file formats) that would be standardized across hospitals. We decline at this time to be more prescriptive in our approach; however, we may revisit these requirements in future rulemaking should we find it is necessary to make improvements in the display and accessibility of hospital standard charge information for the public. Regarding the display of payer-specific negotiated charges, we recommend hospitals consult their rate sheets or rate tables within which the payer-specific negotiated charges are often found. Such rate sheets typically contain a list of common billing codes for items and services provided by the hospital along with the associated payer-specific negotiated charge or rate. We believe it is possible to make this information public in a single comprehensive machine-readable file by, for example, using multiple tabs in an XML format. For example, one tab could show a list of individualized items and services and associated gross charges derived from the hospital's chargemaster while another tab could display the individualized items and services and service packages for a specific payer's plan based on the rate sheet derived from the hospital's contract with the payer. We also note that service packages can often be associated with a common billing code such as a DRG or APC or other payer modifier that is identified on the rate sheet. We clarify that for service packages, we do not intend each and every individual item or service within the service package to be separately listed. For example, if a hospital has a payer-specific negotiated charge (base charge) for a DRG code, the hospital would list that payer-specific negotiated charge and associated DRG code as a single line-item on its machine-readable file.

Further, as described in more detail in section II.D.1 of this final rule, we disagree with commenters who indicated that standard charges are

meaningless to consumers. We agree, however, that for insured patients, the payer-specific negotiated charge does not in isolation provide a patient with an individualized out-of-pocket estimate. Because the additional details of a consumer's benefit structure (for example, the copay or deductible) are not standard charges maintained by hospitals, we did not propose that hospitals would be required to make these data elements public. However, as we explained, the hospital standard charges, specifically, the gross charge and the payer-specific negotiated charges, are critical data points found on patient EOBs which are designed to communicate provider charges and resulting patient cost obligations, taking third party payer insurance into account. When a patient has access to payer-specific negotiated charge information prior to obtaining a healthcare service (instead of sometimes weeks or months after the fact when the EOB arrives), combined with additional information the patient can get from payers, it can help the individual determine his or her potential out-of-pocket information for a hospital item or service in advance. As previously noted, we agree with commenters who indicate that the machine-readable file would contain a large amount of data, however, we believe that a single data file would be highly useable by the public because all the data would be in one place. By ensuring accessibility to all hospital standard charge data for all items and services, these data will be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare.

Comment: One commenter suggested that the machine-readable file include the "claim allowable," which is comprised of the sum of the co-pay, coinsurance, deductible and health insurance company payment. A few commenters indicated CPT codes and ICD procedure codes should be included to facilitate apples-to-apples comparisons and ensure so inpatient facilities do not have a way to extend charges to cash-pay patients and inflate patient charges.

Response: We thank the commenters for their input. We believe the "claim allowable" referred to by the commenter is analogous to the payer-specific negotiated charge, which is the rate negotiated by hospitals that includes both the payer and patient portion. In other words, as explained in section II.D.3 of this final rule, the payer-specific negotiated charge is the

discounted rate that the hospital has negotiated with the third party payer and is typically displayed as the second charge listed on the patient's EOB. As expressed by commenters, additional information from the payer is necessary to determine how the "negotiated rate" or "allowed amount" is apportioned between the payer and the patient. As explained in the CY 2020 OPPI/ASC proposed rule, we do not believe that ICD procedure codes should be included because, while useful, such information might be difficult to associate with a single item or service or be otherwise difficult to display in a file that is intended mainly for further computer processing. In summary, we believe the proposed data elements represent the necessary elements (standard charges, service description, and code) to ensure hospital charge information is relevant to consumers, usable, and comparable, so we are finalizing as proposed.

Comment: Several commenters stated that there can be multiple revenue codes for a single service, leading to consumer confusion and repetitive information. One commenter recommended that CMS eliminate revenue code as a standardized data element because some procedures have the same charge, but the revenue code differs.

Response: We believe the revenue code is an important data element for the reasons described in the CY 2020 OPPI/ASC proposed rule, but we are sympathetic to commenters who indicated that including such a code may exponentially increase the number of fields in the comprehensive machine-readable file and make the file difficult to manage. We believe the commenter indicated this because the revenue center code is specific to each hospital department which may offer the same or similar items and services to other hospital departments. If a hospital were to list out each item or service provided in each revenue center separately, the list of items and services could be replicated many times over. We are therefore not finalizing this data element as a requirement, but continue to encourage its inclusion and use by hospitals where appropriate to improve the public's understanding of hospital standard charges. For example, if an item or service has a different charge when provided in a different revenue center (that is, department), the hospital could list just that one item twice—once for the revenue center that has the different standard charge and once for the standard charge that applies to all other revenue centers.

Comment: Several commenters suggested alternatives to the standard

data elements for reporting all items and services. For example, some suggested including ICD-10 procedure codes, one suggested posting separate charges for administrative cost of government and insurance regulations, and another suggested hospitals make public the costs related to cost-shifting and uncompensated care, the availability of providers, whether the provider takes all forms of payment. One commenter suggested leveraging a group of various stakeholders to develop and validate these standards. One commenter also suggested that a healthcare consumer should have the right to view a line itemized medical bill before and after the time of service, which would contain the full name (no abbreviations) of each medical test as spelled out in the AMA CPT manual for which a medical provider wants paid accompanied by the five (5) digit CPT billing code as per the AMA CPT manual. Two commenters asserted that failure to provide an easy to understand fee schedule in advance, combined with hospitals failure to provide an itemized bill, results in the unfair and unethical practice known as surprise medical billing.

Response: We appreciate the commenters' alternative suggestions and interest in reducing the risk of surprise billing by providing consumers with an advance itemized bill of each medical service. We note that this final rule would not constrain hospitals from providing an itemized bill in advance, ICD-10 codes, or other information that consumers may find helpful to understand the cost of their care. At this time, however, we believe that the common data requirements we are finalizing provide sufficient information for consumers to compare hospital standard charges.

Final Action: We are finalizing with modifications our proposals for common data elements that must be included in the comprehensive machine-readable file that contains all standard charges for all items and services provided by the hospital. Specifically, we are finalizing a requirement that the machine-readable list of hospital items and services include the following corresponding information, as applicable, for each item and service:

- Description of each item or service (including both individual items and services and service packages).
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding payer-specific negotiated charge that applies to each

item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.

- The corresponding de-identified minimum negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding de-identified maximum negotiated charge that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding discounted cash price that applies to each item or service (including charges for both individual items and services as well as service packages) when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the CPT code, HCPCS code, DRG, NDC, or other common payer identifier.

We are codifying these requirements at new 45 CFR 180.50(b). We believe that these elements are necessary to ensure that the public can compare standard charges for similar or the same items and services provided by different hospitals. We are not finalizing the revenue center code as a required data element, but we continue to encourage its inclusion and use by hospitals where appropriate to improve the public's understanding of hospital standard charges.

3. Machine-Readable File Format Requirements

To make public their standard charges for all hospital items and services, we proposed to require that hospitals post the charge information in a single digital file in a machine-readable format. We proposed to define a machine-readable format as a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, .JSON and .CSV formats. A Portable Document Format (PDF) would not meet this definition because the data contained

within the PDF file cannot be easily extracted without further processing or formatting. We proposed to codify these format requirements at proposed new 45 CFR 180.50(c) and the definition of machine-readable at proposed new 45 CFR 180.20. We explained our belief that making public such data in a machine-readable format would pose little burden on hospitals because many, if not all, hospitals already keep these data in electronic format in their accounting systems for purposes of, for example, ensuring accurate billing. However, we sought comment on this assumption and the burden associated with transferring hospital charge data into a machine-readable format.

As an alternative, we considered proposing to require that hospitals post their list of all standard charges for all items and services using a single standardized file format, specifically .XML only, because this format is generally easily downloadable and readable for many healthcare consumers, and it could simplify the ability of price transparency tool developers to access the data. However, we did not want to be overly prescriptive in our requirements for formatting. We sought public comments on whether we should require that hospitals use a specific machine-readable format, and if so, which format(s). Specifically, we sought public comment on whether we should require hospitals to make all standard charge data for all items and services available as an .XML file only.

In addition, we considered formats that could allow direct public access to hospital standard charge information and we sought public comment from all stakeholders, particularly hospitals and innovative IT vendors, regarding such technologies or standards that could facilitate public access to real-time updates in a format to make it easier for information to be available when and where consumers want to use it. We specifically sought public comment on adopting a requirement that hospitals make public their standard charges through an open standards-based Application Programming Interface (API) (sometimes referred to as an "open" API) through which they would disclose the standard charges and associated data elements discussed in section XVI.E.2 of the CY 2020 OPPI/ASC proposed rule (84 FR 39582 through 39583). We also sought public comment on the additional burden that may be associated with a requirement that hospitals make public their standard charges through a standards-based API.

Comment: Several commenters supported the use of API-based methods to access pricing information, noting that APIs are largely efficient and not burdensome to implement. A few commenters believed this would also encourage the development of an innovative health ecosystem that would facilitate the most user-friendly interface for consuming and presenting the information to patients. A few commenters supported the development of industry-wide API standard or requiring a standards-based API, which would leverage widely-recognized, national standards. One commenter suggested that CMS require all stakeholders in the healthcare industry to adopt standardized data exchange methods for pricing information to allow the primary care or other referring physician to be able to have the price conversation with the patient as decisions are made. Another commenter urged the use of APIs to be able to export a complete health record with both price and clinical information. One commenter recommended that CMS use consensus-based data standards for the posting of machine-readable files, as stated in the June 24, 2019 Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patients First.

Response: We appreciate comments on this issue. We believe that standardizing exchange of hospital standard charge and other data is an important goal, but we believe that finalizing our requirement that hospitals make their standard charge information available to the public online in a machine-readable format is a good initial step. We continue to work on policies designed to advance the use of APIs to support interoperability in collaboration with other federal partners, such as the Office of the National Coordinator (ONC). As hospital disclosure of standard charges matures, and Fast Healthcare Interoperability Resources (FHIR) or other consensus-based standards for data pricing endpoints develop, we may revisit the issue and consider proposing in future rulemaking approaches using API or other technology.

Final Action: We are finalizing as proposed the requirement that hospitals post their standard charge information in a single digital file in a machine-readable format. We are finalizing our definition of machine-readable format as a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, .JSON and

.CSV formats. A PDF would not meet this definition because the data contained within the PDF file cannot be easily extracted without further processing or formatting. We are finalizing these format requirements at new 45 CFR 180.50(c) and the definition of machine-readable at new 45 CFR 180.20.

4. Location and Accessibility Requirements for the Comprehensive Machine-Readable File

In the CY 2020 OPPTS/ASC proposed rule, we explained that we reviewed how hospitals are currently implementing our updated guidelines, which took effect on January 1, 2019, and we expressed concern that some charge information made public by hospitals may be difficult for the public to locate. For example, information may be difficult to locate if the public is required to click down several levels in order to find the information. We also expressed our concern about barriers that could inhibit the public's ability to access the information once located. For example, we indicated that we were aware that some hospitals require consumers to set up a username and password, or require consumers to submit various types of other information, including, but not limited to, their email address, in order to access the data. We expressed concern that these requirements might deter the public from accessing hospital charge information.

Accordingly, we proposed that a hospital would have discretion to choose the internet location it uses to post its file containing the list of standard charges so long as the comprehensive machine-readable file is displayed on a publicly-available web page, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated, and the standard charge data are easily accessible, without barriers, and the data can be digitally searched. For purposes of these proposed requirements: (1) "displayed prominently" would mean that the value and purpose of the web page¹⁴³ and its content¹⁴⁴ is clearly communicated, there is no reliance on breadcrumbs¹⁴⁵ to help with navigation, and the link to the standard charge file is visually distinguished on the web

page;¹⁴⁶ (2) "easily accessible" would mean that standard charge data are presented in a single machine-readable file that is searchable and that the standard charges file posted on a website can be accessed with the fewest number of clicks;¹⁴⁷ and (3) "without barriers" would mean the data can be accessed free of charge, users would not have to input information (such as their name, email address, or other personally identifying information (PII)) or register to access or use the standard charge data file. We proposed to codify this requirement at proposed new 45 CFR 180.50(d).

We encouraged hospitals to review the HHS Web Standards and Usability Guidelines (available at: <https://webstandards.hhs.gov/>), which are research-based and are intended to provide best practices over a broad range of web design and digital communications issues.

We also requested public comments on an alternative we considered, which would have required hospitals to submit a link to the standard charges file to a CMS-specified central website, or submit a link to the standard charge file to CMS that would be made public on a CMS web page. Such a method could have allowed the public to access standard charge information for their purposes in one centralized location. We stated that we believed this could reduce potential confusion about where to find standard charge information and potentially allow standard charge information to be posted alongside CMS hospital quality information. It could also assist in the assessment of hospital compliance with section 2718(e) of the PHS Act. In spite of these possible benefits, we did not propose to require hospitals to submit or upload a link to their standard charge information to a CMS-specified centralized website because we believed such an effort could be unnecessarily duplicative of ongoing State and private sector efforts to centralize hospital pricing information and potentially confuse consumers who may reasonably look to a hospital website directly for charge information. However, we stated that because we appreciate the advantages of having all data available through a single site, we considered this alternative and sought public comments. We sought comment on this alternative option, specifically, whether the burden outweighs the advantages.

Finally, we sought public comments on potential additional requirements, including easily-searchable file naming

¹⁴³ <https://webstandards.hhs.gov/guidelines/49>.

¹⁴⁴ Nielsen J. (2003, November 9). The ten most violated homepage design guidelines. Alertbox. Available at: <http://www.useit.com/alertbox/20031110.html>.

¹⁴⁵ <https://webstandards.hhs.gov/guidelines/78>.

¹⁴⁶ <https://webstandards.hhs.gov/guidelines/88>.

¹⁴⁷ <https://webstandards.hhs.gov/guidelines/181>.

conventions and whether we should specify the website location for posting rather than our proposed requirement that would permit hospitals some flexibility in choosing an appropriate website. Current instances of machine-readable charge files posted on hospital websites contain variable file types, file names, and locations on each website. Standardizing file name or website location information could provide consumers with a standard pathway to find the information and would provide uniformity, making it easier for potential software to review information on each website. Specific requirements for file naming conventions and locations for posting on websites could also facilitate the monitoring and enforcement of the requirement. Therefore, we sought public comments on whether we should propose to adopt these additional requirements or other requirements related to these issues.

Comment: A few commenters supported the development and use of centralized price transparency websites. For example, two commenters noted that the use of a centralized posting repository would aid in monitoring to ensure hospital compliance. One commenter agreed that the information should be required to be placed in a standardized location, such as a standardized “pricing” uniform resource locator (URL), expressing a belief that it would go a long way toward simplifying the presently time-consuming and confusing process when attempting to comparison shop for healthcare. The commenter indicated that, when combined with the machine-readability requirements, such as a standardized location would enable a wide variety of benchmarking and comparison-shopping services that are not possible today. One commenter supported the alternative concept for centralizing the standard charge data from each hospital into a CMS website to which hospitals would link from their respective websites, and quality data would be posted alongside the charge information. Another commenter did not support a central location that would contain all the links, expressing a belief that the requirement to make the charge information “displayed prominently” on the hospitals website would be sufficient. A few commenters suggested that CMS host a centralized list of machine-readable pricing websites and recommended that these websites be incorporated into the existing CMS National Plan and Provider Enumeration System (NPPES). Another commenter suggested that CMS launch and maintain a centralized data

portal, similar to CMS’ Hospital Compare website, with tightly defined file constructs in order to ensure the submission of consistent information by providers so that comparisons could be made. A few commenters suggested that CMS leverage existing price transparency efforts by states, including requirements to report pricing information or publish instructions on hospital websites to facilitate consumer access to pricing information. One commenter noted that states with APCDs and price transparency websites centralize and compare costs/prices and other attributes across providers and payers, providing a platform for disseminating standardized information. The commenter suggested that CMS leverage this experience, invest in interoperability, and advance this work across states to support consumers. Several commenters suggested alternative approaches to enable public access to price transparency information. One commenter recommended the development of a transparency website that incorporates a radius-distance search tool to view and compare hospital charges. The commenters noted that CMS shares the contents of the NPPES database on a regular basis as public use files due to the inevitability of FOIA requests. A few commenters supported the use of an independent third-party online database, with one commenter noting that this approach would not increase burden on hospitals or clinicians, in alignment with CMS’ stated policy goals.

Response: We appreciate the many suggestions from stakeholders related to ensuring public access to hospital standard charge information. We agree with stakeholders that centralizing the standard charges information disclosed by hospitals could have many advantages for finding the files and for monitoring to ensure compliance. We decline to finalize such a policy at this time, however, we will continue to consider a requirement for hospitals to submit to CMS their files, or a link to where such files may be located on the internet, for future rulemaking. We agree with commenters that a naming convention could assist in locating hospital charge data files and are therefore finalizing a requirement that hospitals use a CMS-specified naming convention, which, as discussed in the CY 2020 OPPS/ASC proposed rule, we believe will help stakeholders more easily locate the comprehensive machine-readable file that contains all hospital standard charge information. We are finalizing the following naming

convention that must be used for the file: <ein>.<hospital-name>_standardcharges.[json|xml|csv] in which the EIN is the Employer Identification Number of the hospital, followed by the hospital name, followed by “standardcharges” followed by the hospital’s chosen file format.

CMS thanks the commenters for their input on the use of APCDs. We note that this rule does not require hospitals to contribute data to an APCD, but recognize that States with APCDs may seek to integrate the publication of hospital standard charge data and negotiated charges with ongoing price transparency and interoperability efforts. Moreover, we are finalizing our policy to permit hospitals to choose an appropriate public facing website and web page on which to make public its comprehensive machine-readable list of all standard charges for all items and services.

Comment: A few commenters agreed with our proposals for data accessibility, specifically that accessing the hospital charge information would not require consumers to input information (such as their name, email address, or other personal identifying information) or register. One commenter suggested, however, that this requirement does not appear to be in alignment with *Medicare.gov*, which the commenter notes requires visitors to provide personal, identifying information (such as date of birth) when reviewing options for Medicare health plans.

Response: We thank commenters for their support for barrier free access to consumer cost comparison information and are finalizing as proposed the requirement hospitals provide barrier-free access to their machine-readable file of hospital standard charges for all items and services provided by the hospital. The comment about access to *Medicare.gov* is inaccurate; the public may review and compare plans and pricing anonymously—with or without a drug list—without signing into anything or providing personal information. The website requires only a zip code entry in order to narrow down the available plans. Even if the website did require submission of some personal information, we do not believe it is a good analogy for access to a data file. A better analogy might be access to CMS public use file data. Such data is also made public online in a machine-readable format and does not require users to create an account or enter PII to download. In contrast, beneficiary access to a personalized online portal containing or using personalized information (such as would allow a patient to review and select a Medicare

Advantage health plan or to access one's own claims data) would seem to us to be very different. We are therefore finalizing our proposals for barrier-free access as proposed.

Final Action: We are finalizing, with modifications, our proposals related to location and accessibility of the comprehensive machine-readable file of all hospital standard charges for all items and services it provides. Specifically, we are finalizing that a hospital would have discretion to choose the internet location it uses to post its file containing the list of standard charges so long as the comprehensive machine-readable file is displayed on a publicly-available website, it is displayed prominently and clearly identifies the hospital location with which the standard charges information is associated (§ 180.50(d)(1) and (2)). We are finalizing as proposed that the hospital must ensure the standard charge data are easily accessible and without barriers, including but not limited to that the data can be accessed free of charge, without having to establish a user account or password, and without having to submit PII (§ 180.50(d)(3)). We are also finalizing our policy that the data must be able to be digitally searched (§ 180.50(d)(4)). Finally, we are finalizing a modification to also require that the hospital must use a CMS-specified naming convention for the file (§ 180.50(d)(5)). The naming convention for the file must be: <ein>_<hospital-name>_standardcharges.[json|xml|csv].

5. Frequency of Machine-Readable File Updates

The statute requires hospitals to establish, update, and make public their standard charges for each year. Therefore, we proposed to require hospitals to make public and update their file containing the list of all standard charges for all items and services at least once annually (proposed new 45 CFR 180.50(e)). As explained in the CY 2020 OPPTS/ASC proposed rule, we recognize that hospital charges may change more frequently and therefore we encouraged, but did not propose to require, that hospitals update this file more often, as appropriate, so that the public could access the most up-to-date charge information. We also recognized that hospitals may update their charges at different times during the year and may also have various State price transparency reporting requirements that require updates. For purposes of these proposed requirements, we explained that updates that would occur at least once in a 12-month period

would satisfy our proposed requirement to update at least once annually, and also serve to reduce reporting burden for hospitals. In other words, we indicated that the hospital could make public and update its list of standard charges at any point in time during the year, so long as the update to the charge data would occur no more than 12 months after posting.

We also proposed to require hospitals to clearly indicate the date of the last update they made to the standard charge data, and permitted some discretion as to where the hospital indicated the date of the last update. For example, we stated that if a hospital chose to make public its list of standard charges in .XML format, the first row of the spreadsheet could indicate the date the file was last updated. We also stated that the hospital could alternatively choose to indicate the date the file was last updated in text associated with the file on the web page on which it was posted, or could indicate the date in some other way, as long as that date was clearly indicated and associated with the file or location containing the standard charge information.

Comment: A few commenters expressed concern that requiring updates to the data only once every 12 months may mean the data posted will not be useful to consumers because the information posted may be outdated depending on the frequency and timing of contract renegotiation. A few commenters also noted that updating the database on a continual basis during the year would be a significant burden to hospitals, while another commenter suggested that price information should be updated more frequently, whenever the prices are changed. One commenter specifically supported the requirement to update the standard charge information annually. A few commenters recommended that the web page indicate the date of last update. One commenter asked for clarification regarding the process for price disclosure when new medical information is discovered that "changes the care plan" and whether hospitals need to update patients if pricing information has already been provided.

Response: We thank commenters for their support and recommendations. The statute requires hospitals to annually update its list of standard charges, and we believe our proposed requirement for hospitals to update their comprehensive machine-readable list of standard charges at least once in a 12 month period (which we are finalizing) is consistent with its plain language. We recognize the challenges inherent in annual posting of a flat file containing

all hospital standard charges for all items in services. Specifically, we recognize that such data may, for various reasons, become outdated over the course of a 12 month period, but we also recognize that it may be burdensome for a hospital to continually update its standard charge information. We believe our final policy strikes a balance between consumer need to plan and compare prices when seeking care with hospital disclosure burden. We note that in the CY 2020 OPPTS/ASC proposed rule we sought comment on alternative mechanisms (such as requiring data to be presented in an API format) that could allow for access to continuously updated hospital charge information. As noted in section II.E.3 of this final rule, we will continue to consider this option for future rulemaking. We encourage hospitals to make more frequent updates, at their discretion and commend hospitals that choose to go beyond these requirements to more frequently update the standard charge information they make online, or that provide additional consumer-specific estimates based on consumer care plans.

Final Action: At a new 45 CFR 180.50(e), we are finalizing as proposed the requirement for hospitals to make public and update their file containing the list of all standard charges for all items and services at least once annually. For purposes of assessing compliance, such updates must occur at least once in a 12-month period. We are also finalizing the requirement for hospitals to clearly indicate the date of the last update they have made to the standard charge data, with some discretion as to where the date of the last update is indicated, so long as that date is clearly indicated either within the file or otherwise clearly associated with the file.

6. Requirements for Making Public Separate Machine-Readable Files for Different Hospital Locations

As explained in the CY 2020 OPPTS/ASC proposed rule, we indicated our understanding that some hospitals may have different locations operating under a consolidated or single State license, and that different hospital locations may offer different services that have different associated standard charges. To address this circumstance, we proposed at new 45 CFR 180.50(a)(2) that the requirements for making public the machine-readable file containing all standard charges for all items and services would separately apply to each hospital location such that each hospital location would be required to make

public a separate identifiable list of standard charges.

Comment: One commenter supported clearly indicating which hospital location is covered if the hospital is part of a health system. One commenter expressed concern that because academic and teaching institutions have expansive campuses, requiring each health system to fulfill the requirements separately for each hospital location would increase their burden significantly.

Response: We clarify that a hospital need not post separate files for each clinic operating under a consolidated state hospital license; it would be sufficient for a hospital to post a single file of standard charges for a single campus location, if the file includes charges for all items and services offered at the single campus location.

In cases where such off-campus and affiliated sites operate under the same license (or approval) as a main location but have different standard charges or offer different items and services, these locations would separately make public the standard charges for such locations.

Final Action: We are finalizing as proposed at new 45 CFR 180.50(a)(2) (with technical edits for clarity) that the requirements for making public the machine-readable file containing all standard charges for all items and services apply to each hospital location such that a separate identifiable list of all standard charges applicable to each hospital location would also would have to be made public.

F. Requirements for Displaying Shoppable Services in a Consumer-Friendly Manner

1. Background and Overview

In the CY 2020 OP/ASC proposed rule we indicated our belief that requiring hospitals to post on the internet a machine-readable file containing a list of all standard charges for all items and services would be a good first step for driving transparency in healthcare pricing because the access to such data would allow integration into price transparency tools or into EHR systems for use at the point of care or otherwise where and when the information is necessary to help inform patients. As a result of the January 1, 2019 update to our guidance, we received feedback that long lists of charges in a file posted online in a machine-readable format may not be immediately or directly useful for many healthcare consumers because the amount of data could be overwhelming or not easily understood by consumers. Because of this, we considered ways of

requiring or encouraging hospitals to make public standard charges for frequently provided services in a form and manner that would be more directly accessible and consumer friendly. Therefore, in addition to including all their standard charges for all items and services in the machine-readable file, we proposed that hospitals must make public their payer-specific negotiated charges for common services for which consumers may have the opportunity to shop, in a consumer-friendly manner.

First, we proposed requirements for hospitals to display a list of payer-specific negotiated charges for a specified set and number of “shoppable” services. We stated that we believed doing so would enable consumers to make comparisons across hospital sites of care. Second, we made proposals intended to ensure the charge information for “shoppable” services would be presented in a way that is consumer-friendly, including presenting the information as a service package. Third, we made proposals related to location, accessibility, and timing for updates.

We explained our belief that the proposals related to consumer-friendly display of hospital charge information would align with and enhance many ongoing State and hospital efforts. We sought comment from hospitals regarding the extent to which our proposals are duplicative of such ongoing efforts, and how best to ensure consistency of consumer-friendly data display across hospital settings. We further sought comment from consumers regarding their potential engagement with a list of “shoppable” hospital items and services, including whether our proposals would provide for a useful amount of data and data elements that allow for actionable comparisons of “shoppable” hospital provided items and services.

2. Definition of “Shoppable Service”

We proposed that for purposes of this requirement, a “shoppable service” would be defined as a service package that can be scheduled by a healthcare consumer in advance. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a time that is convenient for them. We proposed this definition because it is consistent with definitions proposed by policy experts or used by researchers who identify a service as “shoppable” if a patient is able to determine where and when they will receive services and can compare

charges for multiple providers.¹⁴⁸ Since hospitals may not have insight into whether a particular service is available across multiple providers or where a consumer will ultimately determine where to receive a particular service, we focused our proposed definition on the first aspect, that is, whether or not a service offered by the hospital could be scheduled by the consumer in advance.

Additionally, we proposed that the charges for such services be displayed as a grouping of related services, meaning that the charge for the primary shoppable service would be displayed along with charges for ancillary items and services the hospital customarily provides as part of or in addition to the primary shoppable service. We proposed that hospitals would make public the payer-specific negotiated charge for a primary shoppable service that is grouped together with charges for associated ancillary services because we believe charge information displayed in such a way is consumer-friendly and patient-focused. In other words, we believe that consumers want to see and shop for healthcare services in the way they experience the service. We proposed to define an “ancillary service” as an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service (proposed new 45 CFR 180.20). Ancillary items and services may include laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including post-anesthesia and postoperative recovery rooms), therapy services (physical, speech, occupational), hospital fees, room and board charges, and charges for employed professional services. Ancillary services may also include other special items and services for which charges are customarily made in addition to a routine service charge. For example, an outpatient procedure may include many services that are provided by the hospital, for example, local and/or global anesthesia, services of employed professionals, supplies, facility and/or ancillary facility fees, imaging services, lab services and pre-and post-op follow up. To the extent that a hospital customarily provides (and bills for) such ancillary services as a part of or in conjunction with the primary service, we stated the hospital should group the ancillary service

¹⁴⁸ White C, and Eguchi M. Reference Pricing: A Small Piece of the Health Care Price and Quality Puzzle. *National Institute for Health Care Reform Research Brief Number 18* (2014). Available at: <https://www.mathematica.org/our-publications-and-findings/publications/reference-pricing-a-small-piece-of-the-health-care-price-and-quality-puzzle>.

charges along with the other payer-specific negotiated charges that are displayed for the shoppable service. We indicated that we believed such a practice would be consumer-friendly by presenting standard charge information in a way that reflects how a patient experiences the service.

Examples of primary shoppable services may include certain imaging and laboratory services, medical and surgical procedures, and outpatient clinic visits. The emphasis on shoppable services aligns with various State price transparency efforts and is consistent with stakeholder feedback. Further, this emphasis is consistent with research demonstrating that improving price transparency for shoppable services can have an impact on driving down the cost of healthcare. We proposed to add this definition to our regulations at proposed new 45 CFR 180.20.

Comment: Many commenters generally supported the requirement for hospitals to make public their standard charges for shoppable services, stating that consumers need the ability to shop and compare common hospital services prior to purchase. In particular, one commenter commended CMS for the focus on non-emergency services, for which patients have an opportunity to shop in advance.

Some commenters indicated that the ability to schedule a service in advance alone is not enough to ensure the healthcare service is shoppable. For example, one commenter stated that patients need to have multiple providers available in their insurer's network that provide the service. One commenter argued that there are no healthcare services that could be considered shoppable because beneficiaries are limited to the coverage options in their health plan.

Additionally, commenters suggesting limiting the scope of shoppable services based on individual consumer circumstances, for example, one commenter suggested that the definition of shoppable services be limited to non-covered, non-medically necessary services such as elective cosmetic surgery; otherwise, patients may believe that a shoppable service is not a necessary service. One commenter urged CMS to ensure that the definition of "shoppable services" will always clearly exclude emergency department services and that CMS never introduce a definitional change that could in any way be misconstrued to include them so that patients would not be deterred from seeking emergency care. One commenter suggested that CMS focus price transparency efforts on some

prescription drugs and diagnostic imaging only. A few commenters argued that certain service such as vaginal delivery and cancer treatments would be excluded from being posted as shoppable services because they believe such services are unpredictable and unable to be scheduled in advance.

Response: Our proposed definition for a shoppable service aligns with scholarly sources indicating that the ability to schedule in advance is a key concept for determining the shoppability of a healthcare service. As we explained in the CY 2020 OPPS/ASC proposed rule, we believe it is reasonable to define a service as "shoppable" when a consumer can schedule it in advance and not by additional criteria or concepts that could enhance or reduce the shoppability of a particular service in an individual circumstance. For example, a service may be medically necessary for some patients but not others. A service may be provided in an emergency situation for some patients but not others. A patient may or may not have a plan or insurance network that permits them to receive a service from more than one provider in their region or insurance network. However, such issues are specific to individual circumstances, and are not necessarily the case for all individuals who may have the opportunity to schedule a particular healthcare service from a hospital in advance. We therefore think it is reasonable to use only the first commonly used criterion for the definition of a shoppable service (that the service can be scheduled in advance), as using additional criteria may unduly limit the types of services that may be shoppable for some patients. Moreover, as we noted in the CY 2020 OPPS/ASC proposed rule, we limited the definition of shoppable service to the first commonly used definition (that the service can be scheduled in advance) and did not expand to other commonly used definitions (such as whether or not there is more than one provider in a market) because we are finalizing requirements that apply to hospitals, and hospitals may not be able to determine whether a service is shoppable under other criteria, for example, a hospital may not be aware of whether or not there are other providers of the service available to their patients.

We disagree with stakeholders who asserted that services provided for delivery of babies or that cancer treatments are not able to be scheduled in advance and therefore not shoppable. In most instances, the location for the delivery of a baby is planned well in

advance; at least one analysis of a price transparency tool for non-elderly patients found that vaginal deliveries are one of the most commonly shopped healthcare services.¹⁴⁹ Similarly, patients who receive a cancer diagnosis often seek information about providers that are available to treat them before committing to a treatment course by a particular provider. By ensuring the release of hospital standard charge information, we seek to improve consumer knowledge for the cost side of the value proposition. Nothing in this rule would prohibit hospitals from displaying quality information along with standard charge information, and we encourage hospitals to provide consumers with both cost and quality information in a consumer-friendly manner.

Comment: One commenter disagreed with the focus on shoppable services entirely, citing a study that found that no more than 43 percent of hospital spending is attributable to items and services that can reasonably be scheduled in advance, and suggested CMS focus on other hospital services to impact consumer shopping behavior.

Response: Our research has shown that there is great interest among consumers in taking price into consideration when deciding on treatment options and choice of provider. For example, studies have found that more than 40 percent of healthcare services are potentially shoppable by consumers^{150 151} but such services are typically lower cost services such as laboratory tests, imaging, and office visits, along with some higher-cost procedures such as joint replacements. Researchers estimate that approximately \$36 billion could be saved when consumers are given the ability to shop and compare prices for common shoppable services.¹⁵² As the

¹⁴⁹ Sinaiko AD, and Rosenthal MB. Examining A Health Care Price Transparency Tool: Who Uses It, And How They Shop For Care. *Health Affairs*. April 2016. Available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.0746>.

¹⁵⁰ White C, and Eguchi M. Reference Pricing: A Small Piece of the Health Care Price and Quality Puzzle. *National Institute for Health Care Reform Research Brief Number 18* (2014). Available at: <https://www.mathematica.org/our-publications-and-findings/publications/reference-pricing-a-small-piece-of-the-health-care-price-and-quality-puzzle>.

¹⁵¹ Frost A, and Newman D. Spending on Shoppable Services in Health Care. *Health Care Cost Institute Issue Brief No. 11* (2016). Available at http://www.healthcostinstitute.org/files/Shoppable%20Services%20IB%203.2.16_0.pdf.

¹⁵² Columi B. White Paper: Save \$36 Billion in U.S. Healthcare Spending Through Price Transparency. *Truven Health Analytics*, 2012. Available at: http://www.akleg.gov/basis/get_documents.asp?session=30&docid=14495.

commenter notes, at least one study indicates that approximately 43 percent of the \$524 billion spend on healthcare by individuals with employer-sponsored insurance in 2011 was spent on shoppable services.¹⁵³ We believe these studies taken together support our focus on shoppable services; however, we agree that many non-shoppable hospital and emergency services can be very expensive and account for much of the healthcare spending in the United States.

Comment: One commenter agreed with the necessity of displaying ancillary items and services in conjunction with the primary service to give consumers “true line of sight” into their potential costs, but suggested that CMS use Medicare claims data to identify the highest volume and highest cost ancillary services associated with the 70 proposed CMS-specified shoppable services, and then provide this mapping of service codes in the final rule. Another commenter similarly suggested a “numeric standard” for determining the list of all associated ancillary services by averaging all the required charges associated with the primary services, since in some cases only a small minority of patients who receive the primary service also receive the ancillary services.

Several commenters requested that CMS clarify how hospitals would determine which services they “customarily” provide to meet the requirements for displaying ancillary services with the primary shoppable service. A few commenters expressed concern that the definition for ancillary services is not adequately clear, and, as a result, hospitals may not interpret ancillary services consistently and ultimately cause confusion for consumers. One commenter suggested that since complex service packages are difficult to unbundle and shop for in isolation, truly shoppable services should be limited to those that can be grouped into a reliable service package or are typically only administered as an independent service (which the

commenter suggests be referred to as discrete services). A few other commenters suggested that in their hospitals, all supplies, drugs, ancillary tests, anesthesia, and recovery are charged separately by contracted clinicians or facilities apart from the primary service and therefore their hospital could not meet the proposed display requirements for standard charges for shoppable services.

Response: We believe that each hospital should be able to query its administrative billing system or EHR system by CPT code to determine what other services or line items from other departments (laboratory, radiology, etc.) are typically billed with the primary shoppable service and present this in a consumer-friendly manner to prospective patients. Although this information may differ across hospitals, we anticipate this effort will be beneficial to consumers who wish to understand their likely cost of care, the items and services that are included, and how each might vary by hospital. We further believe that hospitals should have flexibility to determine how best to display the primary shoppable service as well as the associated ancillary services in a manner that is consumer-friendly. We note that many hospitals and hospital price estimator tools are already making this information available and suggest that hospitals unfamiliar with such efforts look to such tools and displays for suggestions on how to display such information in a consumer-friendly manner. Further, including ancillary services and presenting them together as a shoppable service package conforms with recommended best practice for displaying to consumers prices for shoppable services.¹⁵⁴

Further, we appreciate the suggestions made by commenters on opportunities for hospitals to report ancillary services by highest volume, frequency, and cost. Since, as the commenter noted, the availability of these services varies by hospital, we decline to impose a standard for the number and types of ancillary services provided.

We appreciate the comment about limiting shoppable services only to those that can be reliably bundled into service package and to include individual services only when they are always offered as an individual service.

We recognize that these practices may differ from hospital to hospital. Each hospital, therefore, must determine whether it customarily provides ancillary services in conjunction with the primary shoppable service and if so, how best to communicate and display them. We offer in Table 2 an example template for a display of shoppable service packages which communicates the standard charge for the primary service along with standard charges for ancillary services customarily provided by the hospital. We note that our final rules would require a hospital to display the primary shoppable service charges along with the charges for the ancillary services it provides and hospitals are not required to indicate other ancillary services that are typically furnished by other providers involved in the primary shoppable service. However, for sake of consumer-friendly presentation, we strongly encourage and recommend that the hospital indicate all ancillary services the customer may expect as part of the primary shoppable service, and to indicate they may be billed separately by other entities involved in their care for such services.

Finally, we agree that hospitals may not customarily provide ancillary services with some shoppable services. Such services may be “simple” or “discrete” as described by commenters, meaning that they are typically experienced by the consumer and billed for by the hospital in the same way—as a single service. In this case, as in the example in Table 2, such services would be listed as a single shoppable service. As a result, we are finalizing a modification to our definition of “shoppable services” to remove the reference to a “service package.” We believe removing the term “package” from the definition is necessary to clarify that not every shoppable service is a service package. In certain instances, a primary “shoppable service” may be an individual item or service or a service package. Additionally, not all shoppable services are necessarily associated with additional ancillary services. We believe this will help clarify and simplify the definition. In so doing, however, we do not intend to imply that the display of ancillary services is no longer needed or important; we are still finalizing our policy that hospitals display the ancillary services along with each primary shoppable service, as applicable.

¹⁵⁰ White C. and Eguchi M. Reference Pricing: A Small Piece of the Health Care Price and Quality Puzzle. *National Institute for Health Care Reform Research Brief Number 18* (2014). Available at: <https://www.mathematica.org/our-publications-and-findings/publications/reference-pricing-a-small-piece-of-the-health-care-price-and-quality-puzzle>.

¹⁵¹ Frost A. and Newman D. Spending on Shoppable Services in Health Care. *Health Care Cost Institute Issue Brief No. 11* (2016). Available at http://www.healthcostinstitute.org/files/Shoppable%20Services%20IB%203.2.16_0.pdf.

¹⁵² Coluni B. White Paper: Save \$36 Billion in U.S. Healthcare Spending Through Price Transparency. *Truven Health Analytics*, 2012. Available at: http://www.akleg.gov/basis/get_documents.asp?session=30&docid=14495.

TABLE 2—SAMPLE OF DISPLAY OF SHOPPABLE SERVICES

Hospital XYZ Medical Center			
Prices Posted and Effective [month/day/year]			
Notes: [insert any clarifying notes or disclaimers]			
Shoppable service	Primary service and ancillary services	CPT/HCPCS code	[Standard charge for Plan X]
Colonoscopy	primary diagnostic procedure	45378	\$750
	anesthesia (medication only)	[code(s)]	\$122
	physician services	Not provided by hospital (may be billed separately)	
	pathology/interpretation of results	Not provided by hospital (may be billed separately)	
Office Visit	facility fee	[code(s)]	\$500
	New patient outpatient visit, 30 min	99203	\$54
Vaginal Delivery	primary procedure	59400	[\$]
	hospital services	[code(s)]	[\$]
	physician services	Not provided by hospital (may be billed separately)	
	general anesthesia	Not provided by hospital (may be billed separately)	
	pain control	Not provided by hospital (may be billed separately)	
	two day hospital stay	[code(s)]	[\$]
	monitoring after delivery	[code(s)]	[\$]

Comment: Several hospital commenters expressed concern that the volume of plans, in some cases more than 100, with which they have contracted rates would present a challenge with respect to collecting and posting ancillary items and services for each primary service.

Response: In the CY 2020 OPPS/ASC proposed rule, we proposed that hospitals make public their payer-specific negotiated charges for at least 300 shoppable services in a consumer-friendly manner. We are finalizing this policy because we believe it is necessary to present hospital standard charge information in a more consumer-friendly manner than simply to make all standard charges for all items and services public in a comprehensive machine-readable file. We did not propose that hospitals display their gross charges in a consumer-friendly format because, as many hospitals commented on the FY 2019 IPPS/LTCH PPS rule in which we updated our guidance to require hospitals to make public their chargemaster rates online in a machine-readable format, such charges are not relevant to most consumers, even to self-pay consumers who are often provided discounted rates by the hospital. As discussed in more detail in section II.D of this final rule, we are also finalizing three additional types of

standard charges: (1) The discounted cash price, (2) the de-identified minimum negotiated charge, and (3) the de-identified maximum negotiated charge. We believe these types of standard charges are important and relevant to consumers and therefore will include these types of standard charges in the data elements hospitals must display in a consumer-friendly manner. We discuss this in more detail in section II.F.4 of this final rule.

We recognize that hospitals will be presenting much of their standard charge data in a manner that has historically not been made available to the public. For many hospitals, particularly large hospitals, this may involve display of data for potentially many dozens of payers and plan products. This rule will not require hospitals to change any of their charging or billing practices, but, rather, to provide their standard charge information to the public in a consumer-friendly manner, that is, in a way that more closely approximates hospital provided services as they are experienced by the consumer. A detailed assessment of the estimated burden on hospitals may be found in section V of this final rule.

We note that the final rules, as discussed in more detail in II.F.5 of this final rule, provide hospitals with

flexibility to determine the format they wish to use in order to make these data consumer-friendly and readily accessible. For hospitals that lack resources, flat files posted online may be the simplest and least expensive option. In such cases, we believe it would be reasonable and permissible under our final rules related to the consumer-friendly display of shoppable services for a hospital to post one file of shoppable services for each set of standard charges displayed. For example, the hospital could post one consumer-friendly file for each list of the payer-specific negotiated charges the hospital has established with each payer for its list of 300 shoppable services, a stand-alone consumer-friendly file of discounted cash prices for shoppable services, and a stand-alone consumer-friendly file of the de-identified minimum and maximum negotiated charges for each of the shoppable services. In this way, consumers could search for and review only the charges that are standard for their particular insurance plan for 300 shoppable services provided by the hospital in a consumer-friendly format. Self-pay individuals could search for and review a file focused on providing them with discounted cash price information for each of the shoppable services.

Final Action: We are modifying the definition of “shoppable service” to remove the phrase “shoppable service package” and finalizing a definition of “shoppable services” to mean a service that can be scheduled by a healthcare consumer in advance. We are finalizing that when the shoppable service is customarily accompanied by the provision of ancillary services, the hospital must present the shoppable service as a grouping of related services, meaning that the charge for the primary shoppable service (whether an individual item or service or service package) is displayed along with charges for ancillary services. We finalize our definition of “ancillary service” for purposes of section 2718(e) of the PHS Act to mean an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service (new 45 CFR 180.20). As explained in the CY 2020 OP/ASC proposed rule, ancillary items and services may include laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including post-anesthesia and postoperative recovery rooms), therapy services (physical, speech, occupational), hospital fees, room and board charges, and charges for employed professional services. Ancillary services may also include other special items and services for which charges are customarily made in addition to a routine shoppable service charge. For example, an outpatient procedure may include additional services that are provided by the hospital, for example, local and/or global anesthesia, services of employed professionals, supplies, facility and/or ancillary facility fees, imaging services, lab services, and pre- and post-op follow up.

3. Selected Shoppable Services

We proposed to require hospitals to make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services that we identify in Table 3 that are provided by the hospital, and as many additional shoppable services selected by the hospital as are necessary to reach a combined total of at least 300 shoppable services (new 45 CFR 180.60(a)).

In a study of 2011 claims by autoworkers, researchers identified a set of 350 frequently billed healthcare services that consumers could schedule in advance and for which there was variation in charges across providers.¹⁵⁵

¹⁵³ Health Care Cost Institute. Spending on Shoppable Services in Health Care. Issue Brief #11. March 2016. Available at: https://www.healthcostinstitute.org/images/easyblog_articles/110/Shoppable-Services-IB-3.2.16_0.pdf.

Hospitals that are early adopters of price transparency have suggested that it is possible to initially identify and display good-faith individualized price estimates for at least 350 shoppable healthcare services identified by primary billing codes (including prices for ancillary services) with more sophisticated price transparency tool developers creating and being able to display individualized pricing estimates for at least 1000 shoppable services. In contrast, most States that require hospital posting of shoppable services range in requiring 25–50 shoppable services, with California being the only State that requires the corresponding charge information to include ancillary services. In the CY 2020 OP/ASC proposed rule, we indicated that since these rules would apply to all hospitals operating in the United States, some of which may not have any experience in displaying charges for shoppable services, we believed it would be reasonable to propose a starting point of at least 300 shoppable services for which hospitals would be required to display payer-specific negotiated charges. We further indicated that we anticipated that we would increase this number over time as hospitals become accustomed to displaying charge information to consumers as a grouping of related charges and as such data is more routinely used by consumers.

We also indicated that we believed it would be reasonable to require a portion of the 300 shoppable services to be CMS-specified in order to ensure standardization that would provide consumers with the ability to compare prices across hospital settings. We stated that we further believed it would be prudent to permit hospitals to select a portion of the shoppable services themselves, recognizing that some hospitals may specialize in certain services (for example, specialized procedures) or may serve populations that utilize other shoppable services with more frequency or are more relevant than the ones we have identified for purposes of the CMS-specified services.

The proposed list of 70 shoppable services were selected based on an analysis of shoppable services that are currently made public under State price transparency requirements, a review of services that frequently appear in web-based price transparency tools, an analysis of high volume services and high cost procedures derived from External Data Gathering Environment

www.healthcostinstitute.org/images/easyblog_articles/110/Shoppable-Services-IB-3.2.16_0.pdf.

(EDGE) server data,¹⁵⁶ and a review by CMS medical officers. In other words, we used a combination of quantitative analysis of the EDGE server claims data, a qualitative review of commonly selected services for State and hospital price transparency initiatives and tools, and clinician review to ensure such services could be scheduled in advance in order to identify our list of 70 CMS-specified shoppable services.

In addition to the proposed 70 CMS-specified shoppable services, we also proposed that each hospital would select, at minimum, 230 additional shoppable services, identified by a primary HCPCS, CPT, DRG (or other widely used industry code, as applicable) and make publicly available a list of its payer-specific negotiated charges for each of those shoppable services, including the payer-specific negotiated charges for the shoppable service in both the inpatient setting and the outpatient setting, if different. We further proposed that hospitals select such services based on the utilization or billing rate of the services in the past year. We stated that we believed that enabling hospitals to select most of the shoppable services for which they make their payer-specific negotiated charges available would permit them to tailor their list of shoppable services to their specific patient populations and area of expertise. For example, a children’s hospital could select additional shoppable services that are predominantly provided to children.

Although we indicated that we believed that most hospitals would provide the 70 CMS-specified shoppable services (which are very common and frequently billed by hospitals based on our analysis of claims) it is possible that some hospitals may not offer all of them (for example, specialty hospitals). Therefore, we proposed that hospitals would make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services specified by CMS that are provided by the hospital, plus as many additional shoppable services as would be necessary to reach a total of at least 300 shoppable services.

We articulated an alternative option by which we would specify a larger set of shoppable services and allow

¹⁵⁶ Consistent with 45 CFR 153.700, in States where HHS is operating the risk adjustment program, issuers must submit enrollment, claims, and encounter data for risk adjustment-covered plans in the individual and small group markets through the External Data Gathering Environment (EDGE) servers. Issuers upload enrollee, pharmaceutical claim, medical claim, and supplemental diagnosis information from their systems to an issuer-owned and controlled EDGE server.

hospitals to select up to 70 CMS-specified shoppable services from the larger list for which it would make its payer-specific negotiated charges publicly available. The hospital would then select an additional 230 shoppable services for a total of 300 shoppable services. But we did not propose this because we believe most hospitals provide the 70 CMS-specified shoppable services and because we were concerned that more discretion would erode our desire to ensure consumers can get hospital charge information for a minimum standardized set of services.

We sought public comments on the 70 CMS-specified shoppable services we proposed. We indicated we were particularly interested in feedback regarding the specific services we identified as shoppable services and whether other services should be included because they are more common, more shoppable, or both. We also indicated we were interested in feedback on whether we should require more or less than a total of 300 shoppable services. Specifically, we sought comment from hospitals and consumers on whether a list of 100 shoppable services (or less) would be a reasonable starting point. We also sought public comment on whether we should identify more specific requirements related to hospital-selected shoppable services; for example, requiring hospitals to select their most frequently billed shoppable services (that are not included in the CMS-specified list).

Comment: Many commenters provided opinions about the number of shoppable services that hospitals would be required to display. Several commenters indicated the total number of shoppable services should be increased to more than 300. For example, one commenter suggested that the list of shoppable services be as robust as necessary, using an example of some price transparency platforms that include up to 8,000–9,000 procedures. One commenter suggested that CMS expand on the required list of 70 and leverage the experience of states to add more services. One commenter suggested that all hospital services should be displayed because any non-emergent service provided by the hospital could be scheduled in advance. In contrast, many commenters supported decreasing the total number of shoppable services, arguing that a lower number would be more manageable and less burdensome for hospitals. For example, one commenter stated that the list of shoppable services should be limited to the 70 that CMS initially provided without expanding.

Several commenters argued that requiring a total of 300 shoppable services is excessive, especially for small rural hospitals and CAHs that do not provide surgical, magnetic resonance imaging (MRI), or obstetric care, with one commenter suggesting that 75–100 total items and services would be more reasonable. One commenter suggested reducing the number of shoppable services to reflect the small number of inpatient services provided by LTCHs. One commenter specifically suggested that rather than selecting 230 shoppable services, hospitals should select 100 total services distributed evenly across the 25 highest price inpatient services, the 25 highest dollar value inpatient services (calculated using price per service multiplied by the number of services provided), the 25 highest price outpatient services, and the 25 highest dollar value outpatient services.

Response: As we indicated in the CY 2020 OPSS/ASC proposed rule, we believe that 300 shoppable services is a reasonable number based on research,¹⁵⁷ discussions with hospital executives who are early adopters and indicated it is possible to initially identify and display good-faith individualized price estimates for at least 350 shoppable healthcare services identified by primary billing codes (including prices for ancillary services), and discussions with more sophisticated price transparency tool developers who identify and display more than 1,000 shoppable services. By contrast, we recognized that most States that require hospital posting of shoppable services require 25–50 shoppable services, with California being the only State that requires the corresponding charge information to include ancillary services. Thus, we determined that 300 shoppable services would be a reasonable starting point. While we agree that nearly all hospital items and services could be considered “shoppable” because nearly all could be scheduled in advance, we continue to believe that a total of 300 services strikes a balance between the need for consumer-friendly presentation of shoppable services and hospital burden and are therefore finalizing as proposed our requirement that hospitals make public 70 CMS-specified shoppable services along with an additional 230

hospital-selected shoppable services for a total of 300 shoppable services.

Further, as indicated in the CY 2020 OPSS/ASC proposed rule, we recognized that some hospitals may not offer all 70 CMS-specified services. Therefore, we proposed and are finalizing a requirement that hospitals would make public their list of standard charges for as many of the 70 shoppable services specified by CMS that are provided by the hospital, plus as many additional shoppable services as would be necessary to reach a total of at least 300 shoppable services. We agree with commenters that selecting shoppable services based on the highest price and highest dollar value inpatient and outpatient services are good examples of criteria for hospitals to consider as they determine their hospital-selected 230 shoppable services, however, many such services are not as common as other shoppable services provided by the hospital. We believe that hospitals should make final determinations based on how commonly such services are provided to their patient population, and thus we are finalizing as proposed our requirement that hospitals select such services based on the utilization or billing rate of the services in the past year. In other words, the hospital must take into consideration the frequency with which they provide services that meet the definition of ‘shoppable’ to the patient population they serve when determining the hospital-selected shoppable services. We note that nothing would preclude a hospital from taking additional information (such as the cost of the services) into consideration as they develop their list of 230 shoppable services.

In light of commenters that asserted that some small or specialty hospitals may not offer 300 services that could be scheduled by consumers in advance, we are modifying our requirements to finalize a policy that in cases where a hospital does not provide 300 services that could be scheduled by consumers in advance, the hospital must list as many of the services it provides that could be scheduled by patients in advance (that is, the hospital must list as many shoppable services as it provides).

Comment: Several commenters cited the need for uniformity in hospital selection of shoppable services. A few commenters agreed that shoppable services should be standardized to allow for comparability for consumers. A few commenters argued that patients would not be able to adequately compare pricing information for the items and services in 70 CMS-identified shoppable services that are performed in non-

¹⁵⁷ White C. and Eguchi M. Reference Pricing: A Small Piece of the Health Care Price and Quality Puzzle. *National Institute for Health Care Reform Research Brief Number 18* (2014). Available at: <https://www.mathematica.org/our-publications-and-findings/publications/reference-pricing-a-small-piece-of-the-health-care-price-and-quality-puzzle>.

hospital settings. One commenter suggested that CMS define a specific CPT code range to clarify which procedures are required among the list of shoppable services to ensure uniformity and accuracy. One commenter suggested that these requirements be phased in gradually, starting with a requirement to post standard charges for “simpler” visits initially, and then include surgeries, DRGs, and services that are more complicated. A few commenters expressed concerns that the variability in how hospitals bundle items and services would not yield accurate consumer comparisons for shoppable services.

Response: To ensure some degree of uniformity in the shoppable services hospitals make public in a consumer-friendly manner, we proposed and are finalizing 70 CMS-specified hospital services identified by CPT and other commonly used billing codes. As we stated in the CY 2020 OPPTS/ASC proposed rule, the list of 70 shoppable services were selected based on an analysis of shoppable services that are currently made public under State price transparency requirements, a review of services that frequently appear in web-based price transparency tools, an analysis of high volume services and high cost procedures derived from EDGE server data,¹⁵⁸ and a review by CMS medical officers. In other words, we used a combination of quantitative analysis of the EDGE server claims data, a qualitative review of commonly selected services for State and hospital price transparency initiatives and tools, and clinician review to ensure such services could be scheduled in advance in order to identify our list of 70 CMS-specified shoppable services. Based on this analysis, we believe that these 70 CMS-specified shoppable services are commonly provided by hospitals and we believe hospital display of these services will ensure consumers have access to standard charges for a minimum set of shoppable services.

We recognize that many of the shoppable services included on the list of 70 CMS-specified services are provided by settings other than hospitals; however, our requirements apply only to hospitals (as defined at 45

CFR 180.20), and not when they are provided by non-hospital sites of care. Therefore this information is useful to consumers when they are comparing services across hospital settings. While non-hospital sites of care are not subject to these regulations we are finalizing, we encourage non-hospital sites of care that offer the same shoppable services to standardize their displays of charges so that consumers have more options and information available to them.

We appreciate that beginning with “simpler” shoppable services could provide a phased pathway for hospitals to make public their shoppable services; however, we decline to adopt this approach because some of the more “complex” shoppable services are those for which consumers routinely shop (for example, colonoscopy or vaginal delivery). We recognize that there may be some variability in the method used by hospitals to establish and display standard charges for shoppable primary services and associated ancillary services, and we encourage hospitals to communicate in consumer-friendly ways what is or is not included in the hospital’s prices for a shoppable service and its ancillary services.

Comment: Several commenters offered comments related to the services included on the CMS-specified list of 70 shoppable services. For example, one commenter provided a list of 23 services they suggested removing from the 70 CMS-specific shoppable services due to their variability in cost, charge structure, charge amounts, and associated complexity for providers to develop a sound “proposed rate.” The list provided by the commenter included procedures identified by DRG that are typically divided into those with and without major comorbid conditions or complications (MCC).

A few commenters indicated their belief that the services provided by cancer hospitals are not shoppable, and one commenter argued that the list of 70 CMS-specified shoppable services are irrelevant to cancer hospitals because cancer hospitals do not offer standalone services (such as imaging, laboratory or surgical services). Instead, such hospitals provide integrated disease management with disease-specific financial counseling. One commenter indicated that specialty hospitals (such as children’s hospitals, orthopedic, or cancer facilities) should have customized lists of shoppable services.

A few commenters requested that Evaluation and Management (E&M) services be removed from the list because E&M services are billed by providers in an office setting and not hospitals. A few commenters requested

that laboratory testing be removed from the list with one commenter requesting that CMS remove 14 routine laboratory tests included in the required list of 70 shoppable items and services because they are among the least costly services and are less central to patients’ economic and site of care decisions, and suggested that CMS replace them with higher cost procedures more likely to be separately paid when performed in a hospital setting. One commenter stated that the list of shoppable services is too long and includes codes that are not billed by many hospitals and rarely scheduled in advance, for example, laboratory tests and CPT code 93000 for electrocardiogram. By contrast, one commenter encouraged CMS to include clinical laboratory test pricing as part of the standard charge information hospitals are required to post, and requested that CMS ensure the requirements under this rule are consistent with the type of data required to be reported to CMS under section 216(a) of the Protecting Access to Medicare Act (PAMA).

One commenter requested clarification on whether posting an average charge based on historical cases would be sufficient if the hospital does not charge based on the specific CMS-specified CPT or DRG codes. Another commenter pointed out that the standard DRG codes in the list of 70 CMS-specified shoppable services correspond to MS-DRGs and not to DRGs used by third party payers (for example, All Patients Refined (APR)-DRGs). One commenter requested clarification on how the 70 CMS-specified shoppable services would be categorized asking whether it would be DRG for all inpatient services only, and if so, what is the packaging type for ambulatory services.

Response: We appreciate that specialty hospitals offer services that are different from most hospitals, however, we do not believe that should be an impediment to specialty hospitals displaying their charges for shoppable services. Similarly, we believe our requirements have addressed situations in which a hospital does not provide one or more of the 70 CMS-specified shoppable services. Specifically, we proposed and are finalizing a requirement that if a hospital does not provide some of the 70 CMS-specified services, then the hospital would identify enough shoppable services that it commonly provides to its unique patient population so that the total number of shoppable services is at least 300. We believe this policy will ensure that the shoppable services posted are standardized as much as possible across

¹⁵⁸ Consistent with 45 CFR 153.700, in States where HHS is operating the risk adjustment program, issuers must submit enrollment, claims, and encounter data for risk adjustment-covered plans in the individual and small group markets through the External Data Gathering Environment (EDGE) servers. Issuers upload enrollee, pharmaceutical claim, medical claim, and supplemental diagnosis information from their systems to an issuer-owned and controlled EDGE server.

all hospitals while also ensuring specialty hospital have flexibility to make public the most relevant shoppable services for their unique patient populations.

The 70 CMS-specified shoppable services are found in Table 3 and are divided into four broad categories: E&M Services, Laboratory and Pathology Services, Radiology Services, Medicine and Surgery Services. While some such services (for example, E&M or laboratory services) may not be the most expensive hospital services, our analysis indicates they are commonly billed and are healthcare services that are commonly shopped. Such services may be billed by a hospital as part of a hospital inpatient or outpatient visit. As noted above, to the extent such services are not provided by a hospital, the hospital may select additional shoppable services that are relevant to its patient population.

We appreciate commenters who pointed out that the codes numbers listed for DRG procedures are MS-DRG codes and not APR-DRGs or other third party payer service package codes. We recognize this could also be the case for other CMS-specified services that are routinely negotiated by hospitals with third party payers as packaged services. For example, the same or similar shoppable service may be paid as a service package by two different payers that use two different common billing codes (for example, an MS-DRG by Medicare versus an APR-DRG by another third party payer). As such, we will permit hospitals to make appropriate substitutions and cross-walks as necessary to allow them to display their standard charges for the shoppable services across all their third party payers. Average charges based on prior years would not be acceptable as an average charge is not one of the types

of standard charges we are finalizing in this rule.

Section 1834A of the SSA, as established by section 216(a) of the PAMA, required significant changes to how Medicare pays for clinical diagnostic laboratory tests under the Clinical Laboratory Fee Schedule. Laboratories, including independent laboratories, physician office laboratories and hospital outreach laboratories, that meet the definition of an applicable laboratory are required to report applicable information, which generally includes each private payor rate for each clinical diagnostic laboratory test for which final payment has been made during the data collection period, the associated volume of tests performed corresponding to each private payor rate, and the specific HCPCS code associated with the test. We do not believe that any of the provisions under this rule conflict with or duplicate the requirements under section 1834A of the SSA. While consumer-friendly display of shoppable laboratory services may include similar data (such as payer-specific negotiated charges), the requirement under this rule is to provide that information in a consumer-friendly format to which consumers have easy access.

We decline to make any changes in our list of CMS-specified shoppable services. As explained in the CY 2020 OPPS/ASC proposed rule, we used a combination of quantitative analysis of the EDGE server claims data, a qualitative review of commonly selected services for State and hospital price transparency initiatives and tools, and clinician review to ensure such services could be scheduled in advance in order to identify our list of 70 CMS-specified shoppable services. We are therefore finalizing the 70 CMS-specified shoppable services as proposed.

Final Action: We are finalizing as proposed our requirement for hospitals to make public their standard charges for as many of the 70 shoppable services that we identify in Table 3 that are provided by the hospital, and as many additional shoppable services selected by the hospital as is necessary for a combined total of at least 300 shoppable services (new § 180.60(a)). In response to comments, we are adding a requirement that if a hospital does not provide 300 shoppable services, the hospital must list as many shoppable services as they provide. These requirements will be finalized at 45 CFR 180.60(a). We will also permit hospitals to make appropriate coding substitutions and cross-walks as necessary to be able to display their standard charges for the 70 CMS-specified services across third party payers.

We are further finalizing as proposed that in selecting a shoppable service, a hospital must consider the rate at which it provides and bills for that shoppable service. In other words, the shoppable services selected for display by the hospital should be commonly provided to the hospital's patient population. We note that this proposal, which discussed in the CY 2020 OPPS/ASC proposed rule (84 FR 39589) was inadvertently omitted from the proposed regulation text but we are including it at new 45 CFR 180.60(a).

Finally, we clarify that hospitals should cross-walk and use, as applicable, an appropriate payer-specific billing code (for example, an APR-DRG code) in place of the MS-DRG code indicated for the five procedures in the list of 70 CMS-specified shoppable services that are identified by MS-DRG codes 216, 460, 470, 473, and 743.

TABLE 3—FINAL LIST OF 70 CMS-SPECIFIED SHOPPABLE SERVICES

Evaluation & management services	2020 CPT/HCPCS primary code
Psychotherapy, 30 min	90832
Psychotherapy, 45 min	90834
Psychotherapy, 60 min	90837
Family psychotherapy, not including patient, 50 min	90846
Family psychotherapy, including patient, 50 min	90847
Group psychotherapy	90853
New patient office or other outpatient visit, typically 30 min	99203
New patient office of other outpatient visit, typically 45 min	99204
New patient office of other outpatient visit, typically 60 min	99205
Patient office consultation, typically 40 min	99243
Patient office consultation, typically 60 min	99244
Initial new patient preventive medicine evaluation (18–39 years)	99385
Initial new patient preventive medicine evaluation (40–64 years)	99386

Laboratory & pathology services	2020 CPT/HCPCS primary code
Basic metabolic panel	80048
Blood test, comprehensive group of blood chemicals	80053
Obstetric blood test panel	80055
Blood test, lipids (cholesterol and triglycerides)	80061
Kidney function panel test	80069
Liver function blood test panel	80076
Manual urinalysis test with examination using microscope	81000 or 81001
Automated urinalysis test	81002 or 81003
PSA (prostate specific antigen)	84153–84154
Blood test, thyroid stimulating hormone (TSH)	84443
Complete blood cell count, with differential white blood cells, automated	85025
Complete blood count, automated	85027
Blood test, clotting time	85610
Coagulation assessment blood test	85730
Radiology services	2020 CPT/HCPCS primary code
CT scan, head or brain, without contrast	70450
MRI scan of brain before and after contrast	70553
X-Ray, lower back, minimum four views	72110
MRI scan of lower spinal canal	72148
CT scan, pelvis, with contrast	72193
MRI scan of leg joint	73721
CT scan of abdomen and pelvis with contrast	74177
Ultrasound of abdomen	76700
Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus	76805
Ultrasound pelvis through vagina	76830
Mammography of one breast	77065
Mammography of both breasts	77066
Mammography, screening, bilateral	77067
Medicine and surgery services	2020 CPT/HCPCS primary code
Cardiac valve and other major cardiothoracic procedures with cardiac catheterization with major complications or comorbidities	216
Spinal fusion except cervical without major comorbid conditions or complications (MCC)	460
Major joint replacement or reattachment of lower extremity without major comorbid conditions or complications (MCC)	470
Cervical spinal fusion without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	473
Uterine and adnexa procedures for non-malignancy without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	743
Removal of 1 or more breast growth, open procedure	19120
Shaving of shoulder bone using an endoscope	29826
Removal of one knee cartilage using an endoscope	29881
Removal of tonsils and adenoid glands patient younger than age 12	42820
Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope	43235
Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope	43239
Diagnostic examination of large bowel using an endoscope	45378
Biopsy of large bowel using an endoscope	45380
Removal of polyps or growths of large bowel using an endoscope	45385
Ultrasound examination of lower large bowel using an endoscope	45391
Removal of gallbladder using an endoscope	47562
Repair of groin hernia patient age 5 years or older	49505
Biopsy of prostate gland	55700
Surgical removal of prostate and surrounding lymph nodes using an endoscope	55866
Routine obstetric care for vaginal delivery, including pre-and post-delivery care	59400
Routine obstetric care for cesarean delivery, including pre-and post-delivery care	59510
Routine obstetric care for vaginal delivery after prior cesarean delivery including pre-and post-delivery care	59610
Injection of substance into spinal canal of lower back or sacrum using imaging guidance	62322–62323
Injections of anesthetic and/or steroid drug into lower or sacral spine nerve root using imaging guidance	64483
Removal of recurring cataract in lens capsule using laser	66821
Removal of cataract with insertion of lens	66984
Electrocardiogram, routine, with interpretation and report	93000
Insertion of catheter into left heart for diagnosis	93452
Sleep study	95810
Physical therapy, therapeutic exercise	97110

4. Required Corresponding Data Elements

We proposed that the consumer-friendly charge information the hospital makes available to the public online for the CMS and hospital-selected shoppable services must include certain corresponding data elements in order to ensure that consumers understand the hospital's payer-specific negotiated charge for each shoppable service and can use that information to make comparisons across hospitals. Specifically, we proposed that the consumer-friendly display of payer-specific negotiated charge information contain the following corresponding information for each of the 70 CMS-specified and at least 230 hospital-selected shoppable services:

- A plain-language description of each shoppable service. For example, hospitals would not be required, but are invited, to review and use the Federal plain language guidelines.¹⁵⁹
- The payer-specific negotiated charge that applies to each shoppable service. If the hospital does not provide one or more of the CMS-specified shoppable services, the hospital may indicate "N/A" for the corresponding charge or otherwise make it clear that the service is not provided by the hospital. Each payer-specific charge must be clearly associated with the name of the third party payer.
- A list of all the associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service.
- The location at which each shoppable service is provided by the hospital (for example, Smithville Campus or XYZ Clinic), including whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both. If the payer-specific negotiated charge for the shoppable service varies based upon location or whether the hospital provides the shoppable service in the inpatient versus the outpatient setting, the hospital would be required to identify each payer-specific negotiated charge.
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, but not limited to, the CPT code, the HCPCS code, the DRG, or other commonly used service billing code.

We proposed that hospitals make public the payer-specific negotiated charge for a shoppable service in a manner that groups the payer-specific negotiated charge for the primary shoppable service along with charges for associated ancillary services because we believe charge information displayed in such a way is consumer-friendly and patient-focused. In other words, we believe that consumers want to see and shop for healthcare services in the way they experience the service. We recognized that not all hospitals will customarily provide exactly the same ancillary items or services with a primary shoppable service and therefore we believe it is important for hospitals to display a list of which ancillary services are included in conjunction with or as part of the primary shoppable service.

We proposed to codify these proposed required data elements at proposed new 45 CFR 180.60(b). We sought public comments on these data elements and whether there are additional data elements that should be displayed to the public in a consumer-friendly manner. We emphasized that nothing in our proposal was meant to inhibit or restrict hospitals from including additional data elements that would improve the ability of healthcare consumers to understand the hospital's charges for shoppable services.

Comment: Some commenters offered suggestions on specific data elements they felt would be necessary to provide consumers with accurate understanding of the shoppable services provided by hospitals. For example, one commenter suggested that CMS specifically require that hospitals list both their technical and professional fees to provide a more accurate picture of potential costs. The commenter argued that including such charges would reduce the likelihood of surprise billing as these additional fees often come in the form of an additional charge or bill to consumers. The commenter cited a new state law in Minnesota requiring that all provider-based clinics that charge a separate facility fee for visits give notice to patients and publicly post a disclosure on their website stating that patients may receive a separate charge or billing for the facility component, which may result in a higher out-of-pocket expense. Another commenter suggested the consumer-friendly display of standard charges should take into account cost-shifting and uncompensated care, federal requirements such as EMTALA, the availability of providers for after-hours care, and whether the provider takes all forms of payment.

A few commenters expressed concern that the proposal does not provide hospitals adequate specificity as to how the data should be formatted to ensure that information is meaningful and presented in a consumer-friendly manner. Many commenters stated that display of standard charges for shoppable services would be incomplete without corresponding data on healthcare quality to allow consumers to understand value. A few commenters recommended requiring hospitals to include quality information alongside price in a meaningful way, with one suggesting that we also draw on the large body of research on healthcare quality measures and presentation format, including volume information. The commenter, however, cautioned that if CMS took this route, procedure complications data would be difficult for consumers to interpret. The commenter recommended that leveraging key measures already being used in various quality efforts, in addition to aligning measures across public and private payers, could help reduce consumer confusion. One commenter urged CMS to establish a Health Quality Roadmap in reference to section 4 of the June 24, 2019 Executive Order on Improving Price and Quality Transparency to establish common quality measurements, align inpatient and outpatient measures, and eliminate low-value or counterproductive measures. The commenter suggested that quality and outcomes data is more valuable to patients than transparency of hospital charges, arguing that they provide information for patients to seek out providers with the best track record. The commenter stated that providing data on readmissions, frequency or revision surgery and mortality, and especially elective procedures such as total joint arthroplasty, would encourage providers to use the best protocols.

Several commenters indicated that information on provider referrals as a required element would be necessary to decrease healthcare costs and to shift consumers to lower cost and higher quality options. One commenter stated that further outreach is necessary to determine what kinds of price information and which methods of display would influence consumer behavior.

As noted in section II.D.4 of this final rule, several commenters supported including a definition of standard charges to reflect the discounted cash price that would be given to a self-pay consumer and the de-identified minimum and maximum negotiated charges because they believe this

¹⁵⁹ See Federal plain language guidelines, available at <https://plainlanguage.gov/guidelines/>.

information would be beneficial and relevant to consumers. A few commenters believed such standard charges could be confusing to consumers.

Response: We recognize many state legislatures have undertaken efforts to reduce surprise billing and applaud such efforts. We are finalizing as proposed our requirement that hospitals make public and display all ancillary items and services they provide with the primary shoppable service as one of the required data elements. As part of our requirements, hospitals would be required to display facilities fees and fees for services of employed clinicians. However, in accordance with our final policies for defining hospital items and services (section II.C of this final rule) hospitals would not be required to make public the professional fees for all clinicians practicing in hospital-based clinics. We note that nothing in this rule would prevent hospitals from undertaking disclosure charges for all clinicians practicing in a hospital-based clinics, however, and encourage hospitals to do so as a way of improving price transparency for consumers.

We thank commenters for their interest in improving consumer awareness of quality data. We agree that quality is a necessary consideration for consumers deciding on how and where to obtain the highest value medical items and services, however, section 2718(e) of the PHS Act does not require hospitals to disclose quality information. We note that comparative hospital quality information is readily available to the public¹⁶⁰ and that nothing in this final rule would prohibit hospitals from posting quality information along with their standard charge information. We further note that we included an RFI in the CY 2020 OPPS/ASC proposed rule so as to gather feedback that we may consider for our ongoing price transparency and value-based initiatives.

Similarly, although data elements such as referrals, additional places of service, availability of the provider for after-hours care, and what form of payment the provider accepts are all important considerations in driving improvements in value care, we believe requiring hospital disclosure of these data elements is beyond the scope of section 2718(e) of the PHS Act. In addition, we believe our policies represent a balance between data elements that would be useful for the public while being sensitive to

hospitals' burden in meeting requirements. We note, however, that nothing in this final rule would prevent a hospital from displaying additional data elements it believes the public would find useful.

Finally, we are making several modifications to the list of data elements that hospitals would be required to make public for its consumer-friendly display of standard charges.

First, we are modifying the list of data elements to align with and include the three new types of standard charges we finalized in section II.D of this final rule. Specifically, we will include the discounted cash price, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge, along with other necessary conforming changes to the list of required data elements throughout. Specifically, we are finalizing the following as data elements:

- The payer-specific negotiated charge that applies to each shoppable service (and corresponding ancillary services, as applicable). We clarify that the hospital must identify and clearly associate each set of payer-specific negotiated charges with the name of the third party payer and plan. For example the hospital's list of payer-specific negotiated charges for Payer X's Silver Plan could be in one tab or column in a spreadsheet titled "Payer X: Silver Plan" while the list of payer-specific negotiated charges for Payer Y's Gold Plan could be in another tab or column titled or labeled as "Payer Y: Gold Plan."
- The discounted cash price that applies to each shoppable service (and corresponding ancillary services, as applicable). If the hospital does not offer a discounted cash price for one or more shoppable services (or corresponding ancillary services), the hospital must list its gross charge.
- The de-identified minimum negotiated charge that applies to each shoppable service (and corresponding ancillary services, as applicable).
- The de-identified maximum negotiated charge that applies to each shoppable service (and corresponding ancillary services, as applicable).

Second, in the list of data elements related to the types of standard charges, we are finalizing a few clarifying edits to ensure hospital understanding that the requirement to display the standard charge for a shoppable service applies to each primary shoppable service and to each corresponding ancillary service (as applicable). In other words, the display of standard charges for the shoppable service grouping means display of each

charge of the component parts of the shoppable service grouping (for example, the hospital must list the charge associated with the primary shoppable service plus the charge(s) for each ancillary service not already included in the primary shoppable service). In so doing, we are removing the separate requirement to list all the associated ancillary services and instead incorporating the requirement into the list of data elements related to the types of standard charges.

Third, we are clarifying that if the hospital does not offer one or more of the 70 CMS-specified shoppable services, the hospital must clearly indicate that fact with respect to every type of standard charge required for consumer-friendly display. The hospital may use "N/A" for the corresponding charge or use another appropriate indicator to communicate to the public that the service is not provided by the hospital. We are finalizing this requirement as a separate data element.

Fourth, we are finalizing the requirement that the hospital include a plain-language description of each shoppable service, as proposed. For example, hospitals would not be required but are invited to review and use, the Federal plain language guidelines.¹⁶¹ Fifth, we are modifying the data element related to the location of each shoppable service in light of the additional types of standard charges that hospitals must list for the shoppable services to refer more broadly to the "standard charges" rather than to "payer-specific negotiated charges" in each instance it appears. Specifically, we are finalizing that the location at which each shoppable service is provided by the hospital (for example, Smithville Campus or XYZ Clinic), including whether the *standard charges* for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both. If the *standard charge* for the shoppable service varies based upon location or whether the hospital provides the shoppable service in the inpatient versus the outpatient setting, the hospital would be required to identify each *set of standard charges*.

Finally, we are finalizing without modification the requirement to display any primary code used by the hospital for purposes of accounting or billing for the shoppable service and associated ancillary services, including, but not limited to, the CPT code, the HCPCS code, the DRG, or other commonly used

¹⁶⁰ AHRQ website, Comparative Reports on Hospitals, at <https://www.ahrq.gov/talkingquality/resources/comparative-reports/hospitals.html>.

¹⁶¹ See Federal plain language guidelines, available at <https://plainlanguage.gov/guidelines/>.

service billing code. We note that, as discussed in section II.F.3 of this final rule, hospitals may use, as applicable, an appropriate payer-specific billing code (for example, an APR-DRG code) in place of the MS-DRG code indicated for the five procedures in the list of 70 CMS-specified shoppable services that are identified by MS-DRG codes 216, 460, 470, 473, and 743.

Comment: Several commenters raised concerns with the time, effort, and technical challenges for hospitals of posting billing and charge codes as part of the consumer-friendly display of standard charge data for shoppable services. One commenter stated that the coding elements and concepts required do not exist or are not maintained in hospital chargemasters, but flow to posted charges through other interfaces. Several commenters indicated they believed that the size and scope of the data that would need to be presented would be quite large, with commenters estimating that the resulting file could be 300 lines long with dozens of columns or could lead to 100,000 rows of data with millions of fields. One commenter indicated that the size and complexity of the data might crash the hospital's website. One commenter stated that in order to compile, display, and maintain service packages for the select shoppable services, a sophisticated relational database analysis with web-based display modules would be necessary unless the hospital has existing software. Similarly, another commenter stated that to comply with the new regulation, it would need to work with its web development team and EHR management system vendor to build a shopper functionality and benefits engine and hire additional vendors to maintain functionality and accuracy. One commenter recommended that CMS take additional time to ensure that posting data for shoppable services is fairly applied across provider types and does not require an abundance of resources. One commenter stated that presenting their standard charge information in a consumer-friendly manner would be difficult for hospitals, for example, rural hospitals and CAHs that rely on cost-based reimbursement, that are unable to afford a vendor for software that would aid in the posting of standard charge data.

Response: We acknowledge that not all data elements required for the display of hospital standard charges in a consumer-friendly manner can be derived solely from a hospital's chargemaster. The set of standard charges found in the hospital chargemaster are only one type of

standard charges—the gross charges—which are the undiscounted rates for individual items and services; as pointed out by hospitals that submitted comments in the FY 2019 IPPS/LTCH PPS (83 FR 41686 through 41688), the gross charge does not apply to most consumers of hospital services, for example, consumers with third party payer coverage. In other words, the gross charge is not a standard charge for approximately 90 percent of the hospital's customers who have third party payer coverage. The set of standard charges that applies to consumers with third party payer coverage are the payer-specific negotiated charges the hospital has established with the consumer's third party payer. Such charges are not a part of the hospital's chargemaster. Moreover, many payer-specific standard charges have been negotiated for service packages, as opposed to individual items and services that are listed in the hospital chargemaster. Thus, the data elements required for making public standard charges in a consumer-friendly manner will require hospitals to look beyond their chargemasters and pull the relevant data out of their other accounting and billing systems.

Additionally, we acknowledge that the benefits of compiling these data elements and presenting them in a consumer-friendly manner will likely require more thoughtful effort on the part of hospitals than simply making all their standard charge information public in a comprehensive machine-readable file. For example, identifying and listing the standard charges for ancillary services along with the primary shoppable service may take some thought and clinical input. Translating internal code descriptions into a consumer-friendly plain-language description for items and services provided by the hospital may also require some thought. However, we disagree that consumer-friendly display of hospital standard charge information would overwhelm or "crash" a hospital's website, or that the requirements would necessitate the development of an elaborate or expensive tool. As suggested in section II.F.3 of this final rule, we believe there are low-tech and inexpensive ways to compile hospital standard charge information in files posted online that are consumer-friendly, and, in Table 2, we have offered an example of how a hospital might consider making such information public.

Additionally, we note that we are modifying our list of required data elements to align with and reflect the final policies related to the definition of

"standard charge" as discussed in section II.D of this final rule. As such, the list of data elements would include the discounted cash price, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for each of the 300 shoppable services and their associated ancillary services. Accordingly, and in light of comments, we have increased our burden estimate (section V of this final rule) to reflect and recognize that hospitals may need to put more time and thought into ensuring that their standard charge information is presented in a consumer-friendly manner than we initially believed and to account for posting additional types of standard charges, specifically, the addition of the discounted cash price and the display of the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge for each shoppable service and corresponding ancillary services.

Final Action: We are specifying the data elements that hospitals must include in their online posting of shoppable services in order to ensure that consumers understand the hospital's standard charges for each shoppable service and can use that information to make comparisons across hospitals.

As noted in responses to comments, we are making several clarifying edits and modifications to align with final policies including: (1) Modifications to align with and include the three new types of standard charges we are finalizing in section II.D of this final rule, (2) we are removing the separate requirement to list all the associated ancillary services and instead incorporating the requirement into the list of data elements related to the types of standard charges, (3) finalizing as a separate data element and clarifying that if a hospital does not offer one or more of the 70 CMS-specified shoppable services, the hospital must clearly indicate that fact with respect to every type of standard charge required for consumer-friendly display, and (4) modifying the data element related to the location of each shoppable service in light of the additional types of standard charges that hospitals must list for the shoppable services to refer more broadly to the three types of standard charges referred to in the section, rather than to "payer-specific negotiated charges" in each instance it appears.

In summary, we are specifying in new 45 CFR 180.60(b) that hospitals must include, as applicable, all of the following corresponding data elements when displaying the three types of

standard charges for its list of shoppable services:

- A plain-language description of each shoppable service.
- An indicator when one or more of the CMS-specified shoppable services are not offered by the hospital.
- The payer-specific negotiated charge that applies to each shoppable service (and to each ancillary service, as applicable). Each list of payer-specific negotiated charges must be clearly associated with the name of the third party payer and plan.
- The discounted cash price that applies to each shoppable service (and corresponding ancillary services, as applicable). If the hospital does not offer a discounted cash price for one or more shoppable services (or corresponding ancillary services), the hospital must list its undiscounted gross charge.
- The de-identified minimum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).
- The de-identified maximum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).
- The location at which the shoppable service is provided, including whether the standard charges for the hospital's shoppable service applies at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both.
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, as applicable, the CPT code, the HCPCS code, the DRG, or other common service billing code.

We note that, as discussed in section II.F.3 of this final rule, hospitals may use, as applicable, an appropriate payer-specific billing code (for example, an APR-DRG code) in place of the MS-DRG code indicated for the five procedures in the list of 70 CMS-specified shoppable services that are identified by MS-DRG codes 216, 460, 470, 473, and 743.

5. Format of Display of Consumer-Friendly Information

In the CY 2020 OPPI/ASC proposed rule, we indicated that we were aware that many hospitals are already communicating charge information to patients in a variety of ways. Some are already making public various types of standard charges for shoppable services available online in various formats. For example, some hospitals offer searchable price transparency tools on

their website that offer estimated charges (averages or individualized out-of-pocket costs) or may display charges for shoppable services in brochures (both online and offline) that contain self-pay discounted prices for a service package. In the CY 2020 OPPI/ASC proposed rule, we indicated that we believed many hospitals are already already meeting or exceeding our proposed requirements by offering, for example, patient-friendly price transparency tools that calculate individualized out-of-pocket cost estimates. We sought comment on whether offering such tools could qualify a hospital to be excepted from some of the proposed requirements, for example, the consumer-friendly display requirements (84 FR 39576).

We further noted in the CY 2020 OPPI/ASC proposed rule that because there are a variety of consumer-friendly ways to display charges for hospital services and because we did not want to restrict hospitals from innovating or from having to duplicate efforts, we did not propose to require hospitals to use a specific format for making such data public online in a consumer-friendly manner. Specifically, unlike our proposals for the comprehensive machine-readable list of standard charges for all items and services (discussed in section II.E of this final rule), we did not propose to require that hospitals make payer-specific charge data public in a single digital file posted online. Instead, we proposed that hospitals retain flexibility on how best to display the payer-specific negotiated charge data and proposed associated data elements to the public online, so long as the website is easily accessible to the public. We indicated that we believed this approach would permit some flexibility for hospitals to, for example, post one or more files online with a list of payer-specific charges for the shoppable services and associated data elements, or, for example, to integrate such data into existing price estimate tools.

Additionally, we did not propose, but considered, an option that would require hospitals to make these data available in API format. As explained in more detail in section II.E.3. of this final rule, an API enabled format could allow consumers to access the data by searching for it directly when they do not have a computer by, for example, putting a CPT code in the URL path of the hospital to render in one's mobile phone browser the gross or payer-specific negotiated charge for the service. For example, a consumer searching for the price of a blood test for cholesterol (CPT code 80061) at fictional

hospital ABC could look it up by inserting the URL path <https://hospitalABC.com/api/80061>.

We further recognized not all consumers have access to the internet. Therefore, we proposed to require that hospitals make certain data elements available in a consumer-friendly manner offline (84 FR 39589 through 39590). Specifically, we proposed that the hospital would provide a paper copy (for example, a brochure or booklet) of the information to consumers upon request within 72 hours of the request. We proposed to codify this provision at proposed new 45 CFR 180.60(c).

Comment: A few commenters expressed concern that the proposal did not provide hospitals adequate specificity as to how the data should be formatted to ensure that information is meaningful and presented in a consumer-friendly manner.

A few commenters indicated that the requirement to provide to the patient "a paper copy (for example, a brochure or booklet)" of the information is available to consumers upon request within 72 hours of the request" would be challenging to implement because it would be costly and time consuming, and the volume of data would be enormous. Two commenters suggested hospitals should be able to charge a fee to cover the costs of printing a paper copy. One commenter suggested that if individuals do not have access to internet, public libraries provide free internet access to patrons. Two commenters suggested that CMS should permit hospitals to limit the size and contents of the patient-requested paper equivalent (for example, limiting the response to the payer-specific negotiated charges that apply to the individual's circumstances).

Response: In the CY 2020 OPPI/ASC proposed rule we indicated that, because there are a variety of consumer-friendly ways to display charges for hospital services and because we did not want to restrict hospitals from innovating or from having to duplicate efforts, we did not propose to require hospitals to use a specific format for making such data public online in a consumer-friendly manner. We therefore proposed and are finalizing a policy that hospitals retain flexibility on how best to display their standard charge data and proposed associated data elements to the public in a consumer-friendly manner online, so long as the online information is easily accessible to the public. We continue to believe that this approach would permit some flexibility for hospitals to, for example, post one or more files online with a list of payer-specific charges for

the shoppable services and associated data elements, or, for example, to integrate such data into existing price estimate tools. We have included a sample template in Table 2 as an example of the format that would meet our requirements, although hospitals are not required to use this template.

Additionally, in light of our final policy to permit hospitals flexibility to choose an appropriate format, we are not finalizing the proposal that the hospital make available a paper copy. We generally agree with commenters who indicated that a paper format could be burdensome, however, if we determine that lack of a paper copy of hospital standard charges is preventing consumers from accessing hospital charge information, we may revisit this in future rulemaking.

Comment: Commenters stated that they were concerned that consumer-friendly display of standard charges for shoppable services might not provide the consumer with sufficient understanding of their actual costs, with several commenters expressing concern that the payer-specific negotiated charge would differ significantly based on the severity of the patient's condition, leading to variation between the amount displayed in a consumer-friendly format and the amount received by the hospital from the third-party payer. Because of this, commenters suggested that, in order to display standard charges in a "consumer-friendly" format, the information must include data on out-of-pocket costs, with several commenters stating that this information should be specific to the individual's health insurance plan.

Response: We recognize the need and desire for consumers to anticipate their out-of-pocket costs. We believe understanding the payer-specific negotiated charge is a necessary first step towards consumers having insight into the cost of their healthcare and being in a better position to choose the healthcare coverage and setting that is most advantageous to them. We expect consumers will use the hospital standard charge information in conjunction and communication with their providers and carriers to understand their unique cost sharing obligations. Further, we agree that a consumer-friendly online display of shoppable services that would return an immediate out-of-pocket price estimates is preferable to a flat file of standard charges posted online. For this reason we considered and are finalizing as described in more detail below, a policy to deem a hospital price estimator tool as meeting some of the requirements under 45 CFR 180.60. We agree with

commenters who indicated that sometimes circumstances during the course of treatment can alter price estimates and because of this we encourage hospitals to continue to engage in patient education, communication, and heightened transparency regarding the cost estimates they provide.

We further emphasize that hospitals are not precluded from providing customized one-on-one financial counseling to consumers, and we applaud hospitals that take the additional step to provide this information to consumers on an individual basis through financial counseling in addition to meeting the posting requirements for the public files.

Comment: Many commenters indicated that many hospitals are already communicating financial obligations to consumers in advance in a variety of consumer-friendly ways. For example, several commenters stated that many hospitals provide good faith estimates, financial counseling services, or have available call centers and/or patient-friendly pricing tools on their websites for use by patients. A few commenters asserted that providing patient-specific estimates, such as a patient's likely out-of-pocket costs based on data provided by the patient's insurer, is more helpful to consumers than sharing charges online as proposed because such information is personalized based on individual circumstances.

Some commenters specifically requested relief from one or more of the requirements under this rule as a result of hospital efforts to communicate personalized out-of-pocket information. Specifically, a few commenters suggested that hospitals that already provide internet-based price estimator tools or good faith estimates to consumers (for brevity, we henceforth refer to such an application as a price estimator tool) be exempt from the requirements of the rule. For example, one commenter suggested that if hospitals offer tools that allow patients to obtain out-of-pocket estimates for 300 shoppable services (including the 70 specified by CMS), they should be considered to have met their obligations under the rule. This commenter further suggested that CMS could set the expectation that hospitals opting for this approach provide estimates for all payers with which they have negotiated rates. A few commenters suggested that this flexibility to provide consumer-friendly charge information in this manner would be beneficial for reasons such as mitigating the risk of disclosure

of data that some regard as trade secret or confidential while providing the same baseline information (gross charges) as required under the rule as well as more accurate information about patients' out of cost based on personalized estimates from their plan specific information. Other commenters explained that a price estimator tool that provides meaningful cost information to patients would be more useful to patients than voluminous data sets. One commenter specifically requested that no hospital offering a pricing tool should be exempted from releasing the comprehensive machine-readable data.

A few commenters noted that there are potential limitations associated with the information a patient receives through consumer-friendly pricing tools because providers cannot always estimate what services a patient will need, how they will respond to treatment, and whether complications as a result of co-morbidities or other issues will arise that would require additional services. For example, one commenter noted that accurate price estimation may depend on data elements such as payer coverage/benefit information, hospital/payer contract information, physician order and diagnosis, which may be contained in the hospital's EHR system.

Some commenters that supported an exemption for hospitals that have established a price estimator tool, indicated that if adopted, CMS should specify what qualifies as an acceptable price estimator tool and made specific suggestions for tool functionality, although in some cases these suggestions were made in the context of price estimator tools that could be offered by health insurers rather than hospitals. Suggestions for consumer-friendly tool functionality included:

- Provide users with an estimate of the overall cost and the out-of-pocket costs, including out-of-pocket costs based on an individual's insurance policy.
- Notify user of the availability of financial aid, payment plans, and assistance in enrolling for Medicaid or state program.
- Include a disclaimer about the limitation of the estimation, such as to advise the user to consult with their health insurer to confirm individual payment responsibilities, such as remaining deductible balances.
- Indicate quality of care in the healthcare setting.
- Do not require PII; users would not be required to use any form of account, username, or password to use the price estimator tool.

- Make estimates available in English, Spanish, and other languages as preferred.

- Offer an ad hoc service where a patient can obtain a cost estimate telephonically and/or via email.

- Be prominently featured on the hospital home page, and use plain and obvious language to help ensure that consumers can find it.

- Hospitals should advertise this tool to patients and generate interest.

Several commenters generally encouraged CMS to take steps to facilitate the development and voluntary adoption of price estimator tools by convening stakeholders, including the Departments of Labor and Treasury, to identify best practices, recommending minimum standards for common features, and developing solutions to common technical barriers.

Response: We appreciate commenters' careful consideration of and detailed suggestions for an approach for regarding hospitals as having met the requirement for making public their standard charge information in a consumer-friendly manner. In the CY 2020 OPPS/ASC proposed rule, we noted that as a result of the January 1, 2019 update to our guidance, we received feedback that long lists of charges in a file posted online in a machine-readable format may not be immediately or directly useful for many healthcare consumers because the amount of data could be overwhelming or not easily understood by consumers. We further recognized in the CY 2020 OPPS/ASC proposed rule that hospital standard charges, while necessary for consumers to understand their potential out-of-pocket obligations, are not sufficient in and of themselves. In section II.D of this final rule, we stated that we agree, for example, that the payer-specific negotiated charge does not, in isolation, provide a patient with an individualized out-of-pocket estimate. We referred to the GAO report¹⁶² we described in the CY 2020 OPPS/ASC proposed rule which supports our assertion that payer-specific negotiated charges are a critical piece of information necessary for patients to determine their potential out-of-pocket cost obligations. In other words, in order for an insured individual to determine an out-of-pocket estimate in advance of committing to a healthcare service with a particular provider, the insured individual must have several data

points including the total charge (which is the payer-specific negotiated charge) for the item or service and their particular benefits under their insurance plan (for example, their co-pay or deductible) in order to determine their personalized out-of-pocket obligation.

More often than not, patients see all this information after the service has been provided in the form of their EOBs. As explained in II.D of this final rule, EOBs are designed to communicate provider charges and resulting patient cost obligations, taking third party payer insurance into account. The payer-specific negotiated charge is a critical data point found on patient's EOB. We further explained that when a consumer has access to payer-specific negotiated charge information prior to receiving a healthcare service (instead of sometimes weeks or months after the fact when the EOB arrives), in combination with additional information from payers, it can help the patient estimate his or her potential out-of-pocket cost.

Because of this, in the CY 2020 OPPS/ASC proposed rule, we considered ways of requiring or encouraging hospitals to make public standard charges for frequently provided services in a form and manner that would be more directly accessible and consumer friendly.

Therefore, in addition to including all their standard charges for all items and services in the machine-readable file, we proposed that hospitals must make public their payer-specific negotiated charges for common services for which consumers may have the opportunity to shop, in a consumer-friendly manner. The intent of these provisions was to ensure that the hospital standard charges made public in the comprehensive machine-readable file would be more accessible to the average consumer so that consumers could use the information, combining it with additional necessary benefit information from their insurer, to estimate their individual out-of-pocket cost obligations in advance of receiving a healthcare service from the hospital.

We are persuaded by commenters' suggestions that some hospitals offering online price estimator tools that provide real-time individualized out-of-pocket cost estimates should receive consideration and potential relief from some of the requirements for making public standard charges, particularly as it relates to our intent and goals for requiring that hospitals communicate their standard charges in a consumer-friendly manner. We believe voluntarily offering an online price estimator tool has merit because the hospital standard charges as defined in this final rule are used to develop the individual's out-of-

pocket estimate in an even more consumer-friendly way than what we proposed within the limits of our statutory authority. We believe that price estimator tools pick up where our rule ends and take the additional steps that would otherwise be required by the consumer to determine their individualized out-of-pocket by combining hospital standard charge information with the individual's benefit information directly from the insurer. Thus, although some hospital price estimator tools may not display standard charge information in the consumer-friendly manner in the precise ways we proposed and are finalizing under this rule, they do appear to accomplish the goal and intent of ensuring such information is available in a consumer-friendly manner for purposes of individuals to directly determine their specific out-of-pocket costs in advance of committing to a hospital service. Thus, we believe it is possible that hospitals with price estimator tools could be considered as having accomplished the goals we intended to achieve by requiring hospitals to repackage and display their standard charge information for common shoppable services in a consumer-friendly manner. We emphasize, however, that hospitals would still be required to publish all standard charges in a machine-readable file consistent with the requirements we finalize in section II.E of this final rule.

We are finalizing, as modifications to our proposal, in a new 45 CFR 180.60, that a hospital may voluntarily offer an internet-based price estimator tool and thereby be deemed to have met our requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner. We believe this accommodation is responsive to comments indicating that the requirements to make public shoppable services in a consumer-friendly format are duplicative of efforts by hospitals that offer individualized internet-based price estimator tools.

We considered the minimum necessary functionality requirements a price estimator tool must embody to satisfy this new policy. As reflected in the comments we received on this topic, we recognize that different hospitals may maintain different types of internet-based healthcare cost price estimator tools, and that the market for, and technology behind, these applications is growing. Therefore, we believe it is important to ensure there is flexibility for the data elements, format, location and accessibility of a price estimator tool that would be considered to meet the requirements of 45 CFR 180.60. We

¹⁶² GAO. Health Care Price Transparency: Meaningful Price Information Is Difficult for Consumers to Obtain Prior to Receiving Care. Publicly released October 24, 2011. Available at: <https://www.gao.gov/products/GAO-11-791>.

believe that the requirements we are establishing in this final rule, for certain minimum data and functionality of a price estimator tool for purposes of meeting the requirements under new 45 CFR 180.60, are a starting point. We appreciate and will consider the commenters' suggestions that we seek stakeholder input for future considerations related to the price estimator tool policies we are finalizing, including to identify best practices, common features, and solutions to overcoming common technical barriers.

Therefore, we are finalizing a modification to our proposed policy to specify in new 45 CFR 180.60(a)(2) that a hospital that maintains an internet-based price estimator that meets certain criteria is deemed to have met our requirements at 45 CFR 180.60. The price estimator tool must:

- Allow healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.
- Provide estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.
- Is prominently displayed on the hospital's website and be accessible without charge and without having to register or establish a user account or password.

To be clear, we believe that a price estimator tool would be considered internet-based if it is available on an internet website or through a mobile application. We considered the additional suggestions by commenters related to ensuring that price estimator tools are consumer-friendly. In our review of available online price estimator tools offered by hospitals, we observed that their look and feel are not uniform, so, in this final rule, and so as not to be overly proscriptive or restrict innovation, we are not at this time finalizing a specific definition of a consumer-friendly format for price estimator tools or any additional criteria. However, we encourage hospitals to take note of current estimator tool best practices and seek to ensure the price estimator tools they offer are maximally consumer-friendly. For example, we encourage, but will not require in this final rule, that hospitals provide appropriate disclaimers in their price estimator tools, including acknowledging the limitation of the estimation and advising the user to consult, as applicable, with his or her health insurer to confirm individual

payment responsibilities and remaining deductible balances. Similarly, we encourage, but do not require in this final rule, that hospital pricing tools include: (1) Notification of the availability of financial aid, payment plans, and assistance in enrolling for Medicaid or a state program, (2) an indicator for the quality of care in the healthcare setting, (3) and making the estimates available in languages other than English, such as Spanish and other languages that would meet the needs of the communities and populations the hospital serves.

We note that although we decline to be more prescriptive at this time, we may in the future revisit our policy to deem hospital online price estimator tools as having met requirements if we determine such tools are not meeting our goals for making hospital charge information meaningful to consumers. We further note that a hospital that meets the requirements for offering an internet-based price estimator tool would still be required to make public all standard charges for all hospital items and services online in a comprehensive machine-readable format as discussed in section II.E of this final rule and finalized under 45 CFR 180.50.

Comment: A few commenters addressed monitoring and oversight of price transparency tools. For example, one commenter suggested that CMS, or another federal agency, establish standards and require certain disclosures for software application developers of consumer-facing platforms for hospital standard charge data. This commenter expressed concern about consumers losing faith in cost transparency tools as they begin interacting with them, stemming from consumer-facing platforms that are not presenting information accurately or not using information appropriately.

Another commenter suggested that standards must be in place for CMS to monitor and evaluate the impacts of price transparency tools, to help ensure there are not unintended effects, and to identify best practices. The commenter suggested that this includes developing a better understanding of any potential misinterpretations of the data by patients, as well as the extent to which hospitals may misrepresent rates.

Response: For purposes of implementing section 2718(e) of the PHS Act, we will monitor and enforce compliance with the requirements to make public standard charges (as described in section II.G. of this final rule). This will include ensuring that hospitals have made public their standard charges in both ways required

under these rules. Specifically, we will monitor to ensure that hospitals have made public all their standard charges for all items and services they provide in a comprehensive online machine-readable file format and have either made public standard charges for shoppable services in a consumer-friendly format (according to the requirements at 45 CFR 180.60), or have voluntarily offered an online price estimator tool. Although comments suggesting that CMS impose monitoring or enforcement efforts on software application developers are beyond the scope of the standard charge disclosure requirements we proposed, and that we are finalizing at new 45 CFR part 180 as discussed in this final rule, we note that HHS has ongoing efforts to improve health information exchange including through the ONC¹⁶³ and recently promulgated proposed interoperability rules designed to expand access to health information and improve the seamless exchange of data in healthcare.¹⁶⁴

Final Action: We are finalizing as proposed to specify in new 45 CFR 180.60(c) that hospitals retain flexibility on how best to display to the public online their standard charges in a consumer-friendly manner, so long as the website is easily accessible to the public.

Based on the comments received, we are not finalizing our proposal to require that hospitals provide a paper copy (for example, a brochure or booklet) of information on consumer-friendly shoppable services to consumers upon request within 72 hours of the request.

We are finalizing a modification to our proposal at new 45 CFR 180.60(a)(2) to specify that a hospital is deemed by CMS to meet the requirements of 45 CFR 180.60 if the hospital maintains an internet-based price estimator tool which meets the following requirements:

- Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.
- Allows health care consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.

¹⁶³ HealthIT.gov website, Laws, Regulation, and Policy, at <https://www.healthit.gov/topic/laws-regulation-and-policy>.

¹⁶⁴ CMS.gov website, Interoperability, at <https://www.cms.gov/Center/Special/Topic/Interoperability-Center.html>.

- Is prominently displayed on the hospital's website and accessible to the public without charge and without having to register or establish a user account or password.

6. Location and Accessibility Requirements

Additionally, we proposed that hospitals make the data elements proposed in section XVI.F.4. of the CY 2020 OPPS/ASC proposed rule (84 FR 39589 through 39590) public online in such a way that the standard charges and associated data elements could be easily located and accessed by consumers.

First, we proposed that a hospital would have discretion to select an appropriate internet location to post the standard charge information required under this section (that is, the payer-specific charges for shoppable services and associated data elements). We further proposed that the website location be publicly available, that the data be displayed prominently and clearly identify the hospital location with which the standard charge information is associated, and that the standard charge data be easily accessible, without barriers, and that the data could be digitally searched. For purposes of the proposed requirements: (1) "displayed prominently" meant that the value and purpose of the web page¹⁶⁵ and its content¹⁶⁶ is clearly communicated, there is no reliance on breadcrumbs¹⁶⁷ to help with navigation, and the link to the standard charge information is visually distinguished on the web page;¹⁶⁸ (2) "easily accessible" meant that standard charge data are presented in format that is searchable by service description, billing code, and payer, and that the standard charge data posted on the website can be accessed with the fewest number of clicks;¹⁶⁹ and (3) "without barriers" meant the data can be accessed free of charge, users would not have to input information (such as their name, email address, or other PII) or register to access or use the standard charge data. We proposed to codify this requirement at proposed new 45 CFR 180.50(d).

We encouraged hospitals to review the HHS Web Standards and Usability Guidelines (available at: <https://webstandards.hhs.gov/>), which are research-based and are intended to

provide best practices over a broad range of web design and digital communications issues.

We sought comment on these proposed location and accessibility requirements, including whether there were additional requirements that should be considered to ensure public access to payer-specific negotiated charges for shoppable services.

Comment: Several commenters noted the importance of making the information easily accessible and consumer-friendly. Specifically, a few commenters noted that it is important for hospitals to make this information easy or intuitive for lay-people to find on the websites.

Other commenters made recommendations for requirements related to accessibility of consumer-friendly hospital charge information such as:

- Display on the website home page and clear indicators such as "Price Check" or "Cost Estimator" in the text for the link, rather than terms like "Tools and Resources."
- Conform with American with Disabilities Act (ADA) accessibility standards.
- Make information available in multiple languages based on the hospital's population.

One commenter noted that rural consumers have less access to broadband, making it more difficult for them to access this information online. One commenter recommended that public outreach efforts, content generation, and coordination with existing user channels are needed to educate and engage audiences.

Response: We thank commenters for their suggestions and agree that hospitals should seek to make their standard charge information easy or intuitive for lay-people to find on their websites. We would expect hospitals to post information in a format accessible to people with disabilities or to otherwise ensure that individuals with disabilities can readily access hospital standard charge information, in accordance with applicable federal or state laws.¹⁷⁰ We encourage hospitals to post this information in a language and manner that is consumer-friendly for their specific markets and to use terms to refer to their standard charge information that are clear indicators. While we are not finalizing any specific requirements related to either of these

two issues at this time, we will continue to consider these suggestions, and should the information prove to be difficult to find or access, we may revisit these in future rulemaking.

Regarding the concern related to rural consumers being able to access online hospital charge information, we note that in July 2019, the Federal Communications Commission authorized \$524 million in funding over the next decade to expand broadband to unserved rural homes and businesses.¹⁷¹ We agree that the availability of hospital charge information as a result of these final rules should be widely publicized. We plan to engage in communicating and publicizing these final rules and encourage other interested stakeholders to engage in communications strategies to enhance public awareness of the availability of hospital standard charge information.

Comment: One commenter agreed that CMS' proposed location, accessibility, and technical requirements would allow patients to easily access standard charge information for shoppable services. A few other commenters expressed that being able to access standard charge information should be like comparing prices for groceries. One commenter suggested that hospitals clearly link the consumer-friendly list of shoppable services with the comprehensive machine-readable file of all items and services. A few commenters suggested that there be a standardized CMS file and web page format for displaying standard charges for shoppable services, arguing this would more easily enable cost comparisons across different facilities.

Response: We appreciate commenter's support for our location and accessibility requirements and are finalizing them as proposed. We agree with commenters who believe that comparing prices for healthcare services should be as transparent as comparison pricing in other industries. We will continue to consider whether and how best to link the comprehensive machine-readable file and the consumer-friendly display of shoppable services. We agree that an exemplar template (not one that we will presently require) would be beneficial to help standardize format for displaying charges for shoppable services in a consumer-friendly format, and we have included such examples in II.F.5 of this final rule. However, as explained in II.F.5 of this final rule, we believe

¹⁶⁵ <https://webstandards.hhs.gov/guidelines/49>.

¹⁶⁶ Nielsen J. (2003, November 9). The ten most violated homepage design guidelines. Alertbox. Available at: <http://www.useit.com/alertbox/20031110.html>.

¹⁶⁷ <https://webstandards.hhs.gov/guidelines/78>.

¹⁶⁸ <https://webstandards.hhs.gov/guidelines/88>.

¹⁶⁹ <https://webstandards.hhs.gov/guidelines/181>.

¹⁷⁰ The Americans with Disabilities Act, the Rehabilitation Act and the ACA (see 45 CFR 92.202) require auxiliary aids and services when needed to communicate effectively with people with disabilities. <https://www.ada.gov/effective-comm.pdf>.

¹⁷¹ FCC. FCC Authorizes \$524 Million for Rural Broadband Expansion in 23 States. News Release, July 15, 2019. Available at: <https://www.fcc.gov/document/fcc-authorizes-524-million-rural-broadband-expansion-23-states>.

hospitals should retain flexibility to determine a format that displays charges for their shoppable services in a consumer-friendly manner.

Comment: A few commenters suggested that patients needed to be able to access standard charge information for shoppable services through a secure portal that is password protected, and that the secure portal be tied to their actual health plan coverage while minimizing the risk that other providers will demand higher rates from payers.

Response: We thank the commenters for their recommendation. However, in the interest of keeping access to the consumer-friendly display of shoppable services barrier-free, we disagree with requiring hospitals to develop a secure portal. As part of the requirements for making standard charges public, hospitals would not post any PII to the internet and consumers would not be asked to provide any in order to view payer-specific negotiated charges.

Final Action: We are finalizing with technical modification our requirements for location and accessibility of information on consumer-friendly shoppable services. Specifically, we are finalizing with modification that a hospital must select an appropriate publicly available internet location for purposes of making public the standard charge information for shoppable services in a consumer-friendly format.

We are also finalizing with technical modification that the information must be displayed in a prominent manner that identifies the hospital location with which the standard charge information is associated.

Finally, we are finalizing with technical modification the shoppable services information must be easily accessible, without barriers, including, but not limited to, ensuring the information is: (i) Free of charge; (ii) accessible without having to register or establish a user account or password; (iii) accessible without having to submit PII; (iv) searchable by service description, billing code, and payer. We note that we would expect hospitals would post information in a format accessible to people with disabilities or to otherwise ensure that individuals with disabilities can readily access hospital standard charge information, in accordance with any applicable federal or state laws.

These final provisions are specified in new 45 CFR 180.60(d).

7. Frequency of Updates

The statute requires hospitals to establish, update, and make public their standard charges for each year.

Therefore, we proposed to require hospitals to make public and update the standard charge information proposed in section XVI.F.2 (84 FR 39585 through 39586) at least once annually (proposed new 45 CFR 180.60(e)). We recognized that hospital charges may change more frequently and therefore we encouraged (but are not requiring) hospitals to update this file more often, as appropriate, so that the public may have access to the most up-to-date charge information. We also recognized that hospitals update their charges at different times during the year and may also have various State price transparency reporting requirements that require updates. For purposes of these requirements, we believe that updates that occur at least once in a 12-month period will satisfy our proposed requirement to update at least once annually and reduce reporting burden for hospitals. In other words, the hospital could make public and update its list of standard charges at any point in time during the year, so long as the update to the charge data occurs no more than 12 months after posting.

We also proposed to require hospitals to clearly indicate the date of the last update they have made to the standard charge data, with some discretion as to where the date of late update is indicated.

Comment: A few commenters disagreed that annually updating the display of standard charges in the consumer-friendly format would be sufficient to keep consumers apprised of costs. Commenters recommended more frequent updates, citing frequent changes in commercial payer rates. One commenter recommended requiring hospitals to update this information in real time to avoid the possibility of misleading patients with calendar-related gaming around the disclosure of rate hikes or true prices.

Response: We appreciate the commenters' concerns and we agree that timely updates are an important aspect of keeping information relevant to consumers and avoiding confusion, but we believe the plain language of section 2718(e) of the PHS Act currently limits the requirement to make standard charges public to once annually. We strongly support and encourage hospital efforts to make more frequent updates to the standard charge information they make public online.

Final Action: We are finalizing as proposed a policy to require hospitals to make public and update the standard charge information at least once annually (proposed new 45 CFR 180.60(e)). We are also finalizing as proposed a requirement that the

hospital clearly indicate the date that the information was most recently updated. Hospitals would have some discretion as to where the date of late update is indicated.

G. Monitoring and Enforcement of Requirements for Making Standard Charges Public

1. Background

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties. As such, we proposed that we may impose penalties on hospitals that fail to make their standard charges public in accordance with the requirements we finalize under section 2718(e) of the PHS Act. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20549), we sought public comments on a variety of issues related to enforcement of the requirement that hospitals make public their standard charges and noted our intent to address enforcement and other actions to ensure compliance in future rulemaking.

We specifically sought comments on the following:

- What is the most appropriate mechanism for CMS to enforce price transparency requirements?
- Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere?
- How should CMS assess hospital compliance?
- Should CMS publicize complaints regarding access to price information or review hospital compliance and post results? What is the most effective way for CMS to publicize information regarding hospitals that fail to comply?
- Should CMS impose CMPs on hospitals that fail to make standard charges publicly available as required by section 2718(e) of the PHS Act?
- Should CMS use a framework similar to the Federal civil penalties under 45 CFR 158.601 through 158.615, that apply to issuers that fail to report information and pay rebates related to medical loss ratios (MLRs), as required by sections 2718(a) and (b) of the PHS Act, or would a different framework be more appropriate?

As described in the CY 2020 OPPI/ASC proposed rule (84 FR 39591), we received a number of comments in response to this RFI. Many commenters agreed that enforcing this requirement under section 2718(e) of the PHS Act would send an important signal that CMS values transparency and ensure that the public has access to hospital charge information. Some commenters

suggested that CMS model enforcement after various quality reporting programs, such as the Hospital Inpatient and Outpatient Quality Reporting Programs or the LTCH Quality Reporting Program. Some commenters recommended publicizing noncompliant hospitals or providing a mechanism for the public to file complaints against noncompliant hospitals. Some commenters suggested that CMS propose to make the publication of standard charges a Medicare condition of participation or provider enrollment. However, one commenter indicated that revoking a provider agreement over lack of a website disclosure would be unnecessarily punitive. Other commenters warned that subjecting hospitals violating pricing transparency provisions to compliance actions could pose a challenge, particularly for smaller hospitals, and recommended limiting or deferring compliance actions to a later date. Some commenters agreed that imposing monetary penalties on noncompliant hospitals was appropriate, while other commenters believed that CMS does not have authority to enforce section 2718(e) of the PHS Act and, for that reason, should not adopt penalties for noncompliance.

We stated in the CY 2020 OPPTS/ASC proposed rule that we agree with commenters who noted that an enforcement regime signals the value we place on price transparency and assurance of public access to hospital standard charges. We interpret section 2718(b)(3) of the PHS Act as authorizing us to enforce the provisions of section 2718(e). Therefore, we proposed to adopt mechanisms to monitor and enforce our requirements for making standard charges public.

2. Monitoring Methods

Section 2718(e) of the PHS Act requires hospitals to make public their list of standard charges and authorizes the Secretary to promulgate additional criteria that hospitals must satisfy in order to make such charges public. The statute does not prescribe monitoring procedures or the factors we should consider in imposing penalties on hospitals for noncompliance. Based on our experience with the Medicare program and healthcare marketplace plans, we believe it is important for the public to be informed, and, therefore, for CMS to ensure compliance with this statutory requirement. Therefore, we proposed to employ methods to monitor and assess hospital compliance with section 2718(e) of the PHS Act, and specifically proposed new 45 CFR 180.40, 180.50, and 180.60.

In general, we proposed that CMS may use methods to monitor hospital compliance with the requirements under proposed 45 CFR part 180. As explained in the CY 2020 OPPTS/ASC proposed rule, we anticipate relying predominantly on complaints made to CMS by individuals or entities regarding a hospital's potential noncompliance. Therefore, we proposed that our monitoring methods may include, but are not limited to, the following, as appropriate:

- CMS' evaluation of complaints made by individuals or entities to CMS.
- CMS review of individuals' or entities' analysis of noncompliance.

As we gain experience with monitoring compliance with the requirements for proposed 45 CFR part 180, we may consider self-initiating audits of hospitals' websites as a monitoring method. Therefore, we proposed that our monitoring methods may include CMS audit of hospitals' websites.

We proposed to set forth these monitoring methods in the regulations at proposed new 45 CFR 180.70.

Comment: A few commenters suggested that the monitoring and enforcement requirements for making standard charges public should be well defined and robust. A few commenters agreed with CMS' proposal to rely mainly on complaints made to CMS by individuals or entities regarding a hospital's noncompliance, as well as CMS audits of hospitals' websites. One commenter stated that the proposed approach seems reasonable and that the monitoring methods and proposed actions to address noncompliance are appropriately varied and iterative.

A commenter suggested that positive and effective enforcement is needed, such as encouraging community policing efforts that strive for prevention of a problem, and believes this approach could create a more transparent hospital reimbursement system for the public.

A few commenters suggested that the burden of monitoring and enforcement may outweigh its benefits, and one commenter suggested that CMS withdraw altogether its proposed price transparency requirements, including the enforcement processes and CMPs for noncompliance, because of concerns about additional costs of compliance the proposed price transparency policies pose for financially fragile rural safety net providers, in particular Medicare Dependent Hospitals, Rural Referral Centers, and SCHs. One commenter stated that monitoring is a purposeless task.

Response: We appreciate the support of commenters favoring the proposed

approach to monitoring for compliance with the requirements for hospitals to make public standard charges. We disagree with the notion, expressed by one commenter, that monitoring hospitals for compliance with these price transparency disclosure requirements is a purposeless task and that its potential burden outweighs its potential benefits. We do, however, appreciate commenters' concerns about the potential additional burden that monitoring activities may pose for hospitals, though we do not believe the monitoring burden will impact hospitals unless they are not in compliance with the requirements.

We decline to altogether forgo enforcement processes and CMPs for noncompliance as suggested by one commenter. We believe that enforcement of the policies is vital to ensuring that hospitals comply with the requirements to make public standard charges. Given the importance of ensuring that patients have access to data they need to make informed healthcare decisions, we believe monitoring hospitals' compliance with the requirements of new 45 CFR part 180 is critical. Therefore, we are finalizing our proposed monitoring methods. Further, we believe it is important to consistently apply the monitoring and enforcement provisions across all entities that meet the definition of "hospital" that we are finalizing (as discussed in section II.B.2 of this final rule), regardless of factors such as hospital size, revenue, or location.

In response to the commenter suggesting a community policing approach that strives for prevention of compliance problems, we note that the monitoring methods we are finalizing here include CMS' reliance on receipt of complaints made by individuals or entities to help inform CMS of potential issues so that CMS may initiate its own analyses, or CMS review of individuals' or entities' analysis of noncompliance. Further actions to address hospital noncompliance as described in section II.G.3 of this final rule include CMS' issuance of a written warning notice to a noncompliant hospital and CMS' requests for a CAP from a hospital in the event its noncompliance constitutes a material violation of one or more requirements. This approach contemplates that noncompliant hospitals will be offered opportunities to come into compliance with the requirements prior to the imposition of a CMP. Further, we note that these final policies do not preclude individuals or entities from raising their compliance concerns directly with hospitals, and for

hospitals to voluntarily address disclosure deficiencies.

Comment: A few commenters addressed the scope of CMS' monitoring of hospital compliance to make public standard charges. A few commenters expressed support for meaningful oversight and enforcement by CMS to ensure the quality and accuracy of the standard charge information hospitals are required to disclose pursuant to this rule. One commenter recommended that CMS should have a system in place to ensure that rates are being updated regularly in accordance with the requirements.

Response: We appreciate commenters' support for and interest in CMS' monitoring activities. In response to comments regarding the scope of CMS' proposed monitoring of hospitals with respect to compliance with these requirements to make public standard charges, we believe our authority is broad and includes, for example, our ability to monitor the accuracy of the information made public, and whether the information is made public in the form and manner and with the frequency specified in this final rule.

According to the monitoring methods we are finalizing in this final rule, we anticipate relying on complaints made by individuals or entities, or individuals' or entities' analysis of noncompliance, as the basis for being notified about inaccuracies in the information made public by hospitals. To be clear, such notifications would not directly underlie an enforcement action. Rather, such notifications would merely trigger our independent analysis and conclusions, of which complainant's allegations or analyses may become a part, that would underlie any potential enforcement action. Pursuant to the monitoring methods we finalize here, we may also self-initiate the audit of a hospital's website. We anticipate that our review for inaccuracies in reported information would be for egregious and obvious instances of noncompliance, such as (in the extreme) all items and services made public by a hospital having the same value, or no value at all. Further we decline the commenters' suggestion to establish an additional, or different process, to monitor and take actions to address noncompliance in the form of inaccurate data. We anticipate consistently applying our monitoring and enforcement methods when addressing all types of possible violations. As we describe in section II.G.3 of this final rule, we may provide a written warning notice to a noncompliant hospital, request a CAP from a hospital if the noncompliance

constitutes a material violation of one or more requirements, impose a CMP on the hospital if the hospital fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP, and publicize the notice of imposition of a CMP on a CMS website.

Comment: A few commenters suggested, as an alternative approach, that hospitals should be required to report to CMS on their compliance with the requirements. For example, commenters' suggestions included that hospitals should be required to notify CMS of their adherence to price transparency requirements at regular intervals, or that hospitals should be required to submit a form to CMS to prove adherence with the requirements. A few commenters suggested that CMS require hospitals to attest that they are in compliance with the rule. One commenter explained that requiring such an attestation would put hospitals at risk of implicating the federal False Claims Act and associated penalties if they were determined to be noncompliant.

One commenter, seeming to misinterpret the President's Executive Order 13877 on "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (June 24, 2019), suggested a requirement may exist for hospitals to establish a monitoring mechanism to ensure compliance with the price list posting requirement.

Response: We read the final sentence of section 3(a) of Executive Order 13877 to indicate two separate requirements related to the regulation requiring hospitals to publicly post standard charge information; specifically, that the regulation should: (1) Require hospitals to regularly update the posted information, and (2) establish a monitoring mechanism for the Secretary to ensure compliance with the posting requirement, as needed. We believe that (2) means that HHS should establish a monitoring mechanism to ensure hospitals' compliance with the posting requirements.

At this time, we decline to adopt commenters' suggestions that we require hospitals to report or attest to CMS their compliance with these requirements, but as we gain experience with monitoring hospital compliance with the policies we finalize here, we may revisit these issues in future rulemaking.

Comment: A few commenters stated that it is critical for CMS to implement a process for individuals to report noncompliance. One commenter expressed concern over the potential lack of guidance on how individuals or entities would report to CMS a

hospital's noncompliance with the price transparency requirements. In comments on this topic, commenters suggested a variety of methods for how a complaint should be reported to CMS and subsequent actions CMS should take in processing the complaint.

Response: We have established an email address, *PriceTransparencyHospitalCharges@cms.hhs.gov*, through which individuals and entities may report to CMS concerns about hospital compliance with requirements to make public standard charges, including complaints about and analysis of noncompliance.

Comment: Several commenters encouraged CMS to develop robust auditing procedures rather than relying solely on patients to know how to and take steps to report violations.

Response: To clarify, we proposed that monitoring methods include, but are not limited to, CMS' evaluation of complaints made by individuals or entities, CMS review of individuals' or entities' analysis of noncompliance, and CMS audit of hospitals' websites. We agree with the commenters that CMS audit of hospitals may be an important method for monitoring hospitals compliance with the requirements of new 45 CFR part 180.

Comment: Several commenters suggested that CMS work closely with hospitals to ensure they are aware of and understand CMS' monitoring mechanisms. One commenter suggested that CMS ensure both inpatient and outpatient providers have sufficient education and training required for compliance with the proposals. Several commenters suggested that CMS use education and outreach methods that exist within Medicare FFS to promote hospital awareness of and promote compliance with the requirements to make public standard charges.

Response: We thank commenters for their suggestions, and we will consider these suggestions for education and outreach about compliance as we gain experience monitoring hospital compliance with these requirements to make public standard charges. We note that the suggestions of a few commenters focused on methods for education and outreach in relation to the Medicare program, but that the price transparency requirements are not limited to Medicare enrolled hospitals.

Final Action: After considering the comments received on our proposed approach to monitor hospital compliance with the requirements to make public standard charges, we are finalizing our proposal to evaluate whether a hospital has complied with the requirements under §§ 180.40,

180.50, and 180.60. We are also finalizing as proposed that the monitoring methods for determining a hospital's compliance with the requirements for making public standard charges may include, but are not limited to, the following, as appropriate:

- CMS' evaluation of complaints made by individuals or entities to CMS.
- CMS review of individuals' or entities' analysis of noncompliance.
- CMS audit of hospitals' websites.

We are finalizing our proposal to set forth these monitoring methods in the regulations at new 45 CFR 180.70.

3. Actions To Address Hospital Noncompliance With Requirements To Make Public Standard Charges

We proposed that hospitals that CMS identifies as noncompliant would be notified of their deficiencies and given an opportunity to take corrective action to come into compliance. As discussed in section II.G.4. of this final rule, for hospitals determined by CMS to be noncompliant with section 2718(e) of the PHS Act that fail to respond to CMS' requests to submit a CAP or comply with the requirements of a CAP, we proposed that we may impose CMPs and publicize these penalties on a CMS website.

Should we conclude, based upon the proposed monitoring activities previously described, that a hospital is noncompliant with section 2718(e) of the PHS Act and the requirements of proposed 45 CFR part 180, we proposed that CMS may take any of the following actions, which generally, but not necessarily, would occur in this order:

- We may provide a written warning notice to the hospital of the specific violation(s).
- We would request a CAP from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- If the hospital fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP, CMS may impose a CMP on the hospital and publicize the penalty on a CMS website.

As discussed in the CY 2020 OPPI/ASC proposed rule (84 FR 39592), prior to requesting a CAP, or in the case of violations that are deemed nonmaterial violations warranting a CAP, CMS anticipates warning, via written notice, a hospital of noncompliance with one or more of the requirements to make public standard charges (according to section 2718(e) of the PHS Act and the requirements of proposed 45 CFR part 180), and of the need for voluntary corrective action. We would then

reevaluate the hospital's compliance with the statutory and proposed regulatory requirements. Should we determine the hospital remains noncompliant and that the noncompliance constitutes a material violation of one or more requirements, we anticipate requiring that the hospital submit a CAP, and there would be increasing consequences for failure to remedy noncompliance.

We proposed that a material violation may include, but is not limited to, the following:

- A hospital's failure to make public its standard charges required by proposed new 45 CFR 180.40.
- A hospital's failure to make public its standard charges in the form and manner required under to proposed new 45 CFR 180.50 and 180.60.

We proposed that CMS may request that a hospital submit a CAP, specified in a notice of violation issued by CMS to a hospital. A hospital required to submit a CAP must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the CAP.

We proposed that a hospital's CAP must specify elements including, but not limited to, the deficiency or deficiencies that caused noncompliance to occur, the corrective actions or processes the hospital will take to come into compliance with the requirements of 45 CFR part 180, and the timeframe by which the hospital will complete the corrective action. We proposed that a CAP would be subject to CMS review and approval. We proposed that after CMS' review and approval of a hospital's CAP, CMS may monitor and evaluate the hospital's compliance with the corrective actions.

We proposed that a hospital's failure to respond to CMS' request to submit a CAP includes failure to submit a CAP in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital. We proposed that a hospital's failure to comply with the requirements of a CAP includes failure to correct violation(s) within the specified timeframes.

We proposed to set forth in the regulations at proposed new 45 CFR 180.70 the actions CMS may take to address a hospital's noncompliance with the requirements to make public standard charges, and to set forth in proposed new 45 CFR 180.80 the requirements for a CAP.

Comment: A few commenters offered suggestions on the process for CMS and hospitals to address potential noncompliance. One commenter

expressed concern over the potential lack of guidance regarding the process CMS will use to investigate a complaint about a hospital's noncompliance with the price transparency requirements and request corrective action by a hospital. Another commenter stated that any penalties for noncompliance should not be accrued until the hospital has adequate time to respond to complaints. The commenter suggested, at a minimum, a six-month time frame for responding to and resolving the issues brought forward via a complaint.

Response: The regulations we are finalizing at new 45 CFR 180.70 specify the actions CMS will take to address hospital noncompliance. We anticipate that the specifics of each compliance action may depend on the circumstances of the complaint, CMS' determination of noncompliance, and the severity of the violation(s).

Comment: One commenter expressed support for a policy under which CMS would request a CAP before imposing a CMP.

Response: We appreciate the support of the commenter favoring the proposed approach.

Comment: A few commenters indicated it was unclear what would constitute the basis for a finding of a material violation for CMS to determine it is necessary to request a CAP. One of these commenters recommended that CMS further delineate its expectations and grounds under which a CMP is warranted to avoid a system of arbitrary and capricious actions by CMS to penalize hospitals.

These commenters stated that it is unclear what would constitute a finding of noncompliance with a required public disclosure of standard charges or noncompliance with disclosure in the form and manner required by CMS. One commenter specifically asked whether a hospital would only be cited as noncompliant after repeated violations or egregious violations or whether technical issues with formatting and posting of pricing data, including computer server issues, constitute an actionable violation. Another commenter asked if a hospital would be found noncompliant if a hospital made a good faith effort to publish data as required by CMS, but found some requirements impossible to meet. This commenter asked whether a CMP would be imposed on a hospital for failing to achieve something impractical based merely on web-surfing by federal employees absent consumer complaints.

Response: We believe these comments reflect concerns that hospitals will have limited opportunity to take corrective action prior to the imposition of a CMP.

As described in the CY 2020 OPPS/ASC proposed rule (as discussed above), prior to requesting a CAP for a material violation, CMS may issue a written warning notice so that the hospital may take voluntary corrective action to become compliant. We could then reevaluate the hospital's compliance with the statutory and proposed regulatory requirements. Should we determine the hospital remains noncompliant and that the noncompliance constitutes a material violation of one or more requirements, we anticipate requiring that the hospital submit a CAP. We may impose a CMP on a hospital identified as noncompliant that fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP.

We further considered the proposed requirements for a CAP. Upon closer review we believe our proposals to require a hospital to specify in its CAP (i) the deficiency or deficiencies that caused noncompliance to occur, and (ii) the corrective actions or processes the hospital will take to come into compliance with the requirements of this part, among other elements, could raise due process considerations. In particular, the phrasing of these proposed elements suggest that in developing a CAP, the hospital must concur with CMS' finding(s) of noncompliance. This would be potentially problematic for a hospital in the event it seeks to dispute CMS' findings of noncompliance. Therefore, we are finalizing with modification to specify instead that a hospital's CAP must include, among other elements, a description of the corrective actions the hospital will take to address the deficiency or deficiencies identified by CMS. We believe this provision provides hospitals greater flexibility to specify in their CAP considerations about CMS' findings of noncompliance, in addition to actions to address such findings. We anticipate working with hospitals on an individual basis during the corrective action process to address concerns with CMS' findings and concerns about meeting the requirements.

Comment: Many commenters indicated that implementation by January 1, 2020 would not provide enough time to comply with requirements and suggested that CMS consider finalizing an effective date beyond January 1, 2020, or otherwise permit delay or postponement of implementation. Several commenters expressed concern with the complexity of the data extract needed to meet the CY 2020 OPPS/ASC proposed rule's requirements, as well as the availability

of that data within existing online systems or the need to divert hospital personnel to create the files manually given a lack of contract management system.

One commenter expressed that, for those hospitals unable to afford a vendor, the staff labor cost will be astronomical and the likelihood of completing this "herculean" task prior to January 1, 2020, will be very low. This commenter suggested a postponement of the posting of negotiated rates for small rural and critical access hospitals until affordable software is developed and made available to assist with this task.

Another commenter explained that an effective date of January 1, 2020 would not afford hospitals enough time to evaluate consulting services, contract management systems, or hire additional personnel to fulfill these requirements.

Commenters suggested a variety of alternative effective dates. For example, one commenter suggested an effective date of April 2020 or later, a few commenters suggested requiring implementation by January 1, 2021, and one commenter stated it would take a minimum of 2 years to become compliant.

One commenter expressed concern that CMS proposed "an invasive and highly punitive" monitoring and enforcement regime, up to and including CAPs and CMPs, that would take effect January 1, 2020.

Response: We agree with commenters that some hospitals may find it challenging to initially comply with the new requirements of 45 CFR part 180 in a short timeframe, and may need time beyond January 2020 to develop the capacity to meet the new requirements. We also recognize that hospitals vary in the extent to which they already make public standard charge information similar to the data we are requiring hospitals to make public with this final rule. For instance, some hospitals may already comply with similar requirements under state laws, or already voluntarily make such information public and would, therefore, be able to quickly comply with the new requirements.

In light of these considerations, we are finalizing a modification to extend the effective date of policies under new 45 CFR part 180 to January 1, 2021. We believe this duration of delay balances the concerns between providing additional time for hospitals to implement the new requirements while still ensuring that hospitals' standard charges are made public quickly to provide consumers access to this important information. We decline to

create a different effective date for a subset of hospitals, such as rural hospitals, to delay price transparency requirements as we believe the hospital price transparency requirements we finalize here are important to informing all consumers' healthcare decision-making.

In the meantime, we note that existing CMS guidance requires that hospitals make public their gross charges for items and services as found in the chargemaster online in a machine-readable format. We note that this guidance remains in effect until the effective date of the regulations we are establishing with this final rule, which is January 1, 2021.

Comment: A few commenters suggested that CMS take a phased approach to enforcement of the requirements for hospitals to make public standard charges. A few commenters, concerned about the excessive burden imposed by CMS' proposed requirements and the time it may take hospitals to develop the capacity to become compliant, suggested a grace period prior to the imposition of a CMP for noncompliance. A few commenters suggested that CMS phase-in the proposed monitoring and enforcement actions over several years. One commenter recommended that CMS' enforcement actions should begin by publicizing the names of hospitals determined to be noncompliant (referred to by the commenter as "name and shame") prior to giving these hospitals a chance to take corrective action, and then progress to requesting a CAP after several years. According to this commenter, if the implementation of CAPs does not induce full compliance after a few years then CMPs might be prudent.

Response: We believe the monitoring methods we are finalizing as described in Section II.G.2 of this final rule and the actions to address hospital noncompliance described in this section are necessary to ensure compliance. We believe the proposed monitoring methods and enforcement actions give CMS the flexibility to employ a number of methods to be notified of, and investigate, hospital noncompliance, and allow CMS to take enforcement actions that escalate through stages. We believe the proposed approaches to addressing noncompliance, in which CMS (in sequence) issues a written warning notice, requests a CAP if the hospital's noncompliance constitutes a material violation of one or more requirements, and imposes a CMP on the hospital and publicizes the penalty on a CMS website, allows multiple opportunities for hospitals to take

corrective action over a period of time so that they may avoid imposition of a CMP. We decline the commenters' suggestions that we further phase-in the enforcement actions over a number of years, or to establish an approach that routinely provides hospitals a number of years to remedy their noncompliance.

We considered the commenter's suggestion to expand our authority to publicize hospitals determined to be noncompliant with the requirements to make public standard charges. We believe that publicizing a hospital's noncompliance, prior to imposing a CMP (for example), could be an effective tool to raise public awareness of incomplete hospital data (for example), and could encourage hospitals to promptly remedy their violation(s) to avoid being publicly identified as noncompliant. However, at this time, we are finalizing our proposal to publicize on a CMS website the notice of imposition of a CMP. We may revisit through future rulemaking the timing for and approach by which CMS publicizes its determination of a hospital's noncompliance with the requirements to make public standard charges.

Final Action: After considering the comments received, we are finalizing as proposed to set forth in the regulations at new 45 CFR 180.70, actions to address hospital noncompliance with the requirements to make public standard charges. We are finalizing that CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order if CMS determines the hospital is noncompliant with section 2718(e) of the PHS Act and the requirements of 45 CFR part 180:

- Provide a written warning notice to the hospital of the specific violation(s).
- Request a CAP from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose a CMP on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP.

We are finalizing with modifications to set forth in new 45 CFR 180.80 the requirements for CAPs. Specifically, we are finalizing as proposed to specify in 45 CFR 180.80(a) that a hospital may be required to submit a CAP if CMS determines a hospital's noncompliance constitutes a material violation of one or more requirements, which may include, but is not limited to, the following:

- A hospital's failure to make public its standard charges required by new 45 CFR 180.40.

- A hospital's failure to make public its standard charges in the form and manner required under new 45 CFR 180.50 and 180.60.

We are finalizing as proposed to specify in 45 CFR 180.80(b), CMS may request that a hospital submit a CAP, specified in a notice of violation issued by CMS to a hospital.

We are finalizing our proposals, except as noted otherwise, to specify in 45 CFR 180.80(c) the following provisions related to CAPs:

- A hospital required to submit a CAP must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the CAP.
- We are finalizing modifications that a hospital's CAP must specify elements including, but not limited to the corrective actions or processes the hospital will take to address the deficiency or deficiencies identified by CMS, and the timeframe by which the hospital will complete the corrective action.
- A CAP is subject to CMS review and approval. After CMS' review and approval of a hospital's CAP, CMS may monitor and evaluate the hospital's compliance with the corrective actions.

We are finalizing as proposed to specify in 45 CFR 180.80(d) provisions for identifying a hospital's noncompliance with CAP requests and requirements:

- A hospital's failure to respond to CMS' request to submit a CAP includes failure to submit a CAP in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital.
- A hospital's failure to comply with the requirements of a CAP includes failure to correct violation(s) within the specified timeframes.

We are finalizing a modification to extend the effective date of the final policies to January 1, 2021.

4. Civil Monetary Penalties

We proposed that we may impose a CMP on a hospital that we identify as noncompliant with the requirements of proposed 45 CFR part 180, and that fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP as we describe earlier.

We proposed that we may impose a CMP upon a hospital for a violation of each requirement of proposed 45 CFR part 180. The maximum daily dollar amount for a CMP to which a hospital may be subject would be \$300. We proposed that even if a hospital is in violation of multiple discrete requirements of proposed 45 CFR part

180, the maximum total sum that a single hospital may be assessed per day is \$300.

Further, we proposed to adjust the CMP amount annually by applying the cost-of-living adjustment multiplier determined by the Office of Management and Budget (OMB) for adjusting applicable CMP amounts pursuant to the *Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*. This multiplier, based on the Consumer Price Index for All Urban Consumers (CPI-U), not seasonally adjusted, is applied to the CMPs in 45 CFR 102.3. For instance, the cost-of-living adjustment multiplier for 2018, based on the CPI-U for the month of October 2017, not seasonally adjusted, was 1.02041 (83 FR 51369).

As discussed in the CY 2020 OPPI/ASC proposed rule, given the importance of compliance with the price transparency policies, we believe this proposed CMP amount strikes a balance between penalties that are sufficiently harsh to incentivize compliance but not excessively punitive. We reviewed CMP amounts for other CMS programs that require reporting information and we believe our proposed \$300 maximum daily dollar amount for a CMP is commensurate with the level of severity of the potential violation, taking into consideration that nondisclosure of standard charges does not rise to the level of harm to the public as other violations (such as safety and quality issues) for which CMS imposes CMPs and, therefore, should remain at a relatively lower level.

We considered applying lower and higher maximum dollar amounts for a CMP for noncompliance with the requirements of proposed 45 CFR part 180. For example, we considered that CMS has imposed \$100 per day penalty amounts with respect to other compliance matters, such as where health insurers fail to comply with premium revenue reporting and rebate requirements found at 45 CFR 158.606. The basis for the CMPs under 45 CFR 158.606 is the number of individuals affected. With respect to the disclosure requirements under proposed 45 CFR part 180, where the lack of information could affect an unknown number of consumers and in myriad ways (for example, not just individuals who paid more for items and services), we noted our belief that it would not be feasible to utilize a "per person" type basis. We also considered proposing higher maximum daily dollar amounts, such as \$400 per day, \$500 per day or more.

Further, we considered establishing a cumulative annual total limit for the

CMP to which a hospital is subject for noncompliance with proposed 45 CFR part 180. For example, we considered applying a cumulative annual total limit of \$100,000 per hospital for each calendar year. However, such an approach could, for example, prevent accrual of additional penalties on hospitals that remain noncompliant for multiple years.

If CMS imposes a penalty in accordance with the requirements of proposed 45 CFR part 180, we proposed that CMS provide a written notice of imposition of a CMP to the hospital via certified mail or another form of traceable carrier. This notice may include, but would not be limited to, the following:

- The basis for the hospital’s noncompliance, including, but not limited to, the following: CMS’ determination as to which requirement(s) the hospital violated; and the hospital’s failure to respond to CMS’ request to submit a CAP or comply with the requirements of a CAP.

- CMS’ determination as to the effective date for the violation(s). This date would be the latest date of the following:

- ++ The first day the hospital is required to meet the requirements of proposed 45 CFR part 180.

- ++ If a hospital previously met the requirements of this part but did not update the information annually as required, the date 12 months after the date of the last annual update specified in information posted by the hospital.

- ++ A date determined by CMS, such as one resulting from monitoring activities specified in proposed new 45 CFR 180.70, or development of a CAP as specified in proposed new 45 CFR 180.80.

- The amount of the penalty as of the date of the notice.

- A statement that a CMP may continue to be imposed for continuing violation(s).

- Payment instructions.

- Intent to publicize the hospital’s noncompliance and CMS’ determination to impose a CMP on the hospital for noncompliance with the requirements of proposed 45 CFR part 180 by posting the notice of imposition of a CMP on a CMS website.

- A statement of the hospital’s right to a hearing (as described in section II.H. of this final rule).

- A statement that the hospital’s failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal.

Further, in the event that a hospital elects to appeal the penalty, and if the CMP is upheld only in part by a final and binding decision, we proposed that CMS would issue a modified notice of imposition of a CMP.

We proposed that a hospital must pay a CMP in full within 60 calendar days after the date of the notice of imposition of a CMP from CMS. In the event a hospital requests a hearing (as described in section II.H. of this final rule), we proposed that the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision to uphold, in whole or in part, the CMP. We also proposed that if the 60th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

We also proposed to publicize, by posting on a CMS website, our notice of imposition of a CMP on a hospital for noncompliance with these requirements, and any subsequently issued notice of imposition of a CMP for continuing violations. In the event that a hospital requests a hearing, we proposed that CMS would indicate in its posting that the CMP is under review. If the CMP amount is upheld, in whole, by a final and binding decision, we would maintain the posting of the notice of imposition of a CMP on a CMS website. If the CMP is upheld, in part, by a final and binding decision, we would issue a modified notice of imposition of a CMP, and would make this modified notice public on a CMS website. If the CMP is overturned in full by a final and binding decision, we would remove the notice of imposition of a CMP from a CMS website.

In addition, we proposed that CMS may issue subsequent notice(s) of imposition of a CMP, as described in this section of the CY 2020 OPPS/ASC proposed rule, that result from the same instance(s) of noncompliance.

We proposed to set forth in proposed new 45 CFR 180.90 the proposed CMPs for hospitals determined by CMS to be noncompliant with requirements for making standard charges public.

We sought comment on whether the proposed amount of a CMP, in combination with making public on a CMS website our notice of imposition of a CMP, were reasonable and sufficient to ensure hospitals’ compliance with the proposed requirements to make public standard charges. We were interested in public comments on our proposed \$300 maximum daily dollar amount for a CMP for noncompliance with section 2718(e) of the PHS Act and proposed 45 CFR part 180. In particular, we sought comment on whether we should impose

stronger penalties for noncompliance, or whether we should further limit the maximum amount of penalty we would impose on a hospital for a calendar year and the methodology for creating such a limit (for instance through limiting the maximum daily penalty amount, by establishing a cumulative annual total limit on the penalty amount, or both). We sought comment on unintended consequences of the proposed penalties for noncompliance. We also sought commenters’ suggestions on whether other penalties should be applied for noncompliance with section 2718(e) of the PHS Act.

Comment: Several commenters stated that the imposition of CMPs for noncompliance with the requirements to make standard public charges exceeds CMS’ authority under section 2718(e) of the PHS Act. These commenters challenged CMS’ reliance on section 2718(b)(3) as the basis for enforcing the requirements that hospitals make their standard charges public, and specifically as the basis for imposing a CMP on a hospital for noncompliance with the requirements to make public standard charges. These commenters asserted that section 2718(b)(3) applies only to the MLR and rebate requirements imposed by the ACA on health insurance issuers offering group or individual health insurance coverage under section 2718 of the PHS Act. A few commenters explained that had Congress intended to require the Secretary to enforce the requirement for public availability of hospital standard charge information, it would have constructed the provisions of section 2718 of the PHS Act differently. A few commenters presented a review of the legislative history of section 2718 of the PHS Act, suggesting that the phrasing of section 2718(b)(3), referring to its applicability to “this section,” was a drafting error, and suggested that Congress intended to apply this provision only to MLR provisions within the section. A few commenters further asserted that absent an express mandate for the Secretary in section 2718(b)(3) of the PHS Act to enforce the requirements for hospitals to disclose their standard charges under a different provision of law (namely, section 2718(e)), the Secretary may neither imply an intent to do so nor reverse its previous rulemaking policy that limited the use of that enforcement authority to issuers that do not comply with MLR and rebate requirements imposed under section 2718(b). One commenter explained that interpreting section 2718(b)(3) of the PHS Act as CMS does leads to an absurd result.

A few commenters explained that HHS has not previously suggested that it could take enforcement action with respect to section 2718(e) of the PHS Act, which the commenters suggest means the agency lacked such powers. Specifically, one commenter suggested that HHS implicitly recognized that its enforcement authority under section 2718(b)(3) of the PHS Act should be read as confined to enforcing the MLR requirements when it adopted subparts D through F of 45 CFR part 158, stating that these provisions implement enforcement authority in section 2718(b)(3) and provide for enforcement of the reporting obligations set forth in section 2718(a) and rebate requirements in section 2718(b). Another commenter expressed that CMS has not previously asserted its ability to assess CMPs under section 2718(b)(3) of the PHS Act on noncompliant hospitals, or previously claimed any enforcement authority related to section 2718(e) of the PHS Act.

Response: We continue to believe section 2718(b)(3) of the PHS Act, based on its plain meaning, authorizes the Secretary to enforce the provisions of section 2718 of the PHS Act and to provide for appropriate penalties under section 2718 of the PHS Act, including section 2718(e) of the PHS Act. It is not absurd to say that Congress wanted to provide HHS authority more generally to enforce all of the requirements set out in section 2718. Further, HHS has not previously conceded that it lacked authority to issue such rules for enforcing, or penalties pursuant to, section 2718(e) of the PHS Act in promulgating regulations pursuant to sections 2718(a) and (b). In fact, as we explained in earlier rulemaking, we have been considering developing regulations, through notice and comment rulemaking, to establish enforcement mechanisms to address hospital noncompliance with section 2718(e) (83 FR 20548 through 20550; 83 FR 41686 through 41688).

Therefore, consistent with our proposal, we continue to believe we have the legal basis to impose penalties on hospitals that fail to make their standard charges public in accordance with the requirements we finalize under section 2718(e) of the PHS Act. Accordingly, as described in this section and elsewhere in this final rule, we are finalizing our proposals to enforce the requirements under new 45 CFR part 180, and to potentially impose CMPs for noncompliance with the requirements of new 45 CFR part 180.

Comment: A few commenters supported CMS' efforts to take enforcement actions and a few

commenters supported the proposal to impose financially significant CMPs on large hospitals for noncompliance with the requirements to make public standard charges. A few commenters suggested that CMS forgo imposition of CMPs altogether while others suggested that CMS limit use of CMPs (particularly to avoid excessive financial penalties) or not impose CMPs on certain types of providers, such as IRFs or rural hospitals.

Several commenters explained that the proposed CMPs were overly punitive, and suggested CMS forgo imposing CMPs. One commenter explained that CMPs are typically reserved for fraud and abuse, and opposed imposition of CMPs for price transparency requirement noncompliance, which is more likely to be based in technical difficulties or IT system limitations. A few commenters cited concerns about imposing CMPs on noncompliant hospitals in light of the complexity of making public standard charge data and the short timeframe by which hospitals would have to come into compliance. One commenter explained that it is not necessary to impose CMPs for noncompliance with price transparency requirements given that hospitals have undertaken numerous initiatives to enhance price transparency in recent years, and that they are making significant progress in this complex area.

Response: We appreciate commenters supporting the importance of enforcement actions and the imposition of CMPs on hospitals as a method for ensuring compliance with the requirements to make public standard charges. We decline the commenters' suggestions that we not finalize the proposed use of CMPs as an enforcement mechanism. Given the importance of the requirements for hospitals to make public standard charges, we believe CMPs serve as an appropriate enforcement action to address noncompliance. As we explained in Section II.G.2. of this final rule, we believe it is important that we apply a consistent approach to imposing CMPs on noncompliant hospitals across all entities, regardless of factors such as hospital size, revenue or location. Therefore, we decline to adopt the commenters' suggestions that we apply alternative policies to a subset of hospitals, such as rural safety net providers. Further, we disagree with the commenter's suggestion that we forgo establishing the authority to impose CMPs for noncompliance in light of the demonstrated commitment to price transparency by some, but not all, institutions.

We respond to comments on the amount of CMPs elsewhere in this section of this final rule. Under the actions to address hospital noncompliance which we are finalizing in this final rule, we anticipate that hospitals would have the opportunity to take corrective action prior to the imposition of a penalty. As we have described elsewhere in Section II.G of this final rule, prior to imposing a CMP on a hospital, we anticipate issuing a written warning notice and requesting a CAP from the hospital as initial steps to promote compliance. We may impose a CMP on a noncompliant hospital if it fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP. By complying with the requirements, a hospital can avoid financial penalties. We also note that hospitals determined to be noncompliant, and subject to a CMP, can avoid accruing larger amounts of CMPs by coming into compliance with the requirements.

Comment: Comments on the amount of the CMP were mostly polarized, with some suggesting lower amounts and other suggesting higher amounts than the proposed \$300 maximum daily dollar amount for a CMP. A recurring concern in comments was that the CMP amount could be overly burdensome and potentially detrimental to the continued operation of a small hospital with low margins, particularly CAHs, while posing an inadequate incentive for hospitals (particularly larger hospitals) to comply because the CMP amount does not pose a real financial burden. As one commenter explained, a large hospital could decide that \$300 per day (\$109,500 per year) is worth paying in order to not disclose information that could lead to payers with higher rates wanting to pay them less in light of discovering other payers have more favorable negotiated rates. A few commenters suggested that the proposed CMP amount is trivial for certain hospitals, compared, for instance, to the salaries of hospital executives, or the hospital's total revenue. One commenter expressed concern that stakeholders will view the noncompliance penalty as a new business expense rather than an incentive to comply with the transparency requirements. Another commenter explained that the proposed CMP amount is too low to compel hospitals to comply if they are adamantly opposed to making public this information.

Another commenter noted that under the PAMA and 42 CFR 414.504(e), applicable laboratories that do not report applicable information as

required may be subject to a CMP in an amount of up to \$10,000 per day for each failure to report or each misrepresentation or omission in reporting. The commenter suggested that compliance with these data reporting requirements was below expectations; therefore, the commenter suggested that it would be unlikely that the proposed \$300 maximum daily dollar amount for a CMP would be sufficient to encourage prompt reporting of pricing data by hospitals.

One commenter suggested that CMS increase the CMP amount, recommending the penalties be consistent with information blocking penalties (according to section 4004 of the 21st Century Cures Act), which can be up to \$1 million per violation (which we note is applicable to health IT developers, health information networks, and health information exchanges),¹⁷² explaining that failure to disclose price information would be information blocking.

A few commenters suggested alternative approaches, such as using factors that allow for scaling of the CMP amount. In particular, a few of these commenters suggested scaling penalties to ensure rural hospitals are not unduly burdened. For example, one commenter suggested that CMPs should be adjusted based on bed size and rural or urban designation. Another commenter suggested that CMS consider scaling the penalty based on the number of patients treated at the facility within a given year. If this information is not available due to lack of data on patients who self-pay or are insured by non-government payers, the commenter suggested that CMS scale the CMP amount according to the number of Medicare beneficiaries served in a given year. The commenter explained this approach could allow CMS to not overly penalize smaller hospitals while also providing a sufficient incentive for hospitals to comply.

Response: We appreciate the comments received on the proposed \$300 maximum daily dollar amount for a CMP. Given that commenters tended to be divided between those in favor of lower and higher amounts, we believe the proposed amount strikes an appropriate balance between these concerns, and we are therefore finalizing this amount as proposed.

The \$300 maximum daily dollar amount for a CMP for noncompliance with 45 CFR part 180 is lower than CMPs imposed under certain other

authorities administered by HHS agencies, where an entity's noncompliance poses immediate jeopardy, results in actual harm, or both. We believe the relatively lower amount for a CMP, for a hospital's noncompliance with requirements to make public standard charges, is reasonable since failure to make this information available is less serious than noncompliance that poses or results in harm to a patient.

At this time, and given the nature of potential noncompliance with the requirements we are finalizing for hospitals to make public standard charges, we decline to impose penalties higher than the proposed amount. We decline to impose the higher penalties that are applicable to health IT developers, health information networks, and health information exchanges for information blocking under the 21st Century Cures Act, for interfering with, preventing, or materially discouraging access, exchange, or use of electronic health information. We also decline to impose a potentially higher CMP amount, such as is applicable to laboratories under PAMA, for noncompliance with reporting information which could affect payment rate setting by CMS.

We also note that the \$300 maximum daily dollar amount, when accrued over a year, is higher than our estimate of the cost per hospital to comply with the requirements to make public standard charges in the initial period of implementation (as described in Section V of this final rule). We considered commenters' concerns that a relatively lower CMP amount may be insufficient to encourage compliance if the cost of making public standard charges, or the value to the hospital of not disclosing standard charge data, is higher than the total annual amount of the CMP. For this reason, we believe it is important to maintain a sufficiently sizeable CMP sum and therefore decline commenters' suggestions to finalize a maximum daily dollar amount for a CMP that is less than \$300.

We appreciate the commenters' concerns that some hospitals may prefer to forgo meeting the requirements of 45 CFR part 180 (for example, to not expend resources on reporting or to protect pricing information they consider sensitive), and, instead, face compliance actions including a \$300 maximum daily dollar amount for a CMP. We decline at this time to increase the amount of the CMP based on this concern alone, but as we gain experience with implementing the policy we intend to monitor for such occurrences, and may revisit the need to

adjust the amount of the CMP in future rulemaking.

We would need to further evaluate the feasibility of implementing a sliding scale CMP approach across institutions that meet the definition of hospital according to new 45 CFR 180.20 (as discussed in section II.B of this final rule). We believe it would be especially challenging to find a reliable source of data that provides for a scalable factor across all institutions that meet the definition of hospital. Therefore, we decline the commenters' suggestions to scale the CMP amount based on such factors as hospital bed size, location or patient volume. However, we anticipate that we will continue to consider this issue, and may revisit use of a CMP scaling methodology in future rulemaking. At this time, we are finalizing as proposed a policy that allows for a standardized daily maximum CMP amount.

Comment: One commenter supported the alternative we described in the CY 2020 OPPI/ASC proposed rule, which was to apply a cumulative annual total limit (or cap) on the penalty amount, though the commenter did not specify what this limit should be and suggested only that it be a reasonable amount.

Response: We believe we have struck an appropriate balance in determining the \$300 maximum daily dollar amount for a CMP, and we therefore decline at this time to finalize applying a cumulative annual total limit on the CMP amount. We appreciate the commenter's support for this alternative approach.

Comment: One commenter disagreed with the proposal that CMS publicize the notice of imposition of a CMP on a CMS website, explaining that this amounted to public shaming which the commenter believes has no benefit and seems petty.

Response: We continue to believe it is appropriate to publish the notice of imposition of a CMP on a CMS website to identify hospitals determined to be noncompliant with the requirements to make public standard charges. We believe this information will help inform the public of noncompliant hospitals and is an opportunity to demonstrate the outcome of CMS' monitoring and enforcement activities for these important requirements.

Final Action: After considering the comments received, we are finalizing as proposed policies for imposing a CMP on a hospital that we identify as noncompliant with the requirements of 45 CFR part 180, and that fails to respond to CMS' request to submit a CAP or comply with the requirements of a CAP.

¹⁷² Refer to *HealthIT.gov*, Information Blocking, available at <https://www.healthit.gov/topic/information-blocking>.

We are finalizing as proposed that CMS may impose a CMP upon a hospital for a violation of each requirement of 45 CFR part 180. Further, we are finalizing our proposal that the maximum daily dollar amount for a CMP to which a hospital may be subject is \$300, even if the hospital is in violation of multiple discrete requirements of 45 CFR part 180. The amount of the CMP will be adjusted annually using the multiplier determined by OMB for annually adjusting CMP amounts under 45 CFR part 102.

We are finalizing as proposed that CMS provides a written notice of imposition of a CMP to the hospital via certified mail or another form of traceable carrier. We are also finalizing as proposed the elements of this notice to the hospital, as previously described in this section of this final rule, will include but not be limited to the following:

- The basis for the hospital's noncompliance, including, but not limited to, the following: CMS' determination as to which requirement(s) the hospital has violated; and the hospital's failure to respond to CMS' request to submit a CAP or comply with the requirements of a CAP.

- CMS' determination as to the effective date for the violation(s).
- The amount of the penalty as of the date of the notice.

- A statement that a CMP may continue to be imposed for continuing violation(s).

- Payment instructions.
- Intent to publicize the hospital's noncompliance and CMS' determination to impose a CMP on the hospital for noncompliance with the requirements of 45 CFR part 180 by posting the notice of imposition of a CMP on a CMS website.

- A statement of the hospital's right to a hearing according to subpart D of 45 CFR part 180 (as discussed in section II.H of this final rule).

- A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal.

We are finalizing our proposal that CMS may issue subsequent notice(s) of imposition of a CMP, according to the aforementioned requirements (in short, where investigation reveals there is continuing justification), that result from the same instance(s) of noncompliance.

We are finalizing with a clarifying modification that, in the event that a

hospital elects to appeal the penalty, and if the CMP is upheld, in part, by a final and binding decision, CMS will issue a modified notice of imposition of a CMP, to conform to the adjudicated finding.

We are also finalizing our proposals on timing of payment of a CMP. Specifically, a hospital must pay the CMP in full within 60 calendar days after the date of the notice of imposition of a CMP from CMS. In the event a hospital requests a hearing, pursuant to subpart D of 45 CFR part 180, the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision to uphold, in whole or in part, the CMP. If the 60th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

We are finalizing as proposed that CMS will post the notice of imposition of a CMP on a CMS website, including the initial notice of imposition of a CMP, and subsequent notice(s) of imposition of a CMP that result from the same instance(s) of noncompliance. Further, in the event that a hospital elects to request a hearing, pursuant to subpart D of 45 CFR part 180, CMS will indicate in its posting that the CMP is under review. We are finalizing the following policies regarding the posting of the notice of imposition of a CMP, pursuant to a final and binding decision from the hearing process specified in subpart D of 45 CFR part 180:

- We are finalizing as proposed, CMS will maintain the posting of the notice of imposition of a CMP on a CMS website if the CMP is upheld, in whole.

- We are finalizing with a clarifying modification, CMS will issue a modified notice of imposition of a CMP, to conform to the adjudicated finding, if the CMP is upheld, in part. CMS will make this modified notice public on a CMS website.

- We are finalizing as proposed, CMS will remove the notice of imposition of a CMP from a CMS website if the CMP is overturned in full.

We are finalizing our proposal to specify these policies on CMPs in new 45 CFR 180.90.

H. Appeals Process

Under section 2718(b)(3) of the PHS Act, we proposed to impose penalties on hospitals that fail to make their standard charges public in accordance with the requirements we finalize under section 2718(e). As we described in the CY 2020 OPSS/ASC proposed rule (84 FR 39593 through 39594), we believe it is important to establish a fair administrative process by which a hospital may appeal CMS' decisions to

impose penalties under section 2718(b)(3) regarding the hospital's noncompliance with the requirements of section 2718(e) of the PHS Act and the requirements of proposed 45 CFR part 180. Through various Medicare programs, we have gained experience with administrative hearings and other processes to review CMS' determinations.

We proposed to align the procedures for the appeals process with the procedures established under section 2718(b)(3) of the PHS Act for an issuer to appeal a CMP imposed by HHS for its failure to report information and pay rebates related to MLRs, as required by sections 2718(a) and (b) of the PHS Act, and according to 45 CFR parts 158 and 150. Therefore, we proposed that a hospital upon which CMS has imposed a penalty under proposed 45 CFR part 180 may appeal that penalty in accordance with 45 CFR part 150, subpart D, except as we have otherwise proposed.

Generally, under this proposed approach, a hospital upon which CMS has imposed a penalty may request a hearing before an Administrative Law Judge (ALJ) of that penalty. The Administrator of CMS, at his or her discretion, may review in whole or in part the ALJ's decision. A hospital against which a final order imposing a CMP is entered may obtain judicial review.

For purposes of applying the appeals procedures at 45 CFR part 150 to appeals of CMPs under proposed 45 CFR part 180, we proposed the following exceptions to the provisions of 45 CFR part 150:

- Civil money penalty means a civil monetary penalty according to proposed new 45 CFR 180.90.

- Respondent means a hospital that received a notice of imposition of a CMP according to proposed new 45 CFR 180.90(b).

- References to a notice of assessment or proposed assessment, or notice of proposed determination of CMPs, are considered to be references to the notice of imposition of a CMP specified in proposed new 45 CFR 180.90(b).

- Under 45 CFR 150.417(b), in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to the following:

- ++ The hospital's posting(s) of its standard charges, if available.

- ++ Material the hospital timely previously submitted to CMS (including with respect to corrective actions and CAPs).

- ++ Material CMS used to monitor and assess the hospital's compliance

according to proposed new 45 CFR 180.70(a)(2).

- The ALJ's consideration of evidence of acts other than those at issue in the instant case under 45 CFR 150.445(g) does not apply.

We proposed to set forth in proposed new 45 CFR 180.100 the proposed procedures for a hospital to appeal the CMP imposed by CMS for its noncompliance with the requirements of proposed 45 CFR part 180.

We also proposed to set forth in proposed new 45 CFR 180.110 the consequences for failure of a hospital to request a hearing. If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a CMP described in proposed new 45 CFR 180.90(b), we proposed that CMS may impose the CMP indicated in such notice and may impose additional penalties pursuant to continuing violations according to proposed new 45 CFR 180.90(f) without right of appeal. We proposed that if the 30th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day. We also proposed that the hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with 45 CFR 150.405, unless the hospital can show good cause, as determined at 45 CFR 150.405(b), for failing to timely exercise its right to a hearing.

Alternatively, we considered and sought public comment on following a process for appealing CMPs similar to the approach specified in 42 CFR part 498, subparts D through F. We explained that there are differences between the appeals procedures at 42 CFR part 498 compared to 45 CFR part 150. Under the regulations at 42 CFR part 498, for example, either party dissatisfied with a hearing decision by the ALJ may request Departmental Appeals Board review of the ALJ's decision.

Final Action: We received no comments on our proposed process for a hospital upon which CMS has imposed a penalty under proposed 45 CFR part 180 to appeal that penalty in accordance with 45 CFR part 150, subpart D, except as we otherwise proposed. We are finalizing as proposed to specify in new 45 CFR 180.100 the procedures for a hospital to appeal the CMP imposed by CMS for its noncompliance with the requirements of 45 CFR part 180 to an ALJ, and for the Administrator of CMS, at his or her discretion, to review in whole or in part the ALJ's decision. Specifically, we are finalizing our proposal that a hospital upon which CMS has imposed a penalty

under 45 CFR part 180 may appeal that penalty in accordance with 45 CFR part 150, subpart D, with the exceptions (for the propose of applying the provisions of part 150 to CMPs under part 180) as described in this section of this final rule.

We are also finalizing as proposed to set forth in new 45 CFR 180.110 the consequences for failure of a hospital to request a hearing. If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a CMP described in new 45 CFR 180.90(b), CMS may impose the CMP indicated in such notice and may impose additional penalties pursuant to continuing violations according to new 45 CFR 180.90(f) without right of appeal. If the 30th calendar day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day. The hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with 45 CFR 150.405, unless the hospital can show good cause, as determined at 45 CFR 150.405(b), for failing to timely exercise its right to a hearing.

III. Comments Received in Response To Request for Information: Quality Measurement Relating To Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2020 OPPTS/ASC proposed rule (84 FR 39594 through 39595), we included a RFI related to (1) access to quality information for third parties and healthcare entities to use when developing price transparency tools and when communicating charges for healthcare services, and (2) improving incentives and assessing the ability of healthcare providers and suppliers to communicate and share charge information with patients. We received approximately 63 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

IV. Collection of Information Requirements

A. Response to Comments

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the OMB for review and approval.

We solicited comments in the CY 2020 OPPTS/ASC notice of proposed rulemaking that published in the August 9, 2019 **Federal Register** (84 FR 39398).

For the purpose of transparency, we are republishing the discussion of the information collection requirements (ICR) along with a reconciliation of the public comments we received.

B. ICR for Hospital Price Transparency

In this final rule, we seek to promote price transparency in hospital standard charges to implement section 2718(e) of the PHS Act. We believe that in doing so, healthcare costs will decrease, and consumers can be empowered to make more informed decisions about their healthcare. We believe these finalized requirements will represent an important step towards putting consumers at the center of their healthcare and ensuring they have access to needed information.

In the CY 2020 OPPTS/ASC proposed rule, we noted that hospitals in the United States maintain chargemasters, a list of their gross charges for all individual items and services as part of their standard billing and business practices.¹⁷³ Additionally, we stated that most hospitals maintain electronic data on charges they negotiate with third party payers for hospital items and services as well as service packages. As such, we indicated we believed that the burden for making this information publicly available would be minimal and estimated only a small burden for each hospital to extract, review, and conform the posting of gross charges and third party payer-specific negotiated charges for all hospital items and services in the comprehensive machine-readable format. In addition, we estimated some burden associated with hospitals making public their payer-specific negotiated charges for a set of at least 300 (70 CMS-specified and at least 230 hospital-selected) shoppable services in a consumer-friendly manner, with flexibility for hospitals to determine the most consumer-friendly format. We proposed a policy that hospitals would display the charge for the primary shoppable service along with charges for any ancillary services the hospital customarily provides in conjunction with the primary shoppable service.

We estimated the proposed requirements would apply to 6,002 hospitals operating within the United States under the proposed definition of "hospital." To estimate this number, we subtracted 208 federally-owned or operated hospitals from the total

¹⁷³ Batty M. and Ippolito B. Mystery of The Chargemaster: Examining The Role Of Hospital List Prices in What Patients Actually Pay. *Health Affairs*. April 2017; 36(4): 689–696. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0986>.

number of U.S. hospitals, 6,210 hospitals¹⁷⁴ (6,210 total hospitals—208 federally-owned or operated hospitals).

We concluded that the annual burden per hospital should be calculated with all activities performed by four professions combined. The four professions included a lawyer, a general operations manager, a business operations specialist, and a network and computer system administrator. We estimated an annual burden assessment to be 12 hours (2 hours + 8 hours + 2 hours) per hospital with a cost of \$1,017.24 (\$257.80 + \$592.00 + \$167.44) per hospital. We also estimated a total national burden of 72,024 hours (12 hours × 6,002 hospitals) and total cost of \$6,105,474 (\$1,017.24 × 6,002 hospitals).

Comment: Several commenters were concerned that CMS did not take into account the number of hours needed for specific technical activities or consultation with necessary professionals. For example, a few commenters were concerned that CMS underestimated the cost and time involved in consulting legal and compliance experts on implementation of the rule, suggesting that such investment would be necessary to ensure the hospital had satisfactorily met requirements. A few commenters suggested that CMS take into account the time, resources and input of clinical staff necessary for each hospital to identify and compile each shoppable service or service package and corresponding ancillary services to reach a total of 300 shoppable services. One commenter suggested that the burden estimate take into account the time hospitals need to develop policies and business practices to comply with the requirements of the rule. Several commenters were concerned that the burden estimate did not reflect the need to hire multiple additional full time equivalents (FTEs) to staff multiple departments to comply with the rule to keep up with new charges, technology, monitoring and reporting, and contract negotiations.

A few commenters cited a need for increasing consumer-facing clinical staffing as a result of making public hospital standard charge information. Specifically, one commenter expressed concern that the increased complexity of information available to consumers would result in an increased volume of calls from an average of 25 patients per day to 200 patients per day to its hospital customer service center. As a

result, the commenter stated that the hospital customer service center would need to add 8–10 additional FTEs, resulting in \$500,000 to \$1 million in additional costs per year.

Response: We thank commenters for their input and suggestions on the types of professions, and the time and resources needed to comply with these requirements. Our estimate takes into account the time needed to review and comply with these requirements. We acknowledge that some hospitals may require longer time or greater resources than others to identify and compile their standard charges in a manner consistent with our final rules. For example, some hospitals may have many third-payer contracts while others may have relatively few. Similarly, some hospitals may have already compiled and present their services to the public in a manner that is consumer-friendly as a result of state requirements or voluntarily actions. We also believe that the greatest impact will be in the first year related to organizing the display of information in the form and manner required under this final rule after which the hospital would simply have to update the numbers annually. In order to minimize the burden related to the consumer-friendly display of hospital charges for shoppable services, we are finalizing as modifications to new 45 CFR 180.60 that a hospital offering an internet-based price estimator tool, that meets the requirements we set forth in section II.F.5. of the final rule, is an acceptable alternative method for meeting our requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner. We believe that hospitals that have already been offering price estimator tools will incur less costs to comply with the requirements of the final rule given this accommodation.

Even so, we appreciate the suggestion from commenters that we consider time and input from clinical staff. We agree that clinical input would be helpful to ensure the display of shoppable services is presented the way patients experience their care and to translate billing code descriptions into plain language. As a result, we are adding in the wage of Registered Nurses as a proxy for clinical staff and accounting for 30 hours of clinical assistance per hospital. We believe this time would be important in the initial stages of implementation in order to determine what ancillary services are customarily provided with the provision of the primary shoppable service. We do not believe such clinical expertise would be required for annual updates to the disclosed information in subsequent years. Additionally, in

response to commenters who indicate more time should be allocated for lawyers and general operations managers, we are increasing the number of hours for those professions to 10 hours per hospital. Since the time allocated for lawyers was for reviewing the final rules, we believe these hours should be included in the initial implementation year estimate only. We are also significantly increasing the number of hours needed in the initial implementation year for business operations specialists to complete necessary processes and procedures to gather and compile required information and post it to the internet in the form and manner specified in the final rule.

Finally, we can find no evidence to support the assertion that public disclosure of hospital standard charges increases the number of consumer calls to hospitals, necessitating hiring of additional staff for a hospital customer service center. To the contrary, price transparency research suggests that disclosure of provider charges can reduce administrative costs for a hospital and improve patient satisfaction.¹⁷⁵ We therefore have not included this in our analysis.

Comment: Several hospitals asserted that CMS had underestimated the total administrative burden and cost of meeting the requirements of the rule and disagreed with the 12-hour estimate. Commenters stated several reasons for this concern including not accounting for the number of payers that could be present in a geographic region, the variety of negotiated payment methodologies between hospitals and payers, and the amount and scope of hospital resources required to gather the relevant data from contracts and accounting systems. Some commenters also indicated that the administrative burden and cost estimate should take into consideration the electronic availability and display of data on a user-friendly platform, and the cost to hospitals to regularly update their standard charge information for monitoring and reporting. Commenters cited the complexity of information to be provided and the burden of gathering the data from disparate accounting and billing systems. In particular, commenters indicated that some hospitals do not already have their standard charge data available in any electronic format, stating that they do not have contract management systems.

¹⁷⁴ American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁷⁵ <https://www.advisory.com/research/market-innovation-center/the-growth-channel/2018/12/price-transparency>.

Several commenters disagreed with the estimate based on their experiences with compliance with the requirements under the FY 2019 IPPS/LTCH PPS final rule (83 FR 41144) and state-based price transparency requirements. For example, one commenter indicated that chargemaster posting took 30 minutes to complete while another commenter said they have already exceeded 12 hours just to comply with posting their chargemaster data alone, while another commenter stated their experience in making standard charges public under the FY 2019 IPPS/LTCH PPS final rule task required 60 to 100 hours. Another commenter stated that their medical center spent 6 months of planning and exceeded 50 hours to meet the requirements for price transparency under the FY 2019 IPPS/LTCH PPS final rule. One commenter stated that one of their hospital members voluntarily produced a website that allows consumers to obtain estimates of their total out-of-pocket costs by plugging in information from their insurers. Their online tool covers 500 of their 6,000 chargemaster services items and the hospital estimates it took them 20 FTE hours to set up the basic framework and an ongoing two to four FTE hours per week to continue the build of all services and test for errors and putting real-time insurance information has taken an estimated 150 FTE hours to date. Similarly, another commenter, a professional organization of individuals involved in various aspects of healthcare financial management, writing on behalf of hospital finance and management professionals based on a survey of those individuals their members estimated that the average time required to comply is 150 hours per hospital, based on a survey of its members. One commenter stated that North Carolina implemented a similar process to the “service package” portion of CMS’ proposal that included top 100 DRGs, top 20 outpatient surgeries, and top 20 imaging procedures at the State level with the de-identified minimum, average and maximum “accepted” (collected) for closed accounts. The commenter estimated that this effort required 500 hours of staff time for the first reporting period. Several commenters provided estimates of their anticipated burden and additional required FTEs to comply with the proposed requirements for hospitals to make public standard charges ranging from \$1,000 to over \$450,000 per hospital, 12.5 hours to 4,600 hours per hospital, and 3–10 employees per hospital.

Response: We appreciate the input provided by commenters. As indicated in the CY 2020 OPPS/ASC proposed rule at 84 FR 39579 through 39580, based on an internal analysis of plans in the regulated individual and small group insurance markets under the ACA, we determined that per rating area there is an average of 1 to 400 payers in the small group market (averaging nearly 40 products or lines of service in each rating area) and an average of 1 to 200 payers in the individual market (averaging nearly 20 products or lines of service in each rating area). We therefore acknowledge and have taken into account that hospitals may have many payer-specific negotiated charges to compile and make public. We are also aware that hospitals and payers utilize a variety of payment methodologies in their contracts, which is why we have focused on the base payer rates negotiated between the hospital and payer for the services hospitals provide (section II.D.3 of this final rule). We are also aware that the standard charge information may be housed in disparate systems, for example, the gross charges can be found in a hospital chargemaster while the payer-specific negotiated charges can be found in the hospitals’ revenue cycle management system or in the rate tables associated with the in-network contract.

Some commenters provided implementation estimates based on a hospital system comprised of more than one hospital, and in such instances, we converted the estimate to a per-hospital basis for our analysis. Others (as in the North Carolina example above) appeared to misunderstand the requirements by referencing a need to calculate and determine paid amounts, in contrast to the policies we are finalizing in this rule. Most of the outlier estimates submitted by commenters were unaccompanied by any details regarding the assumptions that were made to develop the estimate. We also noted that some commenters provided burden estimates in reference to development of a consumer-friendly price estimator tool, however, we are not requiring hospitals to develop or display standard charge data in a tool. Our final policies provide hospitals with flexibility to determine the most appropriate internet-based format for purposes of complying with making standard charges public in a consumer-friendly manner. Further, we believe there are a variety of low cost formats a hospital could choose as suggested in section II.F of this final rule. For example, making public standard charges in a spreadsheet posted to a

hospital website would be one way to satisfy the requirements of this final rule. We note that in response to comments on this issue, we have finalized a policy that would reduce hospital reporting burden further, specifically, we are finalizing a policy to specify that a hospital offering an internet-based price estimator tool, that meets the criteria we set forth in new 45 CFR 180.60, would be regarded as having met the requirements to make public their standard charges for selected shoppable services in a consumer-friendly manner. We also believe due to their existing public displays of data, these hospitals already have a framework or business processes that they can leverage that would minimize additional burden.

We also acknowledge that some hospitals may require more time and resources than others to gather the relevant data, prepare for its electronic availability, display it in a consumer-friendly format, and regularly update that information for monitoring and reporting. We believe this to be true because some hospitals are already compiling and reporting similar data to meet State price transparency requirements and some are already making public their charges online in consumer-friendly ways. The wide range of burden hours submitted by commenters appears to support and reflect the notion that hospitals nationwide are at different stages of readiness to offer consumers transparent price information or are at various levels of participation in posting of charge and price information. We also believe that different hospitals may face different constraints when estimating their burden and resources required.

With these considerations in mind, we agree that the burden estimate should be revised to reflect an increased number of hours. Commenters included individuals, hospitals and health systems, hospital associations, and a health finance association. The commenters provided estimates based on both their unique experiences as well as experiences from a wide variety of health financial management experts and members. As noted, estimates submitted by commenters (when calculated on a per hospital basis) ranged from \$1,000 to over \$450,000 per hospital, 12.5 hours to 4,600 hours per hospital, and 3–10 employees per hospital. Most estimates by commenters fell within a range of 60 to 250 hours per hospital and approximately \$4,800 to \$20,000 per hospital, which we conclude is reasonable given our assumption that hospitals are in various states of readiness. Specifically, we

determined that a total burden of 150 hours for the first year is reasonable for hospitals nationwide, based on estimates provided by an organization with broad expertise and membership related to healthcare financial management and a large health care system with multiple hospitals. We believe an estimate of 150 hours per hospital for the first year represents a broad industry view that takes into account the range of hospital readiness and ability to comply with these rules.

Comment: Several commenters referenced the cost of ongoing compliance with the rule in subsequent years and recommended an annualized burden estimate that would be reduced from the initial year of implementation of the requirement to publicize standard charges. However, few commenters provided any specific recommendations as to the potential ongoing costs. One commenter, for example, indicated that they believed an estimate of “several thousand dollars” would be reasonable to purchase software that would automatically update the charges on an annual basis (thus suggesting that there would be no maintenance costs). Two commenters suggested that maintenance costs would be approximately 25 percent of implementation costs, however, these commenters specifically discussed the costs associated with pricing tool development, and not the burden associated with our final policies. Another commenter estimated their compliance would require \$100,000 for the first year working with an outside vendor and close to \$50,000 in the out years, however, this commenter assumed that the file would be updated as frequently as weekly. One commenter shared their experience complying with a North Carolina requirement to calculate and report amounts paid and indicated their maintenance burden was approximately 40 percent of their initial effort.

Response: We agree with commenters that there may be a continued cost of compliance with the rule past the initial year for some hospitals and are therefore adding a burden assessment for maintenance costs. We further agree with commenters that the annualized burden should show a reduction compared to the initial year because hospitals will have made the necessary updates to their software and business operations during the first year, and become more acclimated to the rule. Specifically, we believe there will no longer be a need for hospitals to: (1) Consult with a clinical professional to make a selection of shoppable services or to determine associated ancillary services; or (2) consult with a lawyer to

review the requirements of this final rule as these are actions that will only need to take place prior to the initial public display of data. We therefore estimate that after eliminating the burden hours for these professionals and reducing the applicable burden hours for business and general operations in subsequent years, the total annual national burden for maintenance costs in subsequent years would be 276,092 hours (46 hours × 6,002 hospitals) and total cost of \$21,672,502 (\$3,610.88 × 6,002 hospitals). (See Table 6.)

Comment: Several commenters suggested that CMS engage in further research or solicit additional input from stakeholders and focus groups. Commenters recommended CMS work with a focus group of several large health systems and industry consultants to conduct further studies to understand the actual time and effort for implementation of these requirements. A few commenters suggested that CMS should do more research to better inform the COI and burden estimates and suggested CMS seek in-depth input from hospitals on how their contracts are developed and how negotiated rates may be displayed to include such considerations as the full scope of current hospital reporting and unintended consequences.

Response: We appreciate commenters’ suggestions. However, we believe that we have sufficient input as a result of our many RFIs and listening sessions conducted over the course of the past 18 months, in addition to the helpful input we received from comments to our CY 2020 OPPS/ASC proposed rule. We note that we are making some accommodations in our final policies to relieve hospital burden and to provide additional time for hospitals to come into compliance with these new rules. Additionally, we are increasing our estimated burden in accordance with the recommendations from commenters, and including ongoing maintenance costs.

Final Estimate: In this final rule, we seek to promote price transparency in hospital standard charges so that consumers can be empowered to make more informed decisions about their healthcare. If finalized, we believe these proposed requirements would represent an important step towards putting consumers at the center of their healthcare and ensuring they have access to needed information. We are making modifications to several of our proposed policies that impact our burden estimate. Specifically, we are adding three additional types of standard charges that the hospital

would have to make public: The de-identified minimum negotiated charge, the de-identified maximum negotiated charge and the discounted cash price. We continue to believe that since these data exist in hospital financial and accounting systems (although not always in electronic format), the burden for making this information publicly available would be relatively minimal for posting of gross charges, payer-specific negotiated charges, de-identified minimum negotiated charge, de-identified maximum negotiated charge, and discounted cash prices for all hospital items and services online in a single machine-readable format as specified in the final rule. In addition, we continue to estimate some burden associated with hospitals making public their payer-specific negotiated charges, de-identified minimum negotiated charge, de-identified maximum negotiated charge, and cash discounted price for a set of at least 300 (70 CMS-specified and at least 230 hospital-selected) shoppable services in a consumer-friendly manner, with flexibility for hospitals to determine the most consumer-friendly format.

Although we are increasing the number of the types of standard charges a hospital must make public, we have reduced burden by finalizing a policy to specify that a hospital offering an internet-based price estimator tool, that meets the criteria we set forth in new 45 CFR 180.60, would be deemed as having met the requirements to make public their standard charges for selected shoppable services in a consumer-friendly manner. Because many hospitals already offer such price estimator tools, we believe this policy will serve to minimize the burden while meeting our policy goals of ensuring hospital pricing information can be readily accessible in a consumer-friendly manner.

We estimate that the final rule applies to 6,002 hospitals operating within the United States under the definition of “hospital” discussed in section II.B.1. of the final rule. To estimate this number, we subtract 208 federally-owned or operated hospitals from the total number of U.S. hospitals, 6,210 hospitals¹⁷⁶ (6,210 total hospitals – 208 federally-owned or operated hospitals).

We estimate the hourly cost for each labor category used in this analysis by referencing Bureau of Labor Statistics report on Occupational Employment

¹⁷⁶ American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: <https://www.aha.org/statistics/fast-facts-us-hospitals>.

and Wages (May 2018¹⁷⁷) in Table 4. There are many professions involved in any business’s processes. Therefore, we use the wages of General and Operations Managers as a proxy for management staff, the wages of Lawyers as a proxy for legal staff, the wages of Network and Computer Systems Administrators as a proxy for IT staff, the wage of Registered Nurses as a proxy for clinical staff, and

the wage of Business Operations Specialists as a proxy for other business staff throughout this analysis. Obtaining data on overhead costs is challenging. Overhead costs vary greatly across industries and facility sizes. In addition, the precise cost elements assigned as “indirect” or “overhead” costs, as opposed to direct costs or employee wages, are subject to some interpretation

at the facility level. Therefore, we calculate the cost of overhead at 100 percent of the mean hourly wage in line with the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program (81 FR 57260 and 82 FR 59477, respectively).

TABLE 4—OCCUPATION TITLES AND WAGE RATES

Occupation title	Occupation code	Mean hourly wage (\$/hr)	Fringe benefit (\$/hr)	Adjusted hourly wage (\$/hr)
Lawyers	23–1011	\$69.34	\$69.34	\$138.68
General and Operations Managers	11–1021	59.56	59.56	119.12
Business Operations Specialists	13–1199	37.00	37.00	74.00
Registered Nurses	29–1141	36.30	36.30	72.60
Network and Computer Systems Administrators	15–1142	41.86	41.86	83.72

In order to comply with regulatory updates finalized in the final rule in the initial year of implementation, hospitals would first need to review the rule. We estimate that this task would take a lawyer, on average, 5 hours (at \$138.68 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for Lawyers (23–1011)¹⁷⁸) to perform their review, and a general operations manager, on average, 5 hours (at \$119.12 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for General and Operations Managers (11–1021)¹⁷⁹) to review and determine compliance requirements. Therefore, for reviewing the rule, we estimate 10 burden hours per hospital, with a total of 60,020 burden hours (10 hours × 6,002 hospitals). The cost is \$1,289 per hospital (5 hours × \$138.68 + 5 hours × \$119.12), with a total cost of \$7,736,578 (\$1,289.00 × 6,002 hospitals).

After reviewing the rule, hospitals would need to review their policies and business practices in the context of the defined terms and requirements for information collection then determine how to comply. We believe this will require minimal changes for affected hospitals because the standard charge information to be collected is already compiled and maintained as part of hospitals’ contracting, accounting and billing systems. Some hospitals may have to consult directly with their payer contracts to review and compile payer-

specific negotiated charges. We note that we are finalizing requirements for hospitals to make public five types of standard charges including their gross charges (as reflected in the chargemaster), their payer-specific negotiated charges, discounted cash prices, the de-identified minimum negotiated charge, and the de-identified maximum negotiated charge. All five types of standard charges for all items and services, as finalized, must be made public in a comprehensive machine-readable file online. Additionally, all but gross charges would have to be made public for a total of 300 shoppable services (70 CMS-specified and 230 hospital-selected) in a consumer-friendly manner, including listing the charges for associated ancillary services provided by the hospital so that the hospital charge information is more accessible and easier to digest for consumers seeking to obtain pricing information for making decisions about their treatment.

We estimate it would take a business operations specialist, on average, 80 hours (at \$74 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for Business Operations Specialists, All Other (13–1199)¹⁸⁰) to complete necessary processes and procedures to gather and compile required information and post it to the internet in the form and manner specified by the final rule. For this task,

we estimate 80 burden hours per hospital. The total burden hours are 480,160 hours (80 hours × 6,002 hospitals). The cost is \$5,920 per hospital (80 hours × \$74), with a total cost of \$35,531,840 (\$5,920 × 6,002 hospitals).

We estimate that a network and computer system administrator would spend, on average, 30 hours (at \$83.72 per hour, which is based on the Bureau of Labor Statistics (BLS) wage for Network and Computer Systems Administrators (15–1142)¹⁸¹) to meet requirements specified by this final rule. The total burden hours are 180,060 hours (30 hours × 6,002 hospitals). The cost is \$2,511.60 per hospital (30 hours × \$83.72), with a total cost of \$15,074,623 (180,060 hours × \$83.72).

In addition, in the initial year of implementation, we estimate it would take a registered nurse, on average, 30 hours (at \$72.60 per hour, which is based on Bureau of Labor Statistics (BLS) wage for Registered Nurses (29–1141)¹⁸²) to capture necessary clinical input to determine a representative services package for a given service. We estimate 30 burden hours per hospital. The total burden hours for this task are 180,060 hours (30 hours × 6,002 hospitals). The cost is \$2,178 per hospital (30 hours × \$72.60), with a total cost of \$13,072,356 (\$2,178 × 6,002 hospitals).

¹⁷⁷ Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2018. Available at: https://www.bls.gov/oes/2018/may/oes_nat.htm.

¹⁷⁸ Bureau of Labor Statistics. Occupational Employment and Wage Estimates, May 2018: 23–1011 Lawyers. Available at: <https://www.bls.gov/oes/current/oes231011.htm>.

¹⁷⁹ Bureau of Labor Statistics. Occupational Employment and Wage Estimates, May 2018: 11–1021 General and Operations Managers. Available at: <https://www.bls.gov/oes/current/oes111021.htm>.

¹⁸⁰ Bureau of Labor Statistics. Occupational Employment and Wages, May 2018: 13–1199 Business Operations Specialist, All Other. Available at: <https://www.bls.gov/oes/current/oes131199.htm>.

¹⁸¹ Bureau of Labor Statistics. Occupational Employment and Wages, May 2018: 15–1142 Network and Computer System Administrators. Available at: <https://www.bls.gov/oes/current/oes151142.htm>.

¹⁸² Bureau of Labor Statistics. Occupational Employment and Wages, May 2018: 29–1141 Registered Nurses. Available at: <https://www.bls.gov/oes/2018/may/oes291141.htm>.

Therefore, we are finalizing the total burden estimate for the first year to be 150 hours (10 hours + 80 hours + 30 hours + 30 hours) per hospital with a cost of \$11,898.60 (\$1,289 + \$5,920 + \$2,178 + \$2,511.60) per hospital. We also estimate a total national burden of 900,300 hours (150 hours × 6,002 hospitals) and total cost of \$71,415,397 (\$11,898.60 × 6,002 hospitals). (See Table 5.)

TABLE 5—SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR THE FIRST YEAR

Regulation section(s)	OMB control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting (\$)
§ 180	0938–NEW	6,002	6,002	150	900,300	\$71,415,397

We anticipate that these costs will decline in subsequent years after the first year of finalization of the rule as hospitals gain additional efficiencies or may utilize the business processes and system infrastructures or software that would be built or purchased during the first year. We expect that the cost associated with maintenance would be significantly less than the cost hospitals would incur in the first year and would remain relatively level for a few years. We further believe that the activities associated with maintenance would only require General and Operations Managers, Business Operations Specialists, and Network and Computer Systems Administrators professions listed in Table 4. Utilizing their corresponding Adjusted Hourly Wage rates from this table, we estimate that it would take a general operations

manager, on average, 2 hours to review and determine updates in compliance with requirements. Therefore, we estimate 2 burden hours per hospital, with a total of 12,004 burden hours (2 hours × 6,002 hospitals). The cost is \$238.24 per hospital (2 hours × \$119.12), with a total cost of \$1,429,916 (\$238.24 × 6,002 hospitals).

We also estimate it would take a business operations specialist, on average, 32 hours to gather and compile required information and post it to the internet in the form and manner specified by the final rule. For this task, we estimate 32 burden hours per hospital. The total burden hours are 192,064 hours (32 hours × 6,002 hospitals). Using Adjusted Hourly Wage rates from Table 4, the cost is \$2,368 per hospital (32 hours × \$74.00), with a total

cost of \$14,212,736 (\$2,368 × 6,002 hospitals).

Lastly, we estimate that a network and computer system administrator would spend, on average, 12 hours to maintain requirements specified by this final rule. The total burden hours are 72,024 hours (12 hours × 6,002 hospitals). The cost is \$1,004.64 per hospital (12 hours × \$83.72), with a total cost of \$6,029,849 (72,024 hours × \$83.72).

Therefore, we are finalizing the total annual burden estimate for subsequent years to be 46 hours (2 hours + 32 hours + 12 hours) per hospital with a cost of \$3,610.88 (\$238.24 + \$2,368.00 + \$1,004.64) per hospital. We also estimate a total annual national burden for subsequent years of 276,092 hours (46 hours × 6,002 hospitals) and total cost of \$21,672,502 (\$3,610.88 × 6,002 hospitals). (See Table 6.)

TABLE 6—SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR SUBSEQUENT YEARS

Regulation section(s)	OMB control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting (\$)
§ 180	0938–NEW	6,002	6,002	46	276,092	\$21,672,502

V. Regulatory Impact Analysis

A. Statement of Need

As healthcare costs continue to rise, healthcare affordability has become an area of intense focus. Healthcare spending is projected to consume almost 20 percent of the economy by 2027.¹⁸³ We believe that one reason for this upward spending trajectory in spending is the lack of transparency in healthcare pricing. Additionally, numerous studies suggest that consumers want greater healthcare pricing transparency. For example, a study of HDHP enrollees found that

respondents wanted additional healthcare price information so that they could make more informed decisions about where to seek care based on price.¹⁸⁴ Health economists and other experts state that significant cost containment cannot occur without widespread and sustained transparency in provider prices. We believe there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare coverage costs. We believe healthcare markets could work more efficiently and provide consumers with

higher-value healthcare if we promote policies that encourage choice and competition. The intent of this rule is to promote price transparency in hospital standard charges to implement section 2718(e) of the PHS Act. We believe that in doing so, healthcare costs will decrease through increased competition and consumers will be empowered to make more informed decisions about their healthcare. We believe these finalized requirements will represent an important step towards putting consumers at the center of their healthcare and ensuring they have access to needed information.

We further identified a need to impose CMPs to ensure compliance with the requirements of this final rule. The amount of the CMP is \$300 per day per hospital. We believe this amount to be sufficient to prompt hospitals to

¹⁸³ National Health Expenditure Fact Sheet, Centers for Medicare & Medicaid Services, April 26, 2019. Available at: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html>.

¹⁸⁴ Sinaiko AD, et al. Cost-Sharing Obligations, High-Deductible Health Plan Growth, and Shopping for Health Care: Enrollees with Skin in the Game. *JAMA Intern Med.* March 2016; 176(3), 395–397. Available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2482348>.

timely and properly display standard charges in both machine-readable and consumer-friendly formats in accordance with the requirements of this final rule.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the SSA, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

An RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). In aggregate, we estimate that this rule will cost approximately \$71.4 million for hospitals to implement nationwide, in the initial year of implementation. In subsequent years, we anticipate minimal burden on hospitals for remaining compliant with the requirements to make public standard charges by annually updating

the data they make public because, as explained in the CY 2020 OPPS/ASC proposed rule, we believe most of the effort will be in reviewing the rule for compliance, selecting the hospital ‘shoppable’ services, determining the ancillary services and displaying the shoppable services in a consumer-friendly manner. After the first year, hospitals would only need to update the data at least once every 12 months. We estimate that these annual updates and general operations for complying with the final rule will cost hospitals \$21,672,502 annually after the initial year.

Almost all hospitals operating within the United States will be affected by the requirement to make standard charges public in both a machine-readable, and consumer-friendly manner. Although the level of disclosure of standard charge data required under this final rule is unprecedented, we do not expect the requirements of the final rule to disrupt normal business operations because hospitals already keep and maintain these data within their billing and accounting systems. However, OMB has determined that the actions are economically significant within the meaning of section 3(f) of the Executive Order. Therefore, OMB has reviewed this regulation, and the Department of Health and Human Services has provided the following assessment of its impact.

C. Anticipated Effects

This final rule would affect each hospital (as defined at 45 CFR 180.20) operating within the United States. We estimate that the final rule applies to 6,002 hospitals operating within the United States under the definition of “hospital” discussed in section II.B.1. of this final rule. To estimate this number, we subtracted 208 federally-owned or operated hospitals from the total number of United States hospitals, 6,210 hospitals.¹⁸⁵ In order to comply with regulatory updates finalized in the final rule in the initial year, hospitals would first need to review the rule. We estimate that this task would take a lawyer, on average, 5 hours to perform their review, and a general operations manager, on average, 5 hours to review and determine compliance requirements. We then estimate it would take a business operations specialist, on average, 80 hours to complete necessary processes and procedures to gather and compile required information and post it to the

internet in the form and manner specified by the final rule. We also estimate that a network and computer system administrator would spend, on average, 30 hours to meet requirements specified by this final rule. Lastly, we estimate it would take a registered nurse, on average, 30 hours to capture necessary clinical input to determine a representative services package for a given service. Therefore, we are finalizing the total burden estimate to be 150 hours per hospital for the first year immediately following the finalization of this rule.

For the burden hours in subsequent years, we estimate that it would take a general operations manager, on average, 2 hours to review and determine updates in compliance requirements, a business operations specialist, on average, 32 hours to update necessary processes and procedures to gather and compile required information and post it to the internet in the form and manner specified by this final rule, and a network and computer system administrator would spend, on average, 12 hours to maintain requirements specified by this final rule. Therefore, we are finalizing the total burden estimate for the subsequent years to be 46 hours per hospital.

In order to estimate the cost associated with these activities, we use the hourly cost for each labor category used in this analysis by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2018¹⁸⁶). There are many professions involved in any business’s processes. Therefore, we use the wage rate of a profession as a proxy for professional activities under such category. Also, we calculate the cost of overhead at 100 percent of the mean hourly wage in line with the Hospital Inpatient Quality Reporting Program and the Hospital Outpatient Quality Reporting Program (81 FR 57260 and 82 FR 59477, respectively). As a result, we use adjusted hourly wage rate of \$138.68 for lawyers, adjusted hourly wage rate of \$119.12 for general and operational managers, adjusted hourly wage rate of \$74 for business operations specialists, adjusted hourly wage rate of \$83.72 for network and computer systems administrators and hourly wage rate of \$72.60 for registered nurses. With these numbers, we estimate a cost of \$11,898.60 per hospital with total cost of \$71.4 million for affected hospitals nationwide in the initial period for

¹⁸⁵ American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: <https://www.aha.org/statistics/fast-facts-us-hospitals>.

¹⁸⁶ Bureau of Labor Statistics. National Occupational Employment and Wage Estimates, May 2018. Available at: https://www.bls.gov/oes/2018/may/oes_nat.htm.

implementing the requirements we are finalizing with this rule.

1. Effects on Private Sector

As discussed in the CY 2020 OPPTS/ASC proposed rule (84 FR 39631 through 39632), we considered the estimated effects on the private sector, and welcomed public comments on the impact of the proposed requirements on the private sector. As discussed in the Collection of Information section of this final rule, we continue to believe the burden on hospitals would be minimal. We also indicated that we believe the requirements in the final rule would encourage hospitals to adhere to best practices and industry standards by developing more robust and more efficient revenue integrity processes while working to comply with these requirements. Additionally, we are finalizing policies that could reduce potential compliance burdens, for example, we are finalizing as a modification that a hospital offering an internet-based price estimator tool that meets applicable requirements, is regarded as having met requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner. Some hospitals already offer such tools, so fewer hospitals would need to develop display of consumer-friendly pricing information from scratch. Moreover, such hospitals would spend fewer hours complying because they would only need to review their existing price estimator tool to evaluate whether it meets the criteria specified at 180.60(a)(2).

Therefore, we considered these new variables in estimating burden and cost after the initial period of implementation, and determined their value would largely depend upon the hospitals' initial readiness and compliance status. We believe some variables serve to reduce the hours required for one or more activities associated with complying with the final rule after the first year. For example, to be compliant initially, the hospital must determine its shoppable services and ancillary services for display, must determine the most consumer-friendly format and display site, and must collect payer-specific negotiated charge information from its contracts or existing revenue management cycle process. Such activities are necessary only in the initial period of implementation for hospitals that do not already adhere to industry standards and best practices; once those activities have been completed, a hospital would simply need to update the standard charge data

on an annual basis going forward. In addition, these variables may correlate and drive more changes in factors that would affect cost estimating after the initial period of implementation. Due to these considerations, we provided an updated burden estimate that reduces the number of total annual hours in subsequent years and are finalizing with this rule.

Comment: A few commenters stated that CMS has not demonstrated that the benefit of the policies outweigh the costs of implementing the rule.

Response: We appreciate commenters' input. However, we disagree with this comment. This final rule seeks to further advance hospital price transparency efforts that initiated with the FY 2015 IPPS/LTCH PPS and FY 2019 IPPS/LTCH PPS rules seeking to implement section 2718(e) of the PHS Act. At the time these prior rules were published, and as echoed in the comments we are responding to in this final rule, we heard from many stakeholders and public commenters that more guidelines and specificity around the form and manner in which hospitals make standard charges public would be helpful. Such commenters requested that CMS include requirements for more types of standard charges, as gross charges or the chargemaster alone are not sufficient for patients to estimate their financial obligations or to drive improvements in value-based care. This final rule goes a step farther by requiring hospitals to make public payer-specific negotiated charges, the de-identified minimum negotiated charge, the de-identified maximum negotiated charge, and discounted cash prices, in addition to gross charges for all items and services. Throughout section II of this final rule, we discuss the benefits of informing and empowering the public with hospital price information. These requirements would make public data that consumers could use to better understand the cost of care, and inform their healthcare decision-making, before receiving services. Further, technology vendors may innovate and create new products, including internet-based price estimator tools, or upgrade existing technologies to support hospitals in meeting these requirements and aiding consumers and healthcare providers in using data that is made public by hospitals. Other members of the public, such as employers, would be better informed to monitor insurer effectiveness and to help their employees shop for value.

In section V of this final rule, we analyze effects of these requirements on both the private sector and consumers. In section IV of this final rule, we detail

how we determined the estimated burden of the requirements we are finalizing, at 150 hours with a cost of \$11,898.60 per hospital, and how we arrived at these figures. In the following sub-sections of the RIA, we categorize our analyses within the estimated effects on consumers, small entities, small rural hospitals, and alternatives considered. We provide analyses from these perspectives to demonstrate that these requirements would bring consumers and other stakeholders' insights into healthcare costs, as well as the reasonable burden estimate for hospitals that takes into account commenters' concerns. In summary, we believe the overall benefits to consumers and healthcare markets nationwide will exceed the burden. For the initial year of implementation, we are finalizing an estimate of 150 hours and cost \$11,898.60 per hospital for the burden of the requirements we are finalizing in this final rule that takes into account input from public comments.

Comment: We received some comments on the potential impacts of the proposed hospital price transparency requirements on CAHs, rural hospitals, and SCHs, including their suggestion that CMS exempt these entities from part or all requirements to make standard charges public.

Response: We believe that the benefits to consumers, and to the general public as a whole, outweigh the operational challenges faced by these entities. Further, elsewhere in the RIA (see section V.C.5 of this final rule), we analyze effects on small rural hospitals.

Comment: Many commenters cautioned that disclosure of payer-specific negotiated charges would increase, not decrease, healthcare costs in certain markets due to anticompetitive behaviors or increases in prices as a result of hospital knowledge of better rates negotiated by neighboring hospitals.

Response: We continue to believe, as supported by (for instance) academic research, economics research, or both, that the healthcare market could work more efficiently and provide consumers with high-value healthcare through policies that encourage choice and competition. Research suggests that in a normal market, price transparency (more generally) will result in reduced rates, overall.¹⁸⁷ There are models in the

¹⁸⁷ Christensen HB, et al. 2018. "The Only Prescription Is Transparency: The Effect of Charge-Price-Transparency Regulation on Healthcare Prices." SSRN Scholarly Paper ID 2343367. Rochester, NY: Social Science Research Network. Available at: <https://papers.ssrn.com/abstract=2343367>.

States that have shown that release of the information has driven costs down not up.¹⁸⁸ On aggregate, we believe the effects on competition, resulting from hospital price transparency, would drive down healthcare prices. We acknowledge, that knowledge by a hospital of other hospitals' payer-specific negotiated charges could also drive up rates; especially if a hospital discovers it is currently being paid less than other hospitals by a payer and, thereby, negotiates higher rates. On the other hand, payers may negotiate lower rates, if they discover hospitals have negotiated lower rates with competing payers.

Comment: Typically described in the context of commenters' concerns on specific proposals, and as described within section II of this final rule, commenters suggested a number of possible unanticipated consequences for the private sector of the proposed requirements for hospitals to make public standard charges, including the following:

- The disclosure of payer-specific negotiated charges is likely to result in anti-competitive behavior and anti-trust exposure.
- Under the proposed requirements for hospitals to make public standard charges including payer-specific negotiated charges, hospitals would be exposed to litigation risk, due to the belief that these contractual reimbursement rates are proprietary.
- The proposal would contradict the goals of CMS' Patients-over Paperwork initiative.
- The requirement to disclose standard charges for all items and services as defined under the CY 2020 OPPI/ASC proposed rule would result in hospital closures.
- Complying with the requirements, as proposed, would be cost-prohibitive for CAHs, rural hospitals, and small hospitals, among others.
- The CY 2020 OPPI/ASC proposed rule's focus on standard charges would negatively impact hospitals' transition to value-based care.

Response: We appreciate commenters' concerns, and we have addressed these concerns elsewhere in this final rule. We do not believe that these concerns affect our estimate of the impact of the requirements we are finalizing, and accordingly we decline to adjust our economic analyses based on these concerns alone.

As we detailed in Section IV.B, we estimated the total burden to implement the requirements of this rule to be 150 hours at a cost of \$11,898.60 per hospital. We noted that hospitals nationwide are at different stages of readiness to offer consumers transparent price information or are at various levels of participation in posting of charge and price information. We also believe that different hospitals may face different constraints when estimating their burden and resources required. We believe that some hospitals will already have a framework or business processes in place that they can leverage that would minimize additional burden. However, there will be other hospitals that will have additional burden, above our projected 150 hours we estimated, to meet the requirements of this rule. Therefore, we are providing alternative estimates on a range of hours in this impact analysis. We note that most commenters stated that a reasonable estimate for burden based for implementing existing requirements to disclose standard charges is within the range of 60–250 hours, therefore we are providing cost estimates ranging from 60 hours to 250 hours.

For a low estimate, we now estimate it would take a lawyer 2 hours (at \$138.68 per hour); a general operations manager 2 hours (at \$119.12 per hour); business operations specialist 32 hours (at \$74 per hour), a network and computer system administrator 12 hours (at \$83.72 per hour); a registered nurse 12 hours (at \$72.60 per hour). Therefore, we are providing a low estimate of the total burden for the first year to be 60 hours (2 hours + 2 hours + 32 hours + 12 hours + 12 hours) per hospital with a cost of \$4,759.44 per hospital. Table 7 provides the total cost.

For a high estimate, we now estimate it would take a lawyer 8 hours (at \$138.68 per hour); a general operations manager 8 hours (at \$119.12 per hour); business operations specialist 134 hours (at \$74 per hour), a network and computer system administrator 50 hours (at \$83.72 per hour); a registered nurse 50 hours (at \$72.60 per hour). Therefore, we are providing a high estimate of the total burden for the first year to be 250 hours (8 hours + 8 hours + 134 hours + 50 hours + 50 hours) per hospital with a cost of \$19,794.40 per hospital. Table 7 provides the total cost.

TABLE 7—COST RANGE ESTIMATES

Hours per hospitals	Cost per hospital	Total cost
60	4,759.44	28,566,159
250	19,794.40	118,805,989

2. Effects on Consumers

As discussed in the CY 2020 OPPI/ASC proposed rule (84 FR 39632 through 39633), we considered the estimated effects on the consumers, and welcomed public comments on the impact of the proposed requirements on consumers. As indicated in this final rule, we believe the requirements from this final rule will make public data necessary for healthcare consumers to better understand how the level of price dispersion in various healthcare markets and its impacts on healthcare spending and consumer out-of-pocket costs. The information may also benefit other consumers of these data, for example, employers, third party tool developers, clinicians at the point of care, or economics research to drive value-based policy development. We noted in the CY 2020 OPPI/ASC proposed rule that the negotiated charges for various procedures vary widely within and across geographic regions in the United States.¹⁸⁹ Some factors associated with the level of hospital price dispersion in a geographic area are the hospital's size, healthcare demand, labor costs, and technology, although it was the hospital's market power (level of competition) that was most positively associated with high price dispersion.¹⁹⁰ One major barrier to fully understanding healthcare price variation (and understanding the impact of transparency of healthcare pricing in general) is the lack of availability of negotiated charges to researchers and the public.¹⁹² We continue to believe that requirements from this final rule will make hospital charge information available, which will generate a better understanding of (1) hospital price dispersion, and (2) the relationship between hospital price dispersion and healthcare spending. Additionally, we believe understanding this relationship through the disclosure of pricing data could lead to downward price pressure and reductions in overall spending system-wide.

¹⁸⁹ Kennedy K, et al. Health Care Cost Institute. Past the Price Index: Exploring Actual Prices Paid for Specific Services by Metro Area. Healthy Marketplace Index. April 30, 2019. Available at: <https://www.healthcostinstitute.org/blog/entry/hmi-2019-service-prices>.

¹⁹⁰ Cooper Z, et al. The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured. *The Quarterly Journal of Economics*. December 2015. Available at: <https://pdfs.semanticscholar.org/cb9c/f90786cc39ddac6d88f3ba1074a7c2d5f0a5.pdf>.

¹⁹¹ Bai G and Anderson GF. Market Power: Price Variation Among Commercial Insurers For Hospital Services. *Health Affairs*. Oct 2018; 37(10): 1615–1622. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0567>.

¹⁹² Ibid.

¹⁸⁸ Brown ZY. Equilibrium Effects of Health Care Price Information. *The Review of Economics and Statistics*. Published October 2019; 101:4, 699–712. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.

Consumers may feel more satisfied with their care when they are empowered to make decisions about their treatment. A recent survey¹⁹³ indicated a strong desire for price transparency and openness. Eighty-eight percent of the population polled, demanded improved transparency with their total financial responsibility, including co-pays and deductibles. Other studies such suggest that improving a patient's financial experience served as the biggest area to improve overall customer satisfaction.¹⁹⁴ Literature regarding consumer engagement with existing price transparency interventions demonstrates that disclosing price information positively impacts consumers by allowing them to compare prices for common procedures and shift their demand towards lower-priced options. One study examined consumer use of an employer-sponsored, private price transparency tool and its impact on claims payments for three common medical services: Laboratory tests; advanced imaging services; and clinician office visits.¹⁹⁵ That study found that those who used the tool had lower claims payments by approximately 14 percent for laboratory tests; 13 percent for advanced imaging services; and approximately one percent for office visits compared to those who did not use the tool. Those using the tool mainly searched for information on shoppable services and also tended to have more limited insurance coverage.

Price transparency initiatives have more impact when they are combined with other cost control tools like reference-based pricing. For example, for a plan with reference-based pricing, price transparency tools were associated with a reduction of 32 percent in lab test prices over three years.¹⁹⁶

¹⁹³ See Gruessner V. Consumer Satisfaction Dips When Payers Lack Price Transparency. *Private Payers News* (October 3, 2016). Available at: <https://healthpayerintelligence.com/news/consumer-satisfaction-dips-when-payers-lack-price-transparency>.

¹⁹⁴ See for example, Government Accountability Office. September 2011. Health Care Price Transparency: Meaningful Price Information Is Difficult for Consumers to Obtain Prior to Receiving Care. Available at: <https://www.gao.gov/assets/590/585400.pdf>. Experian Health, Improve the healthcare financial journey. *Patient Engagement* (June 21, 2018). Available at: <https://www.experian.com/blogs/healthcare/2018/06/healthcare-financial-journey/>.

¹⁹⁵ Whaley C, et al. "Association Between Availability of Health Service Prices and Payments for These Services." *JAMA*. 2014; 312(16):1670–1676. Available at <https://jamanetwork.com/journals/jama/fullarticle/1917438>.

¹⁹⁶ Robinson JC, Whaley BA, Brown TT. Association of Reference Pricing for Diagnostic Laboratory Testing With Changes in Patient (2016) *JAMA Int Med*. 2016; 176(9): 1353–1359. Available

Employers have also been encouraging consumers to share in the savings realized from engaging in comparative shopping. The state of Kentucky's public employee benefit program's price transparency shared savings initiative has saved state taxpayers \$13 million dollars since its inception in 2015, and almost \$2 million in cash benefits have been shared with the state's public employees.¹⁹⁷ Another study of a group of 35 self-funded employers who deployed a shared savings program in 2017 demonstrated an overall 2.1 percent cost reduction of the cost of medical care and total savings of \$23 million a year, with 23 percent of the employees receiving shared savings rewards.¹⁹⁸

Finally, studies indicate that the existence of comparative price shopping information has the effect of reducing healthcare costs for everyone, regardless of whether they engage in shopping behavior. A national study of state price transparency efforts found an overall reduction of hospital pricing by 5 percent and a state of New Hampshire effort reduced consumer costs by 5 percent.^{199 200}

Comment: Typically described in the context of commenters' concerns on specific proposals, and as described within section II of this final rule, commenters suggested a number of possible unanticipated consequences for consumers of the proposed requirements for hospitals to make public standard charges, including the following:

- The volume of data required for the display of standard charges under the rule would confuse consumers and potentially cause them to seek out the

at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2536187>.

¹⁹⁷ Rhoads J. Right to Shop for Public Employees: How Health Care Incentives are Saving Money in Kentucky. Foundation for Government Accountability. March 8, 2019. Available at: <https://thefga.org/wp-content/uploads/2019/03/RTS-Kentucky-HealthCareIncentivesSavingMoney-DRAFT8.pdf>.

¹⁹⁸ Whaley CM, et al. Paying Patients To Switch: Impact Of A Rewards Program On Choice Of Providers, Prices, And Utilization. *Health Affairs*. March 2019. Available at: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05068>.

¹⁹⁹ Christensen HB, et al. 2018. "The Only Prescription Is Transparency: The Effect of Charge-Price-Transparency Regulation on Healthcare Prices." SSRN Scholarly Paper ID 2343367. Rochester, NY: Social Science Research Network. Available at: <https://papers.ssrn.com/abstract=2343367>.

²⁰⁰ Brown ZY. Equilibrium Effects of Health Care Price Information. *The Review of Economics and Statistics*. Published October 2019; 101:4. 699–712. Available at: http://www-personal.umich.edu/~zachb/zbrown_eqm_effects_price_transparency.pdf.

cheapest care, rather than the most effective or best quality care.

- The burden of understanding costs of care would shift from hospitals and/or payers to consumers.
- The information on standard charges would still not be sufficient to inform consumers of their plan-specific, out-of-pocket costs. The concerns included that the required information would be insufficient for consumers to rely on, as well as concerns that too much information is being required, will be overwhelming and potentially confusing to consumers.

Response: We appreciate commenters' concerns, and we have addressed these concerns elsewhere in this final rule. We believe the requirements we are finalizing for hospitals to make public standard charges will provide information to consumers that helps inform their healthcare decision-making, and therefore ultimately benefit consumers. Informed decision-making, in turn, may have other positive effects; for example, as research suggests, informed healthcare consumers, that have a price estimate before getting care are more likely to pay their bills in a timely manner.^{201 202}

We do not believe that these concerns about unintended consequences on consumers affect our estimate of the impact of the requirements we are finalizing, and accordingly we decline to adjust our economic analyses based on these concerns alone.

3. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. More than half of 6,002 hospitals are small entities, either by nonprofit status or by having revenues of less than \$41.5 million in any 1 year.²⁰³ We analyzed these hospitals and found that the estimated burden from this final rule never exceeded 1 percent of reported revenue for any hospital in this category, including the

²⁰¹ Kutscher, B. "Report: Consumers demand price transparency, but at what cost?" *Modern Healthcare*. June 2015. Available at: <https://www.modernhealthcare.com/article/20150623/NEWS/150629957/consumers-demand-price-transparency-but-at-what-cost>.

²⁰² HFMA Executive Roundtable: Reimagining Patient Access. December 2015. Available at: <https://api.hfma.org/Content.aspx?id=43731>.

²⁰³ U. S. Small Business Administration, Table of Small Business Size Standards, Matched to North American Industry Classification System Codes (size standards effective August 19, 2019). Available at: https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%202019%2C%202019_Rev.pdf.

hospital with the lowest revenue.²⁰⁴ For the over 3,000 hospitals that meet the standards for small entities defined by the SBA, we estimate the burden from this final rule to be, on average, 0.007 percent of hospital total annual revenue. It is reasonable to assume that the inclusion or exclusion of hospitals with nonprofit status would not drive the percentages to go over the threshold because even the historically lowest revenue hospitals indicate the burden would not exceed at most about 1 percent of total hospital revenue in the most extreme case. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this final rule. As a result, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities.

4. Effects on Small Rural Hospitals

Section 1102(b) of the SSA requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the SSA, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We identified almost 1,900 hospitals as having rural status and fewer than 100 beds. We note that commenters submitted various concerns related to burden for smaller or less resourced hospitals. We have responded to these concerns throughout this final rule. As noted previously, we are aware that hospitals are in varying stages of readiness for implementation of this final rule. While smaller or rural hospitals may not have the staff or automation that larger hospital systems may have (which may increase burden relative to a better resourced hospital or hospital system), they are likely to have far fewer contracts with payers and provide fewer items and services overall, which would reduce rural hospital burden compared to larger hospitals in regions with many payers. For this reason it is difficult to determine a unique impact on small rural hospitals. For these small, rural hospitals, we estimate the burden from this final rule to be, on average, 0.037 percent of hospital total annual

²⁰⁴ CMS Office of the Actuary analysis of 2016 Medicare Cost Report data.

revenue.²⁰⁵ Therefore, we conclude that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

5. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately \$154 million. This final rule contains no such unfunded mandates.

6. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

D. Alternatives Considered

The final rule promulgates rules for hospital compliance with section 2718(e) of the PHS Act and aims to make price information more readily available to the public. As described in the CY 2020 OPPI/ASC proposed rule (84 FR 39633), we considered a number of alternative approaches to maximize the value and accessibility of these data to the public generally and directly to consumers. For example, proposals to require release of hospital standard charge data in an API format. We also considered other types of “standard charges” that could be useful to consumers. For example, in addition to or instead of the requirement to disclose gross charges and payer-specific charges, we sought comment on whether we should consider a definition of ‘standard charge’ to be a volume-driven negotiated charge, the minimum/median/maximum negotiated charge, or all allowed charges. Such charges could be relevant to specific groups of individuals, particularly those with health insurance coverage. We also sought comment on a definition of ‘standard charge’ that might be relevant

²⁰⁵ Hospital Cost Report PUF is used for calculating these statistics. The latest PUF file publicly available is a 2014 dataset as of July 15, 2018, available at this link: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Cost-Report/HospitalCostPUF.html>.

to subgroups of individuals who are self-pay, specifically, types of standard charges representing the discounted cash price for a service package, or the median cash price.

We finalized the definition of standard charges to include gross charge (as discussed in section II.D.2 of this final rule), and payer-specific negotiated charge (as discussed in section II.D.3), as proposed. We finalized modifications to include within the definition of standard charges the discounted cash price (as described in section II.D.4.c of this final rule), as well as the de-identified minimum negotiated charge, and de-identified maximum negotiated charge (as discussed in section II.D.4.d of this final rule). Of the other alternatives considered, we determined that allowed amounts of plans that are not negotiated are already publicly disclosed (as discussed in section II.D.4.b of this final rule), and that the median negotiated charge would have limited usefulness for consumers (as discussed in section II.D.4.d of this final rule). We also decided not to require standardization in the release of hospital standard charges, such as by requiring data be presented in an API format, noting that the requirements we are finalizing in this final rule, for hospitals to make public their standard charges, are a good initial step.

As a result of comments, we considered an alternative in which CMS would specify all 300 shoppable services and specify the corresponding ancillary services. We estimate that this could reduce burden for hospitals by removing the clinical input necessary to develop such service groupings which would result in a first year burden of \$9,721 per hospital, or \$58.3 million for all hospitals.

Finally, we also considered an alternative approach that would require hospitals to make public a comprehensive machine-readable file of all standard charges for all hospital items and services, but not require hospitals to display charges for shoppable services in a consumer-friendly manner. We estimate that this could reduce burden for hospitals by removing the clinical input necessary and decrease the number of hours for the other professions which would result in a first year burden of \$4,860 per hospital, or \$29.2 million for all hospitals.

E. Accounting Statement and Table

In accordance with OMB Circular A-4, Table 8 depicts an accounting statement summarizing the assessment of the benefits and costs associated with this regulatory action.

TABLE 8—ACCOUNTING STATEMENT ESTIMATED IMPACTS
 [CYs 2020–2022]

Category	Primary estimate (million)	Units		
		Year dollars	Discount rate (%)	Period covered
Benefits				
Qualitative	The rule is anticipated to have the potential to reduce the range of prices charged by hospitals such that a net savings would result for payers and consumers from a corresponding reduction in income to hospitals. Price transparency would help to create a healthcare information ecosystem that allows and encourages the healthcare market to tailor products and services to compete for patients, thereby increasing quality, decreasing costs, and helping them live better, healthier lives.			
Costs				
Annualized monetized \$ millions/year	\$39.4	2019	7	2020–2022
	38.7	2019	3	2020–2022

F. Regulatory Reform Analysis Under E.O. 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” This final rule is considered an Executive Order 13771 regulatory action. We estimate the rule generates \$23.0 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

G. Conclusion

The analysis in this section, together with the remainder of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

List of Subjects in 45 CFR Part 180

Definitions, Hospitals, Reporting and recordkeeping requirements.

■ For reasons stated in the preamble of this document, the Department of Health and Human Services amends 45 CFR subtitle A by adding subchapter E to read as follows:

Subchapter E—Price Transparency

PART 180—HOSPITAL PRICE TRANSPARENCY

PARTS 181–199 [RESERVED]

PART 180—HOSPITAL PRICE TRANSPARENCY

Sec.

Subpart A—General Provisions

- 180.10 Basis and scope.
- 180.20 Definitions.
- 180.30 Applicability.

Subpart B—Public Disclosure Requirements

- 180.40 General requirements.
- 180.50 Requirements for making public hospital standard charges for all items and services.
- 180.60 Requirements for displaying shoppable services in a consumer-friendly manner.

Subpart C—Monitoring and Penalties for Noncompliance

- 180.70 Monitoring and enforcement.
- 180.80 Corrective action plans.
- 180.90 Civil monetary penalties.

Subpart D—Appeals of Civil Monetary Penalties

- 180.100 Appeal of penalty.
- 180.110 Failure to request a hearing.

Authority: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

Subpart A—General Provisions

§ 180.10 Basis and scope.

This part implements section 2718(e) of the Public Health Service (PHS) Act, which requires each hospital operating within the United States, for each year, to establish, update, and make public a list of the hospital’s standard charges for

items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. This part also implements section 2718(b)(3) of the PHS Act, to the extent that section authorizes CMS to promulgate regulations for enforcing section 2718(e). This part also implements section 1102(a) of the Social Security Act, which authorizes the Secretary to make and publish rules and regulations, not inconsistent with that Act, as may be necessary to the efficient administration of the functions for which the Secretary is charged under that Act.

§ 180.20 Definitions.

The following definitions apply to this part, unless specified otherwise:

Ancillary service means an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service.

Chargemaster (Charge Description Master or CDM) means the list of all individual items and services maintained by a hospital for which the hospital has established a charge.

De-identified maximum negotiated charge means the highest charge that a hospital has negotiated with all third party payers for an item or service.

De-identified minimum negotiated charge means the lowest charge that a hospital has negotiated with all third party payers for an item or service.

Discounted cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service.

Gross charge means the charge for an individual item or service that is

reflected on a hospital's chargemaster, absent any discounts.

Hospital means an institution in any State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. For purposes of this definition, a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

Items and services means all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples include, but are not limited to, the following:

- (1) Supplies and procedures.
- (2) Room and board.
- (3) Use of the facility and other items (generally described as facility fees).
- (4) Services of employed physicians and non-physician practitioners (generally reflected as professional charges).
- (5) Any other items or services for which a hospital has established a standard charge.

Machine-readable format means a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, .JSON and .CSV formats.

Payer-specific negotiated charge means the charge that a hospital has negotiated with a third party payer for an item or service.

Service package means an aggregation of individual items and services into a single service with a single charge.

Shoppable service means a service that can be scheduled by a healthcare consumer in advance.

Standard charge means the regular rate established by the hospital for an item or service provided to a specific group of paying patients. This includes all of the following as defined under this section:

- (1) Gross charge.
- (2) Payer-specific negotiated charge.
- (3) De-identified minimum negotiated charge.
- (4) De-identified maximum negotiated charge.
- (5) Discounted cash price.

Third party payer means an entity that is, by statute, contract, or

agreement, legally responsible for payment of a claim for a healthcare item or service.

§ 180.30 Applicability.

(a) *General applicability.* Except as provided in paragraph (b) of this section, the requirements of this part apply to hospitals as defined at § 180.20.

(b) *Exception.* Federally owned or operated hospitals are deemed by CMS to be in compliance with the requirements of this part including but not limited to:

(1) Federally owned hospital facilities, including facilities operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities operated by the U.S. Department of Defense.

(2) Hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act.

(c) *Online availability.* Unless otherwise stated, hospital charge information must be made public electronically via the internet.

Subpart B—Public Disclosure Requirements

§ 180.40 General requirements.

A hospital must make public the following:

(a) A machine-readable file containing a list of all standard charges for all items and services as provided in § 180.50.

(b) A consumer-friendly list of standard charges for a limited set of shoppable services as provided in § 180.60.

§ 180.50 Requirements for making public hospital standard charges for all items and services.

(a) *General rules.* (1) A hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in this section.

(2) Each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location.

(b) *Required data elements.* A hospital must include all of the following corresponding data elements in its list of standard charges, as applicable:

(1) Description of each item or service provided by the hospital.

(2) Gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(3) Payer-specific negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.

(4) De-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(5) De-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(6) Discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.

(7) Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), or other common payer identifier.

(c) *Format.* The information described in paragraph (b) of this section must be published in a single digital file that is in a machine-readable format.

(d) *Location and accessibility.* (1) A hospital must select a publicly available website for purposes of making public the standard charge information required under paragraph (b) of this section.

(2) The standard charge information must be displayed in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated.

(3) The hospital must ensure that the standard charge information is easily accessible, without barriers, including but not limited to ensuring the information is accessible:

- (i) Free of charge;
- (ii) Without having to establish a user account or password; and
- (iii) Without having to submit personal identifying information (PII).

(4) The digital file and standard charge information contained in that file must be digitally searchable.

(5) The file must use the following naming convention specified by CMS, specifically: <ein>_<hospital-name>_standardcharges.[json|xml|csv].

(e) *Frequency of updates.* The hospital must update the standard charge information described in paragraph (b)

of this section at least once annually. The hospital must clearly indicate the date that the standard charge data was most recently updated, either within the file itself or otherwise clearly associated with the file.

§ 180.60 Requirements for displaying shoppable services in a consumer-friendly manner.

(a) *General rules.* (1) A hospital must make public the standard charges identified in paragraphs (b)(3) through (6) of this section, for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

(i) In selecting a shoppable service for purposes of this section, a hospital must consider the rate at which it provides and bills for that shoppable service.

(ii) If a hospital does not provide 300 shoppable services, the hospital must make public the information specified in paragraph (b) of this section for as many shoppable services as it provides.

(2) A hospital is deemed by CMS to meet the requirements of this section if the hospital maintains an internet-based price estimator tool which meets the following requirements.

(i) Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

(ii) Allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.

(iii) Is prominently displayed on the hospital's website and accessible to the public without charge and without having to register or establish a user account or password.

(b) *Required data elements.* A hospital must include, as applicable, all of the following corresponding data elements when displaying its standard charges (identified in paragraphs (b)(3) through (6) of this section) for its list of shoppable services selected under paragraph (a)(1) of this section:

(1) A plain-language description of each shoppable service.

(2) An indicator when one or more of the CMS-specified shoppable services are not offered by the hospital.

(3) The payer-specific negotiated charge that applies to each shoppable service (and to each ancillary service, as applicable). Each list of payer-specific negotiated charges must be clearly

associated with the name of the third party payer and plan.

(4) The discounted cash price that applies to each shoppable service (and corresponding ancillary services, as applicable). If the hospital does not offer a discounted cash price for one or more shoppable services (or corresponding ancillary services), the hospital must list its undiscounted gross charge for the shoppable service (and corresponding ancillary services, as applicable).

(5) The de-identified minimum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).

(6) The de-identified maximum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).

(7) The location at which the shoppable service is provided, including whether the standard charges identified in paragraphs (b)(3) through (6) of this section for the shoppable service apply at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both.

(8) Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, as applicable, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), or other common service billing code.

(c) *Format.* A hospital has discretion to choose a format for making public the information described in paragraph (b) of this section online.

(d) *Location and accessibility of online data.* (1) A hospital must select an appropriate publicly available internet location for purposes of making public the information described in paragraph (b) of this section.

(2) The information must be displayed in a prominent manner that identifies the hospital location with which the information is associated.

(3) The shoppable services information must be easily accessible, without barriers, including but not limited to ensuring the information is:

(i) Free of charge.

(ii) Accessible without having to register or establish a user account or password.

(iii) Accessible without having to submit personal identifying information (PII).

(iv) Searchable by service description, billing code, and payer.

(e) *Frequency.* The hospital must update the standard charge information

described in paragraph (b) of this section at least once annually. The hospital must clearly indicate the date that the information was most recently updated.

Subpart C—Monitoring and Penalties for Noncompliance

§ 180.70 Monitoring and enforcement.

(a) *Monitoring.* (1) CMS evaluates whether a hospital has complied with the requirements under §§ 180.40, 180.50, and 180.60.

(2) CMS may use methods to monitor and assess hospital compliance with the requirements under this part, including, but not limited to, the following, as appropriate:

(i) CMS' evaluation of complaints made by individuals or entities to CMS.

(ii) CMS review of individuals' or entities' analysis of noncompliance.

(iii) CMS audit of hospitals' websites.

(b) *Actions to address hospital noncompliance.* If CMS concludes that the hospital is noncompliant with one or more of the requirements of § 180.40, § 180.50, or § 180.60, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

(1) Provide a written warning notice to the hospital of the specific violation(s).

(2) Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements, according to § 180.80.

(3) Impose a civil monetary penalty on the hospital and publicize the penalty on a CMS website according to § 180.90 if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

§ 180.80 Corrective action plans.

(a) *Material violations requiring a corrective action plan.* CMS determines if a hospital's noncompliance with the requirements of this part constitutes material violation(s) requiring a corrective action plan. A material violation may include, but is not limited to, the following:

(1) A hospital's failure to make public its standard charges required by § 180.40.

(2) A hospital's failure to make public its standard charges in the form and manner required under §§ 180.50 and 180.60.

(b) *Notice of violation.* CMS may request that a hospital submit a corrective action plan, specified in a notice of violation issued by CMS to a hospital.

(c) *Compliance with corrective action plan requests and corrective actions.* (1) A hospital required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the corrective action plan.

(2) A hospital's corrective action plan must specify elements including, but not limited to:

(i) The corrective actions or processes the hospital will take to address the deficiency or deficiencies identified by CMS.

(ii) The timeframe by which the hospital will complete the corrective action.

(3) A corrective action plan is subject to CMS review and approval.

(4) After CMS' review and approval of a hospital's corrective action plan, CMS may monitor and evaluate the hospital's compliance with the corrective actions.

(d) *Noncompliance with corrective action plan requests and requirements.*

(1) A hospital's failure to respond to CMS' request to submit a corrective action plan includes failure to submit a corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital.

(2) A hospital's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 180.90 Civil monetary penalties.

(a) *Basis for imposing civil monetary penalties.* CMS may impose a civil monetary penalty on a hospital identified as noncompliant according to § 180.70, and that fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan as described in § 180.80(d).

(b) *Notice of imposition of a civil monetary penalty.* (1) If CMS imposes a penalty in accordance with this part, CMS provides a written notice of imposition of a civil monetary penalty to the hospital via certified mail or another form of traceable carrier.

(2) This notice to the hospital may include, but is not limited to, the following:

(i) The basis for the hospital's noncompliance, including, but not limited to, the following:

(A) CMS' determination as to which requirement(s) the hospital has violated.

(B) The hospital's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in § 180.80(d).

(ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:

(A) The first day the hospital is required to meet the requirements of this part.

(B) If a hospital previously met the requirements of this part but did not update the information annually as required, the date 12 months after the date of the last annual update specified in information posted by the hospital.

(C) A date determined by CMS, such as one resulting from monitoring activities specified in § 180.70, or development of a corrective action plan as specified in § 180.80.

(iii) The amount of the penalty as of the date of the notice.

(iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).

(v) Payment instructions.

(vi) Intent to publicize the hospital's noncompliance and CMS' determination to impose a civil monetary penalty on the hospital for noncompliance with the requirements of this part by posting the notice of imposition of a civil monetary penalty on a CMS website.

(vii) A statement of the hospital's right to a hearing according to subpart D of this part.

(viii) A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal in accordance with § 180.110.

(3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty, to conform to the adjudicated finding.

(c) *Amount of the civil monetary penalty.* (1) CMS may impose a civil monetary penalty upon a hospital for a violation of each requirement of this part.

(2) The maximum daily dollar amount for a civil monetary penalty to which a hospital may be subject is \$300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is \$300.

(3) The amount of the civil monetary penalty will be adjusted annually using the multiplier determined by OMB for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) *Timing of payment of civil monetary penalty.* (1) A hospital must

pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) In the event a hospital requests a hearing, pursuant to subpart D of this part, the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.

(3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(e) *Posting of notice.* (1) CMS will post the notice of imposition of a civil monetary penalty described in paragraphs (b) and (f) of this section on a CMS website.

(2) In the event that a hospital elects to request a hearing, pursuant to subpart D of this part:

(i) CMS will indicate in its posting, under paragraph (e)(1) of this section, that the civil monetary penalty is under review.

(ii) If the civil monetary penalty is upheld, in whole, by a final and binding decision according to subpart D of this part, CMS will maintain the posting of the notice of imposition of a civil monetary penalty on a CMS website.

(iii) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty according to paragraph (b)(3) of this section, to conform to the adjudicated finding. CMS will make this modified notice public on a CMS website.

(iv) If the civil monetary penalty is overturned in full by a final and binding decision according to subpart D of this part, CMS will remove the notice of imposition of a civil monetary penalty from a CMS website.

(f) *Continuing violations.* CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

Subpart D—Appeals of Civil Monetary Penalties

§ 180.100 Appeal of penalty.

(a) A hospital upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except as specified in paragraph (b) of this section.

(b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:

(1) Civil money penalty means a civil monetary penalty according to § 180.90.

(2) Respondent means a hospital that received a notice of imposition of a civil monetary penalty according to § 180.90(b).

(3) References to a notice of assessment or proposed assessment, or notice of proposed determination of civil monetary penalties, are considered to be references to the notice of imposition of a civil monetary penalty specified in § 180.90(b).

(4) Under § 150.417(b) of this title, in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to the following:

(i) The hospital's posting(s) of its standard charges, if available.

(ii) Material the hospital timely previously submitted to CMS (including

with respect to corrective actions and corrective action plans).

(iii) Material CMS used to monitor and assess the hospital's compliance according to § 180.70(a)(2).

(5) The ALJ's consideration of evidence of acts other than those at issue in the instant case under § 150.445(g) of this title does not apply.

§ 180.110 Failure to request a hearing.

(a) If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in § 180.90(b), CMS may impose the civil monetary penalty indicated in such notice and may impose additional penalties pursuant to continuing violations according to § 180.90(f) without right of appeal in accordance with this part.

(1) If the 30th calendar day described in this paragraph (a) is a weekend or a Federal holiday, then the timeframe is

extended until the end of the next business day.

(2) [Reserved]

(b) The hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this title, unless the hospital can show good cause, as determined at § 150.405(b) of this title, for failing to timely exercise its right to a hearing.

PARTS 181–199—[RESERVED]

Dated: November 5, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 7, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–24931 Filed 11–15–19; 4:15 pm]

BILLING CODE 4120–01–P