Requirements for Hospitals to Make Standard Charges Public
SUMMARY OF FINAL RULE

I. Overview

On November 15, 2019, the Centers for Medicare & Medicaid Services (CMS) released a final rule titled *Price Transparency Requirements for Hospitals to Make Standard Charges Public* (CMS-1717-F2). The provision was part of the larger proposed rule for Medicare's hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system for calendar year 2020.[1] Price transparency requirements were not included as part of the 2020 OPPS final rule published in the *Federal Register* on November 12th but were instead released as an independent final rule. *Price Transparency Requirements* will be published in the November 27th issue of the *Federal Register*. CMS originally proposed to make the price transparency requirements effective January 1, 2020 but delayed the effective date to January 1, 2021 in the final rule.

The final rule establishes the 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 they provide. The rule requires all hospitals operating in the United States, United States territories and the District of Columbia to post gross charges, payer-specific negotiated charges, the de-identified minimum and maximum negotiated charge and the cash discount price for all items and services and service packages on a website in a machine-readable format. It additionally requires posting of information for 300 "shoppable" services in a consumer-friendly manner. This latter provision can be met by posting a price calculator tool on the hospital's website. The rule further describes monitoring and enforcement as well as the estimated compliance burden associated with these requirements.

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[1] Henceforth in this document, a year is a calendar year unless otherwise indicated.

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

A. Introduction and Overview

Section 2718(e) of the Public Health Service (PHS) Act requires:

> Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) 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 Social Security Act.

CMS suggests that one reason for the upward spending trajectory of health care spending in the United States is the lack of transparent pricing. It says there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare. The final rule provides references to many research studies and articles that assert price transparency leads to lower and more uniform prices and improved access to care.

For example, CMS cites the Government Accountability Office (GAO) report (2011), "Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care,"[2] 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. According to the GAO report, initiatives that provide access to integrated pricing from both providers and insurers were best able to provide reasonable estimates of consumers' complete costs.

CMS reviews several state laws that require disclosure of pricing information by providers and payers. As of early 2012, there were 62 consumer-oriented, state-based healthcare price comparison websites. The information is required to be submitted in plain language using easily understood terminology.[3] Some self-funded employers are using price transparency tools to incent 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.[4,5] CMS believes that ensuring public access to hospital standard charge data will increase market competition and ultimately drive down the cost of healthcare services, making them more affordable for all patients.

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[2] 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.
[3] 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/1697957.
[4] Brown ZY. What would happen if hospitals openly shared their prices? The Conversation. January 30, 3019. Available at: https://theconversation.com/what-would-happen-if-hospitals-openlyshared-their-prices-110352.
[5] Brown ZY. An Empirical Model of Price Transparency and Markups in Health Care. August 2019. http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf.

Comments/Responses: CMS says the majority of commenters expressed broad support for CMS' proposed policies (in whole or in part) or agreed with the objectives CMS is seeking to accomplish through these requirements. Many organizations commented 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. There were also comments suggesting that the patient's health insurer, not the hospital, should be the primary source of information on the patient's healthcare costs when the patient is insured.

CMS indicates that disclosure of payer-specific negotiated charges can help individuals with high deductible health plans or those with coinsurance determine the portion of the negotiated charge for which they will be responsible. Necessary data to make out-of-pocket price comparisons depends on an individual's circumstances. A self-pay individual may 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.

CMS agrees that there is a role for health insurers in sharing price information with patients but disagrees that insurers alone should bear the complete burden or responsibility for price transparency as in numerous instances, they are not participants in the transaction. On the same day that CMS released this final rule, it released a proposed rule *Transparency in Coverage* (file code CMS-9915-P) that would place complementary transparency requirements on most individual and group market health insurance issuers and group health plans.

A few commenters stated that price transparency should be done only at the state level. Other comments said that CMS' regulations would be very burdensome and contrary to the goals of the Patients over Paperwork initiative. CMS disagreed that price transparency is only a state issue saying that Congress made it a national issue by enacting section 2718(e) of the PHS Act. However, CMS recognizes the potential inconsistencies with state law requirements and is providing hospitals with sufficient flexibility to be in compliance with state and federal law requirements in the final rule. The final rule recognizes that it imposes some burden on hospitals but says it is outweighed by the benefit of informing patients regarding healthcare costs and choices and improving overall market competition.

Final action: CMS is adding new Part 180—Hospital Price Transparency to Title 45 of the Code of Federal Regulations (CFR) that will codify regulations on price transparency that implement section 2718(e) of the PHS Act.

B. Definition of "Hospital"

1. Definition of Hospital

CMS proposed to define a "hospital" as an institution in any of the 50 United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands that is: (1) licensed as a hospital pursuant to state law or (2) approved, by the

agency of such state or locality responsible for licensing hospitals, as meeting the standards to be a licensed hospital. This definition would apply to all Medicare-enrolled hospitals and any institutions that are operating as hospitals under state or local law but might not be considered hospitals for purposes of Medicare participation.

The proposed definition would include critical access hospitals (CAHs), inpatient psychiatric facilities (IPFs), sole community hospitals (SCHs), and inpatient rehabilitation facilities (IRFs) as well as any other type of institution, so long as such institutions are licensed as a hospital (or otherwise approved) as meeting hospital licensing standards.

The definition of "hospital" excludes ambulatory surgical centers (ASCs) or other non-hospital sites-of-care that 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. CMS encourages these non-hospital sites to make public their lists of standard charges in alignment with its requirements so that consumers can make effective pricing comparisons.

Comments/Responses: Commenters generally supported the agency's definition of a hospital although several types of hospitals requested that they be exempted from the requirements. CAHs, long term care hospitals (LTCH) and IRFs provided a variety of arguments for why these hospital types should be exempted from the new regulations. CMS rejected all of the comments stating that patients of IRFs, CAHs, LTCHs, rural hospitals, SCHs among others should have the opportunity to know in advance (as circumstances permit) standard charges for items and services to inform healthcare decision-making.

Some commenters requested CMS expand the definition to physicians, ASCs and other health care providers. Because section 2718(e) of the PHS Act applies to each hospital operating within the United States, CMS does not believe it has the authority to apply the price transparency requirements to non-hospital sites of care.

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. CMS responds that 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.

Final Action: CMS is finalizing its proposal to set forth the definition of "hospital" in the regulations at new 45 CFR §180.20.

2. Special Requirements for Federally-Owned Hospitals

CMS proposed to deem federally-owned or operated hospitals as meeting the requirements of section 2718(e) of the PHS Act when their charges for hospital provided services are publicized to their patients in advance (for example, through the *Federal Register*). Hospitals subject to these special requirements would include 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 Military Treatment Facilities (MTFs).

Comments/Responses: There were no comments on CMS' proposal to deem federally-owned hospitals as meeting the transparency requirements

Final Action: CMS is finalizing its proposal 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.

C. Definition of "Items and Services"

CMS 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 encounter for which the hospital has established a standard charge. For purposes of section 2718(e) of the PHS Act, CMS proposed "chargemaster" to mean the list of all individual items and services maintained by a hospital for which the hospital has established a standard charge.

Each individual item or service found on the hospital chargemaster has a corresponding "gross" charge and may also have a corresponding negotiated discount when hospitals and third-party payers negotiate a flat percent discounted rate off the gross charge for each individual item and service listed on the chargemaster. In contrast to the chargemaster or so-called "fee-for-service" price list, hospitals also routinely negotiate rates with third-party payers for bundles of services or "service packages" in lieu of charging for each item. For purposes of section 2718(e) of the PHS Act, CMS proposed to define a "service package" as an aggregation of individual items and services into a single service.

The proposed definition of "items and services" includes services furnished by physicians and non-physician practitioners employed by hospitals. It does not include services provided by physicians and non-physician practitioners who are not employed by hospitals, but who provide services at a hospital location.

Comments/Responses: Many commenters stated that service packages are often unique to each payer, and the reimbursements negotiated with payers are not necessarily associated with a Health Care Procedure Code System (HCPCS), diagnosis-related group (DRG), National Drug Code (NDC), or Ambulatory Payment Classification (APC). Commenters requested that CMS provide guidance to define outpatient service packages and attribute ancillary services to specific primary services.

CMS responds that 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. The payer-specific charge the hospital has negotiated for a service package (also referred to as the 'base rate') is not found in the

chargemaster but can be found in other parts of the hospital billing and accounting systems or in rate tables or the rate sheets found in hospital in-network contracts with third-party payers. CMS declines to define outpatient service packages stating that doing so would be overly prescriptive. Hospitals will have the flexibility to display their standard charges for service packages that are unique to each of their payer-specific contracts.

Some commenters supported requiring hospitals to post charges for all practitioners who affiliate with a hospital. They believe 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.

CMS responds that physicians and non-physician practitioners not employed by the hospital establish their own charges for services. Charges for their services fall outside the scope of section 2718(e) of the PHS Act as they are not services "provided by the hospital." CMS recommends that hospitals 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.

Several commenters sought clarification on the term "employment," noting there are various employment arrangements that could potentially be subject to the requirements. There were also commenters that said hospitals that employ physicians and non-physician practitioners would be displaying prices that would not be comparable with prices of hospitals that do not employ and do not disclose physician and non-physician practitioner prices.

CMS declines to codify a definition of "employment" to preserve flexibility for hospitals to identify employed physicians or non-physician practitioners under their organizational structure. It further disagrees with commenters that charge comparisons between hospitals employing physicians and those not employing physicians would not be comparable. Hospital employed physicians' and non-physician practitioners' services may be charged as ancillary services to a primary shoppable service. Such ancillary services would be listed separately from the primary shoppable service allowing for comparability among hospitals.

Some 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. CMS disagreed saying that section 2718(e) of the PHS Act does not define "standard charges for items and services." Since hospitals charge patients for the services of their employed physicians and non-physician practitioners, CMS believes it is reasonable for "standard charges" to include charges of the services of employed physicians and practitioners.

Final Action: CMS is finalizing the definition of "items and services" as proposed at new 45 CFR §180.20. Items and services 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. Definition of "Standard Charges"

1. Overview and Background

CMS provides legal justifications in this section for why it has the authority to require disclosure of "payer-specific negotiated charges" as a standard charge. The final rule first reiterates an argument from the 2020 OPPS/ASC proposed rule that hospitals can have different standard charges for various groups of individuals. For purposes of 2718(e) of the PHS Act, 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. CMS' 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 a single fixed amount, but, rather, depends on who is being charged for the item or service such as a third-party payer that has negotiated a rate on its members' behalf.

Next, CMS argues that the final rule requirements are necessary to promote efficient administration of Medicare and Medicaid consistent with section 1102(a) of the Social Security Act (the Act). Section 1102(a) of the Act 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 is charged."

CMS further notes the lack of a definition of "standard charges" in applicable law. It argues that the statute contemplates disclosure of charges other than the list prices as found in the hospital chargemaster because 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. If the statute only required gross charges, CMS argues it would not have required that charges be posted and updated by DRG.

Lastly, CMS argues that the information it is requiring to be available is already available to patients on an explanation of benefits (EOB) furnished to enrollees after healthcare items or services are provided and the claim is adjudicated. The EOB is required by section 2719 of the PHS Act. The EOB provides gross charges and payer-specific negotiated charges to the patient when there is a benefit determination adverse to the patient. This information is needed for the patient to understand the extent of their healthcare costs. CMS argues that its transparency rules are effectively allowing the consumer to 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.

Final Action: CMS is finalizing the definition of standard charges to include gross charges and payer-specific negotiated charges. As described further below, CMS is further adding discounted cash price for self-pay individuals as well as a de-identified minimum, median and maximum negotiated charge as a type of standard charge.

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

CMS proposed to define standard charges as gross charges and payer-specific negotiated charges. 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. The gross charges often apply to a specific group of individuals who are self-pay, but do not reflect charges negotiated by third-party payers.

Comments/Responses: A few commenters stated that gross charges should be the only definition of "standard charge" indicating that other types of "standard charges" are not consistent with the definition of "charges" used in CMS's Provider Reimbursement Manual Part 1 (PRM1) which are:

> 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.[6]

CMS responds that 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. It further argues that the definition "gross charge" for the transparency regulation and PRM1 are synonymous as "gross charge" is the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts. CMS further states that the PRM1 definition of "charges" is for the specific purpose of Medicare cost reporting while the definition of standard charge for the transparency regulations has a different purpose which keep them from being in conflict.

There were various comments concerned about the usefulness of "gross charges" to a consumer. CMS responded that "gross charges" will have utility as 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. "Gross charges" will also be useful to researchers and other academics who can assess regional and national cost trends to determine the effectiveness of price transparency efforts.

Final Action: CMS is finalizing gross charge as a type of standard charge at new 45 CFR §180.20, to mean the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts.

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

CMS proposed to define a "payer-specific negotiated charge" as the charge that the hospital has negotiated with a third-party payer for an item or service. "Third-party payer" for purposes of section 2718(e) of the PHS Act is an entity that by statute, contract, or agreement, is legally

[6] Part I, Chapter 22, Section 2202.4 of the Medicare Provider Reimbursement Manual.

responsible for payment of a claim for a health care item or service. This definition excludes an individual who pays for a health care item or service that he or she receives (such as self-pay patients).

CMS states that many third-party payers do not reveal their negotiated rates, even to individuals on behalf of whom they pay. Having insight into the charges that have been negotiated on one's behalf, however, is necessary for insured health care consumers to determine their potential out-of-pocket obligations prior to receipt of a health care service. Knowing a negotiated charge is also important because a growing number of insured health care consumers are finding that some services are more affordable if the consumer chooses to forego insurance and pay out of pocket.

The rule acknowledges that the impact resulting from the release of negotiated rates is largely unknown. Some stakeholders have expressed concern with the public display of de-identified negotiated rates which may have the unintended consequence of increasing health care costs of hospital services in highly concentrated markets or as a result of anticompetitive behaviors without additional legislative or regulatory efforts.

CMS recognizes that it may be requiring release of a large amount of data. However, CMS indicates that most (if not all) hospitals maintain such data electronically because these data are used routinely for billing, and therefore believes it presents little burden for a hospital to electronically pull and display these data online in a machine-readable format.

Hospitals would display all negotiated charges, including, for example, charges negotiated with Medicare Advantage plans. Hospitals would not include payment rates that are not negotiated, such as those set by Medicare fee-for-service. However, display of a non-negotiated rate would not be precluded.

Comments/Responses: 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. 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.

CMS disagrees with commenters who indicated that payer-specific negotiated charges are meaningless to consumers. When a consumer has access to payer-specific negotiated charges 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 to determine potential out-of-pocket cost.

Several commenters believe that payer-specific negotiated rates are proprietary and requiring their disclosure would infringe upon intellectual property rights under Defend Trade Secrets Act of 2016 (DTSA) and would violate the Freedom of Information Act (FOIA) that protects trade secrets and confidential commercial or financial information against broad public disclosure.

Compelled speech required by CMS' proposed policy would further violate the First Amendment to the United States Constitution.

CMS responds that payer-specific negotiated charges hospitals are already disclosed publicly in a variety of ways, for example, through state databases and patient EOBs. The final rule provides examples where states have released payer and provider specific negotiated rates. CMS does not believe the DTSA is applicable because 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." Further, DTSA applies only to disclosures "not authorized by law." CMS indicates that its rule would be authorizing hospitals to disclose the information. The rule also states that DTSA and FOIA protects disclosure of information by the federal government not by private entities as required by the final rule.

In response to the First Amendment comments, CMS indicates certain factual commercial disclosures are constitutional where the disclosure advances a government interest and does not unduly burden speech. CMS cites Zauderer v. Office of Disciplinary Counsel (471 U.S. 626 (1985) and the Nat'l Inst. of Family and Life Advocates v. Becerra, (138 S. Ct. 2361, 2372, 2376 (2018) that 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. Disclosures here advance the 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. CMS cites to a large number of sources to support this statement.

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. CMS disagrees and referenced its literature review and its economic analysis from the proposed rule (84 FR 39630 through 84 FR 39634) and a variety of sources in the final rule. The final rule argues that these resources support CMS' belief that accessible pricing information would reduce healthcare costs by encouraging providers to offer more competitive rates consistent with predictions of standard economic theory. The rule acknowledges that there could be an unintended effect of increases in prices as well as decreases in prices but indicated that it is the lack of availability of this information that makes the effects of price disclosure uncertain. Several studies cited in the final rule show conflicting conclusions about the effect of price transparency on costs.

Many commenters indicated that payer-specific negotiated charges do not exist in hospital accounting systems or are not available to be reported by hospitals without significant manual effort. Others indicated that consumers should pursue information on out-of-pocket obligations from insurers as opposed to hospitals. There were also comments that said the 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 to the patient.

CMS responded that if the rate sheets are not in electronic form, hospitals can request an electronic copy of their contract and corresponding rate sheet from the third-party payer. The rule acknowledges 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, CMS is requiring the base rates, not the payment received, to be made available. CMS believes the burden to hospitals for making public all payer-specific negotiated charges is outweighed by the public's need for access to such information.

Final Action: CMS is finalizing the 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. "Third-party payer" for purposes of section 2718(e) of the PHS Act is an entity that, by statute, contract, or agreement, is legally responsible for payment of a claim for a healthcare item or service. However, CMS conceded the potential burden associated with making payer-specific negotiated charges publicly available and is delaying the rule's effective date to January 1, 2021.

4. Alternative Definitions for Types of Standard Charges

CMS requested comment on the following options for standard charges in the proposed rule:

Volume-driven negotiated charge. The most frequently charged rate across all rates the hospital has negotiated with third-party payers for an item or service. CMS is not adopting the idea because it could be misleading for consumers who are trying to combine the volume-driven rate with their specific benefit information.

All Allowed Charges. This definition would include charges for all items and services for all third-party payer plans and products, including those that are non-negotiated (such as fee-for-service Medicare rates). CMS is not adopting this idea because it would be redundant to require hospitals to re-disclose already public rates.

Discounted Cash Price. The price the hospital would charge individuals who pay cash (or cash equivalent) for an individual item or service or service package. However, the rule acknowledges that many hospitals do not determine or maintain a standard cash discount that would apply uniformly to all self-pay consumers.

Individual consumers, patient advocates, clinicians, and insurers supported displaying the discounted cash price as beneficial and relevant to consumers, including consumers with third-party payer coverage. Hospitals disagreed saying 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. CMS agreed with commenters that the discounted cash price is important for many self-pay consumers. It clarified that the "discounted cash price" would reflect the discounted rate published by the hospital for cash-paying patients unrelated to charity care discounts.

De-identified Minimum and Maximum Negotiated Charge. Under this definition, the hospital would be required to make public the lowest and highest charges of all negotiated charges across all third-party payer plans and products.

Many commenters supported providing this information as a substitute for payer-specific negotiated charges while others only supported this information being made available in addition to payer-specific negotiated charges. CMS indicated that knowing one's payer-specific negotiated charge in addition to the minimum and maximum negotiated charges is informative of whether an insurer has negotiated well on their patient's behalf.

Final Action: CMS is finalizing a policy at 45 CFR §180.2 that will require hospitals to make publicly available the discounted cash price defined as the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service. In addition, hospitals must also make publicly available the de-identified minimum and maximum charge that a hospital has negotiated with all third-party payers for an item or service.

Effective January 1, 2021, hospitals will be required to make the following five categories of "standard charges" publicly available: 1) gross charge, 2) payer-specific negotiated charge, 3) discounted cash price, 4) de-identified minimum charge across all private payers and 5) de-identified maximum charge across all private payers. Table 1 reproduced from the final rule below provides a template for how this information could be presented:

TABLE 1—SAMPLE DISPLAY OF GROSS CHARGES

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				$2,534.00	

CMS notes that this table only show gross charges and not the other four categories of charges the rule requires hospitals to make available.

E. Public Disclosure in a Comprehensive Machine-Readable File

1. Overview

CMS proposed that standard charges be made public through (1) a comprehensive machine-readable file that makes public all standard charge information for all hospital items and services and (2) a consumer-friendly display of common "shoppable" services derived from the machine-readable file.

Comments/Responses: Commenters indicated that gross charges currently made publicly available are only accessed by insurance brokers, competitors, and reporters. Additionally, the data is too voluminous to navigate and understand. CMS responds that data will be available to be integrated into price transparency tools and EHRs, for clinical decision-making and referrals and to researchers and policy officials to help bring value to healthcare. The response further states that just because the file is large does not make it unusable. CMS makes other large files available (such as the Medicare Provider Utilization and Payment Data files) that are commonly used by a variety of stakeholders, some of whom take the information and present it to users in a consumer-friendly manner.

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

CMS proposed to require that hospitals make public a list of each item or service the hospital provides and that the list include the following:

- Description of each item or service (including both individual items and services and service packages).
- The gross charge that applies in, as applicable, the hospital inpatient setting and outpatient department setting.
- The payer-specific negotiated charge that applies 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 HCPCS code, DRG, National Drug Code (NDC), or other common payer identifier.
- Revenue code, as applicable.

CMS proposed that hospitals associate each standard charge with a CPT or HCPCS code, DRG, NDC, or other common payer identifier, as applicable. Hospitals use revenue codes to associate items and services with various hospital departments. When a hospital charges differently for the same item or service in a different department, CMS proposed that the hospital associate the charge with the department represented by the revenue code, providing the public with the charges they may expect for hospital services provided in different hospital departments.

Comments/Responses: A few commenters sought clarification on how to make public charges for various hospital items and services such as charges based on time. Others stated that charges for hospitals and physicians may be maintained separately, with some indicating that employed

physician charges are not included in their hospital chargemaster. CMS responded that the hospital could list gross charges associated with supplies or the amount it charges per unit of time for time-based services. The final rule refers readers to Table 1 for a template for how to address both of these comments.

Standardizing data definitions was a common comment so that comparisons across hospitals would be for like services. CMS believes 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. It will consider defining elements in a data dictionary or more specificity in data file formats in future rulemaking.

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 that published data may not be accurate due to the myriad ways that payors structure and adjudicate providers' claims. CMS reiterates prior responses recommending that hospitals consult their rate sheets or rate tables within which the payer-specific negotiated charges are often found. 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.

CMS agrees that for insured patients, the payer-specific negotiated charge does not in isolation provide a patient with an individualized out-of-pocket estimate. However, 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.

In summary, CMS believes standard charges, service description, and codes are the necessary elements to ensure hospital charge information is relevant to consumers, usable, and comparable.

Final Action: CMS is finalizing its proposal at 45 CFR §180.50(b) as described above with the following modifications: 1) Revenue code, as applicable will not be a required data element; 2) the de-identified minimum and maximum charge and discounted cash price will be required data elements.

3. Machine Readable File Format Requirements

CMS proposed to require that hospitals post standard charges in a single digital file in a machine-readable format. A machine-readable format would be defined 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. CMS believes that making public such data in a machine-readable format poses little burden on hospitals because many (if not all) hospitals already keep these data in electronic format in their accounting systems for purposes of ensuring accurate billing.

CMS requested comments on only allowing the data to be posted in an XML format and other alternatives that could allow public access to hospital standard charge data in real time. Such technology may require or involve a type of portal or standard(s) in which entities have access to certain non-sensitive data elements or files within the hospital IT system environment, such as the chargemaster, but that otherwise restricts access to (i) sensitive, personal identifying information (PII), (ii) commercial, protected health information, and/or (iii) confidential information. For example, application programming interface (API) standards could be used to facilitate public access to real-time hospital charge information.

More information on API certification criteria and how APIs can be used by patients and health care providers and other entities to exchange electronic information can be found on the website at: https://www.healthit.gov/api-education-module/story_content/external_files/hhs_transcript_module.pdf.

CMS specifically requested public comment on adopting a requirement that hospitals make public their standard charges through an "openly published" (or simply "open") API through which they would disclose the standard charges and associated data elements. An "open API" would simply be one for which the technical and other information required for a third-party application to connect to it is openly published. Open API does not imply that any and all applications or application developers would have unfettered access to sensitive information.

Comments/Responses: Commenters generally supported the use of API-based methods to access pricing information, noting that APIs are largely efficient and not burdensome to implement. There were additional comments supporting the development of industry-wide API standards. CMS responded that it will continue to work on policies designed to advance the use of APIs and measures consensus-based standards for data pricing such as the Fast Healthcare Interoperability Resources as they develop.

Final Action: CMS is finalizing its policy as proposed. The format requirements are at 45 CFR §180.50(c) and the definition of machine-readable is at 45 CFR §180.20.

4. Location and Accessibility Requirements

CMS 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 file is displayed on a publicly-available webpage; it is displayed prominently and clearly identifies the hospital location with which the standard charge information is associated; and the standard charge data are easily accessible, without barriers, and the data can be digitally searched.

As proposed “displayed prominently” would mean that the value and purpose of the webpage and its content is clearly communicated, there is no reliance on breadcrumbs[7] to help with navigation, and the link to the standard charge file is visually distinguished on the webpage. “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. “Without barriers” would mean the data can be accessed free of charge, and 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 file.

Hospitals are encouraged to review the HHS Web Standards and Usability Guidelines (available at: https://webstandards.hhs.gov/) which are intended to provide best practices over a broad range of web design and digital communications issues. CMS also requests comments on requiring hospitals to submit a link to a CMS-specified central website that would make the hospital’s charge data public on a CMS webpage. CMS further requested public comments on including easily-searchable file naming conventions and whether to specify the website location for posting rather than permitting hospitals some flexibility in choosing an appropriate website.

Comments/Responses: Public commenters suggested a wide variety of ideas for making standard charge data publicly accessible including posting the data on a centralized price transparency website such as CMS’. CMS agreed with stakeholders that centralizing the standard charge information disclosed by hospitals could have many advantages for finding the files and for compliance. It is not finalizing such a requirement at this time but will be consider adopting this idea in the future.

Final Action: CMS is finalizing all of its policies described above at 45 CFR §180.50(d)(1) and (2) as proposed with one modification: Hospitals will be required to use the following naming convention to assist in locating hospital charge data files as follows: <employer identification number>_<hospital name>_<standard charges>.[json|xml|csv].

5. Frequency of Updates

CMS proposed to require hospitals update all standard charges at least once annually and clearly indicate the date of the last update.

Comments/Responses: Some commenters were concerned that only requiring annual updates would mean the data would often be outdated. However, other commenters said that updating data on a continual basis would be burdensome to hospitals. CMS responded that its proposed policy strikes a balance between a consumer’s need to plan and compare prices when seeking care with hospital disclosure burden. Alternative mechanisms, such an API format that CMS is considering for the future, could allow for access to continuously updated hospital charge information.

[7] Breadcrumb Navigation is a form of site navigation that shows visitors where they are on a site's hierarchy of pages without having to examine a URL structure.

Final Action: CMS is finalizing the requirement as proposed at 45 CFR §180.50(e). While the regulation only requires annual updates to standard charges, CMS encourages hospitals to make more frequent updates.

6. Requirements for Making Public Separate Files for Different Hospital Locations

CMS' proposed that requirements to post standard charges 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.

Comments/Responses: One commenter expressed concern about the burden associated with listing standard charges for each location separately for health care systems with expansive campuses. CMS clarifies 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. 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: CMS is finalizing the policy as proposed at 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 apply to each hospital location.

F. Selected Shoppable Services

1. Definition of "Shoppable Service"

CMS proposed to define "shoppable service" as a service package that can be scheduled by a health care 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. Additionally, CMS proposed that the charges for such services be displayed as a grouping of related services, meaning that the charge for the shoppable service is displayed along with charges for ancillary items and services the hospital customarily provides as part of or in addition to the primary shoppable service.

Under the proposal, CMS defined "ancillary service" as an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service. To the extent that a hospital customarily provides (and bills for) such services as a part of or in conjunction with the primary service, the hospital should group the service charge along with the other payer-specific negotiated charges that are displayed for the shoppable service.

Comments/Responses: There were a number of comments around emergent vs. non-emergent services. Some commenters wanted CMS to retain the criteria that services must be non-emergent to be considered shoppable. Other commenters said that for a service to be shoppable, patients must be able to select among multiple providers that furnish the same service. Another

commenter indicated that CMS' initiative will have limited impact on controlling healthcare costs as less than 50 percent of spending is associated with the services that can be scheduled in advance.

CMS notes these concerns saying that the same procedures could potentially be furnished on an emergent basis or be scheduled in advance depending on the circumstance. It further states that a given service may or may not be furnished by multiple providers in an area but that hospitals may not be aware of whether other providers are making a given service available to patients. For these reasons, CMS believes that it should focus solely on whether a service can be scheduled in advance as the criteria for when a service is shoppable. While CMS acknowledges that many non-shoppable hospital and emergency services can be very expensive and account for much of the healthcare spending in the United States, it states that approximately $36 billion could be saved when consumers are given the ability to shop and compare prices for common shoppable services.[8]

Commenters requested guidance on services that constitute "ancillary services" (e.g. CMS should use its data systems to identify services provided in conjunction with each other and inform hospitals of which services it would consider to be ancillary to the shoppable service). Other commenters are concerned that ancillary tests, anesthesia and other services are charged separately by contracted clinicians or facilities apart from the primary service making it impossible to meet the proposed display requirements. There were additional comments that some services are, in and of themselves, discrete services which are typically billed as a single service without any additional services as part of a package.

CMS responds that hospitals should have flexibility to determine how best to display the primary shoppable service as well as the associated ancillary services. Each hospital should be able to query its information systems to determine services (laboratory, radiology, etc.) that are typically billed with the primary shoppable service. Many hospitals are already doing this by making price estimator tools available. The final rule acknowledges that clinicians and others may be furnishing and charging for some services furnished with the primary shoppable service. In these circumstances, CMS encourages the hospital to indicate that ancillary services may be billed separately by other entities involved in their care. On the comment about discrete services, CMS is modifying the definition of "shoppable services" to remove the reference to a "service package" to account for situations where a shoppable service is not associated with additional ancillary services.

Final Action: CMS is finalizing its definition of a shoppable service as a service that can be scheduled by a consumer in advance but is removing the phrase "shoppable service package" from the definition. When the shoppable service is customarily accompanied by the 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. These regulations are finalized at 45 CFR §180.20.

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[8] 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 reproduced from the final rule below provides a template for how shoppable services could be presented:

TABLE 2—SAMPLE OF DISPLAY OF SHOPPABLE SERVICES

<table>
<tr><td colspan="2">Hospital XYZ Medical Center</td><td></td><td></td></tr>
<tr><td colspan="2">Prices Posted and Effective [month/day/year]</td><td></td><td></td></tr>
<tr><td colspan="2">Notes: [insert any clarifying notes or disclaimers]</td><td></td><td></td></tr>
<tr><th>Shoppable Service</th><th>Primary Service and Ancillary Services</th><th>CPT/ HCPCS Code</th><th>[Standard Charge for Plan X]</th></tr>
<tr><td rowspan="5">Colonoscopy</td><td>primary diagnostic procedure</td><td>45378</td><td>$750</td></tr>
<tr><td>anesthesia (medication only)</td><td>[code(s)]</td><td>$122</td></tr>
<tr><td>physician services</td><td colspan="2" rowspan="2">Not provided by hospital (may be billed separately)
Not provided by hospital (may be billed separately)</td></tr>
<tr><td>pathology/interpretation of results</td></tr>
<tr><td>facility fee</td><td>[code(s)]</td><td>$500</td></tr>
<tr><td>Office Visit</td><td>New patient outpatient visit, 30 min</td><td>99203</td><td>$54</td></tr>
<tr><td rowspan="7">Vaginal Delivery</td><td>primary procedure</td><td>59400</td><td>[$]</td></tr>
<tr><td>hospital services</td><td>[code(s)]</td><td>[$]</td></tr>
<tr><td>physician services</td><td colspan="2" rowspan="3">Not provided by hospital (may be billed separately) Not provided by hospital (may be billed separately) Not provided by hospital (may be billed separately)</td></tr>
<tr><td>general anesthesia</td></tr>
<tr><td>pain control</td></tr>
<tr><td>two-day hospital stay</td><td>[code(s)]</td><td>[$]</td></tr>
<tr><td>monitoring after delivery</td><td>[code(s)]</td><td>[$]</td></tr>
</table>

2. Selected Shoppable Services

CMS proposed that hospitals make public a list of their payer-specific negotiated charges for as many of the 70 shoppable services that are identified in Table 3 of the final rule (reproduced below) and as many additional shoppable services selected by the hospital as is necessary for a combined total of at least 300 shoppable services (hospitals can select the additional services based on the utilization or billing rate of the services in the past year).

Comments/Responses: Some commenters wanted CMS to require standard charges to be posted for more than 300 services or all of the services a hospital provides. Others wanted the requirements to apply to fewer than 300 services or be limited to the highest volume/cost services furnished by hospitals. CMS responds that it believes 300 shoppable services is a reasonable number based on research[9] and discussions with early adopters of price transparency tools and their developers. In cases where a small hospital or a specialty hospital does not offer 300 services, the hospital must list as many of the services it provides that could be scheduled by patients in advance.

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[9] 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).

There were comments requesting that CMS standardize each shoppable service to allow for better comparability among hospitals. A few commenters asked that CMS extend the requirements to non-hospital settings where some of these services are provided.

CMS responds that its listing of 70 shoppable services was intended to ensure some degree of uniformity among hospitals. The services were selected based on an analysis of shoppable services that are currently made public under existing price transparency tools. CMS acknowledges the comment about standardization and encourages hospitals to describe the services included or excluded from the shoppable services in its web posting. While many of the shoppable services included on Table 3 are provided in settings other than hospitals, CMS only has authority to apply its rules to hospitals. CMS encourages non-hospital sites to standardize and display their charges for consumers as well.

Several commenters suggested services to remove or add to the CMS-specified list of 70 shoppable services. For example, some commenters asked that CMS remove evaluation and management (E&M) and low-cost laboratory services from the list and replace them with higher cost services more important to a patient's site-of-care decision. Another comment noted that CMS listed MS-DRGs while private payers generally use APR-DRGs and asked how such a discrepancy should be handled.

CMS responds that while some services (for example, E&M or laboratory services) may not be expensive hospital services, its analysis indicates they are commonly furnished by a hospital. The response further recognizes that private payers may use different codes than Medicare for the same services (such as APR-DRGs versus MS-DRGs).[10] CMS will permit hospitals to make appropriate substitutions and cross-walks of codes as necessary to allow them to display their standard charges for the shoppable services across all third-party payers.

One commenter requested that CMS ensure the requirements under this rule are consistent with the type of data required to be reported under section 216(a) of the Protecting Access to Medicare Act (PAMA). CMS responded that it does not believe that any of the provisions under its final rule conflict with or duplicate the requirements of section 216(a) of PAMA.[11]

Final Action: CMS is finalizing the list of shoppable services as proposed at 45 CFR §180.60(a) with a modification that if a hospital does not provide 300 shoppable services, the hospital must list as many shoppable services as they provide. Hospitals will also be permitted 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.

[10] This will be true for E&M services as well. Medicare uses a single code (G0463) for an outpatient clinic visit while private payers may use CPT codes that have 5 different payment levels each for new and established patients.
[11] Section 1834A(a) of the Act, as added by section 216 of PAMA, requires CMS to collect private payer rates for clinical laboratory services from applicable laboratories. Section 1834A(a)(10) requires CMS to maintain the confidentiality of that information and not disclose it publicly. The response does not explain how CMS can require hospitals to disclose information that CMS itself is prohibited from disclosing.

TABLE 3—70 CMS-SPECIFIED SHOPPABLE SERVICES

Category/Service	2020 CPT/HCPCS Primary Code
Evaluation & Management Services	
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 or other outpatient visit, typically 45 min	99204
New patient office or 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	
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	
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

Category/Service	2020 CPT/HCPCS Primary Code
Medicine and Surgery Services	**2020 CPT/HCPCS/DRG* 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

*The five codes listed with 3 digits are the MS-DRG assignment. All other 5-digit codes are HCPCS codes.

3. Required Corresponding Data Elements

CMS proposed to require a consumer-friendly display of payer-specific negotiated charge information as follows:

- A plain-language description of each shoppable service. (Hospitals are invited to review and use the Federal plain language guidelines (https://plainlanguage.gov/guidelines).)
- The payer-specific negotiated charge that applies to each shoppable service ("N/A" if it is not a service the hospital provides).
- 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 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 or the outpatient department setting or both.
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, but not limited to, the CPT or HCPCS code, DRG, or other commonly used service billing code.

CMS recognizes that not all hospitals will customarily provide exactly the same ancillary items or services with a primary shoppable service and therefore believes it is important for hospitals to display a list of ancillary services provided in conjunction with the shoppable service.

Comments/Responses: Many commenters offered suggestions on specific data elements that CMS should also require including information on quality. CMS acknowledges and responds to the many comments for specific data elements noting that comparative hospital quality information is readily available to the public[12] and also beyond scope of section 2718(e) of the PHS Act. It further added that hospitals may add elements to their public display beyond the information required by CMS. CMS believes that its final rule policies represent a balance between data elements that would be useful for the public while being sensitive to hospitals' burden in meeting requirements.

Several commenters raised concerns about the time, effort, and technical challenges required by CMS' policy. Comments indicated that the data file CMS is requiring could be tens of thousands of rows with dozens of columns and millions of data points that could potentially crash hospital websites.

CMS acknowledges that the benefits of compiling these data elements and presenting them in a consumer-friendly manner will likely require thoughtful effort on the part of hospitals. However, it disagrees 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. CMS believes there are low tech and inexpensive ways to compile hospital standard charge information in files posted online that are consumer-

[12] AHRQ website, Comparative Reports on Hospitals, at: https://www.ahrq.gov/talkingquality/resources/comparative-reports/hospitals.html

friendly. Table 2 in the final rule provides an example of how a hospital might consider making such information public.

Final Action: CMS is finalizing the proposed data elements required to be posted with modifications. Consistent with policies explained earlier, CMS is requiring the shoppable service to include the de-identified minimum and maximum negotiated charge and discounted cash price. CMS acknowledges that there may be no ancillary services furnished with a shoppable services, so it is removing the separate requirement to list all the associated ancillary services and instead requiring hospitals (as applicable) to provide charges for ancillary services as part of the payer-specific negotiated charge that applies to each shoppable service. The final rule also includes a new requirement to provide each payer-specific negotiated charge to be associated with a name of the third-party payer and plan. The full list of required data elements is included at 45 CFR §186.60(b) and provided below:

- 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.

4. Format of Display of Consumer-Friendly Information

CMS did propose a specific format for making data public online in a consumer-friendly manner. Hospitals would retain flexibility on how best to display the payer-specific negotiated charge data and proposed associated data elements, so long as the website is easily accessible to the public. CMS further proposed to require hospitals to make the data elements available in a consumer-friendly manner offline (for example, in a brochure or booklet) upon request within 72 hours.

Comments/Responses: There were comments that stated the requirement to provide a paper copy of standard charge information would be costly and time consuming. The volume of data would

be enormous. CMS agreed and is not finalizing that proposal although it may revisit the requirement if it determines that lack of a paper copy is preventing consumers from accessing hospital charge information.

Some commenters were concerned that consumer-friendly display of standard charges for shoppable services might not provide the consumer with sufficient understanding of their actual costs based on unique patient or plan circumstances. Many commenters stated that 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 that will be more useful to consumers than sharing charges online. Several commenters suggested that hospitals offering a price estimator tool that allows patients to obtain out-of-pocket estimates for shoppable services should be exempt from or considered to have met their obligations under the rule.

CMS agreed and is finalizing a modification to its proposal that a hospital may voluntarily offer an Internet-based price estimator tool and thereby be deemed to have met the requirements to make public its standard charges for selected shoppable services in a consumer-friendly manner. Hospitals would still be required to publish all standard charges in a machine-readable file consistent with the requirements in section II.E of the final rule.

Final Action: CMS is finalizing its proposal to specify in 45 CFR §180.60(c) that hospitals retain flexibility on how best to publicly display online their standard charges in a consumer-friendly manner, so long as the website is easily accessible to the public. 45 CFR §180.60(a)(2) will specify that a hospital is deemed by CMS to meet its requirements if the hospital maintains an Internet-based price estimator tool that does the following:

- 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.
- 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 the combined total to be at least 300 shoppable services.
- Is prominently displayed on the hospital's website and is accessible without charge and without having to register or establish a user account or password.
- Is available on an Internet website or through a mobile application.

CMS is not requiring but encourages hospitals to take note of current estimator tool best practices and seeks to ensure the price estimator tools they offer are maximally consumer-friendly by:

- 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.
- Notify the consumer about the availability of financial aid, payment plans, and assistance in enrolling for Medicaid or a state program.
- Including an indicator for the quality of care in the healthcare setting.
- 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.

5. Location and Accessibility Requirements

CMS proposed parallel location and accessibility requirements for shoppable services as it did for all items and services. The proposal required that the data must be "displayed prominently," be "easily accessible," presented in format that is searchable by service description, billing code, and payer, accessed with the fewest number of clicks, available free of charge without having to input information or register to access or use the standard charge data.

Final Action: CMS is finalizing the proposal at 45 CFR §180.60(d) with a 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. The information must be displayed in a prominent manner that identifies the hospital location with which the standard charge information is associated. CMS is not requiring but expects that hospitals would post information in a format accessible to people with disabilities in accordance with any applicable federal or state laws.

6. Frequency of Updates

CMS proposed parallel requirements for frequency of updates for shoppable services as it did for all items and services. This proposal is being finalized without change at 45 CFR §180.60(e). Hospitals are also being required to clearly indicate the date that the information was most recently updated.

G. Monitoring and Enforcement

1. Monitoring

CMS had proposed to rely predominantly on complaints by individuals or entities regarding a hospital's potential noncompliance and its review of individuals' or entities' analysis of noncompliance. As it gains experience with compliance review of complaints, CMS may consider self-initiating audits of hospitals' websites as a monitoring method.

Some commenters supported a robust and well-defined monitoring and enforcement process while others suggested that the burden of such a process could outweigh its benefits. Rural providers were concerned about the additional costs and burdens the price transparency policies would pose. Focusing on the monitoring policy, CMS says the burden would only impact noncompliant hospitals. CMS notes that its authority is broad which permits monitoring not only of the accuracy of information made publicly available but also of whether the information is made public in the form, manner and with the frequency the agency specifies. It anticipates review of inaccuracies will be for egregious and obvious instances of noncompliance, such as all items and services having the same value or no value at all. CMS will not require hospitals to report or to attest to their compliance with the requirements of the transparency policies.

The agency establishes an email address, PriceTransparencyHospitalCharges@cms.hhs.gov, through which individuals and entities may report concerns about hospital compliance, which

may include analysis of noncompliance. CMS also agrees with commenters that its own audits of hospital websites may be an important method of monitoring.

Final Action: The agency finalizes its proposals without change; the monitoring methods will be codified at 45 CFR 180.70.

2. Enforcement

Citing the authority of section 2718(b)(3) of the PHS Act, CMS proposed to take any of the following actions when a hospital is non-compliant with section 2718(e) of the PHS Act:

- Issue a written warning notice to the hospital of the specific violation(s).
- Request a corrective action plan (CAP) from the hospital if its noncompliance constitutes a material violation of one or more requirements.
- Impose civil monetary penalties (CMP) and publicize the penalty on a CMS website.

CMS proposed that a material violation may include, but is not limited to, the following:

- A hospital's failure to make public its standard charges.
- A hospital's failure to make public its standard charges in the form and manner required.

Under its proposal, a hospital submitting 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 it must comply with the requirements of the CAP. A hospital's CAP would have to specify elements including, but not limited to, the deficiency or deficiencies that caused noncompliance to occur and the corrective actions or processes the hospital will take to come into compliance. The CAP would be subject to CMS review and approval. CMS may monitor and evaluate the hospital's compliance with the corrective actions.

In response to comments, CMS reviewed its proposed requirements for imposing a CAP and determined they may raise due process considerations; the phrase "deficiency or deficiencies that caused the noncompliance to occur" suggests that in developing a CAP the hospital must concur with the agency's findings. This would complicate a hospital's efforts to dispute any finding of noncompliance. In the final rule, CMS revises the proposed regulation text to instead require that a CAP must include a description of the corrective actions a hospital will take to address the deficiencies identified by CMS.

Commenters objected to the proposed January 1, 2020 implementation date; CMS agrees to delay the effective date one year. It emphasizes that the enforcement process will afford multiple opportunities for a hospital to avoid a civil monetary penalty.

Final Action: The agency finalizes its proposals with the modifications described above; the revised effective date for the transparency policies is January 1, 2021. The enforcement process will be codified at 45 CFR 180.80.

3. Civil Monetary Penalties

CMS proposed to establish a $300 maximum daily amount for any CMP imposed on a noncompliant hospital. This amount would be adjusted annually by applying the cost-of-living adjustment multiplier determined by the Office of Management and Budget for adjusting applicable CMP amounts pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

Under the proposal, if CMS imposes a penalty, it would to provide a written notice to the hospital via certified mail or another form of traceable carrier. The proposed notice could include, but would not be limited to, the following:

- The basis for the hospital's noncompliance, including, but not limited to: 1) CMS' determination as to which requirement(s) the hospital violated; and 2) 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 disclosure requirements.
    - 12 months after the date of the last annual update.
    - A date determined by CMS, such as one resulting from monitoring activities or the date of a CAP.
- 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 any CMP imposed on the hospital on a CMS website.
- A statement of the hospital's right to a hearing.
- 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.

Under the proposal, a hospital must pay a CMP in full within 60 calendar days after the date of the notice of imposition of a CMP or 60 calendar days after the date of a final and binding decision to uphold, in whole or in part, the CMP (moved to the next business day if the 60th day is a weekend or federal holiday). In the event that a hospital requests a hearing, CMS would indicate in its public posting that the CMP is under review. CMS would modify or remove the posting accordingly based on the outcome of the hearing.

Some commenters challenged CMS on its authority to impose CMPs for noncompliance with the transparency requirements; they argued that its reliance on section 2718(b)(3) of the PHS Act for enforcement of hospital price transparency generally was flawed as that section only applies to enforcement of requirements imposed on health insurers to report information and pay rebates related to medical loss ratios. CMS argues that the plain reading of section 2718 of the PHS Act provides sufficient legal basis for its enforcement policies, including the imposition of CMPs.

CMS sought comment on the amount of the CMP; comments ranged from suggesting no CMPs to $1 million per violation. Some commenters noted that CMPs are typically imposed for fraud and abuse violations. Others noted that the $300 CMP amount could be punitive to small or rural providers but negligible for large hospitals; for example, a large hospital could determine that an annual CMP of $109,500 for noncompliance is a cost of doing business. CMS believes that $300 is an appropriate maximum daily CMP for this purpose though it says it will monitor hospital compliance to determine whether to change the amount of the CMP under certain circumstances, such as using a sliding scale approach.

A commenter objected to the agency's proposal to post notice of any CMPs imposed on a hospital on the CMS website. Another commenter suggested posting a notice of noncompliance before a CMP was imposed, citing what it viewed as a beneficial impact of "naming and shaming" a hospital. CMS believes including a notice on its website of CMPs imposed on a noncompliant hospital is important though at this time declines to post notice of any noncompliant hospitals prior to the imposition of a CMP.

Final Action: CMS finalizes its proposals with one clarification in the case of a CMP upheld in part on appeal. If the CMP is upheld in part, CMS will issue a modified notice to conform to the adjudicated finding. The CMP policies will be codified at 45 CFR 180.90.

H. Appeals

CMS did not receive any comments on its proposed appeals process; thus, it finalizes the following policies as proposed for appeals of CMPs imposed pursuant to its enforcement authority for the hospital price transparency policies.

CMS aligns 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 for failure to report information and pay rebates related to medical loss ratios. A hospital upon which CMS has imposed a penalty may request a hearing before an Administrative Law Judge (ALJ). 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 appeals of CMPs:

- Civil money penalty means a civil monetary penalty under new 45 CFR 180.90.
- Respondent means a hospital that received a notice of imposition of a CMP under 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 new 45 CFR 180.90(b).
- Under 45 CFR 150.417(b), in deciding whether the amount of a CMP is reasonable, the ALJ may only consider evidence of record relating to:
    - 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 under new 45 CFR 180.70(a)(2).
- The ALJ's consideration of evidence of acts other than those at issue does not apply.

If a hospital does not request a hearing within 30 calendar days (moved to the next business day if the 30th day is a weekend or federal holiday) of the issuance of the notice of imposition of a CMP, CMS may impose additional penalties pursuant to continuing violations without right of appeal. The hospital will have no right to appeal a penalty with respect to which it has not requested a hearing unless the hospital can show good cause for failing to timely exercise its right to a hearing.

The CMP policies will be codified at 45 CFR §§180.100 and 180.110 as a new Subpart D of Part 180.

III. Comments on Price Transparency Quality Measurement

CMS sought feedback on the following:

- 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
- Improving incentives and assessing the ability of healthcare providers and suppliers to communicate and share charge information with patients

CMS says it received 63 timely comments on this RFI. It neither summarizes those comments nor indicates how it will proceed on these issues.

IV. Collection of Information

In the proposed rule, CMS indicated that the burden for its transparency policies 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 chares in a machine-readable format. The proposed requirements would apply to 6,002 hospitals operating in the United States; this figure excludes 208 federally-owned or operated hospitals. The burden estimate took into account activities from four professions: lawyers, general operations managers, business operations specialists, and network and computer systems administrators. It estimated an annual burden assessment of 12 hours per hospital at a cost of $1,017.24; the total national burden was estimated to be 72,024 hours and $6,105,474.

Commenters were concerned by this estimate. They indicated that the agency failed to take into account a number of factors, including consultation with professionals and specific technical activities. Also omitted from the estimate were time, resources and input of (i) clinical staff to identify and compile each shoppable service or service package, (ii) hospitals to develop policies and business practices to comply with the requirements, and (iii) additional staffing to keep up with new charges, technology, monitoring, reporting and contract negotiations. CMS agrees and adds estimates for clinical staff (at the registered nurse wage level); doubles the estimate for

activities of lawyers and general operations managers; and significantly increases hours for the initial implementation year for business operations specialists.

Commenters objected that the burden estimate failed to account for the number of third-party payers within each region; the variety of negotiated payment methodologies; and the amount and scope of hospital resources required to collect data, to make the data electronically available on user-friendly platforms, and to regularly update the data. Some comments indicated that certain hospitals do not maintain their standard charges in any electronic format. The agency says it considered the number of payers within geographic regions (ranging from 1 to 400) and the variety of payment methodologies. However, it does agree that some hospitals may require more time and resources than others to comply with requirements and revises its burden estimate to reflect more hours. Commenter estimates 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 fell within a range of 60 to 250 hours per hospital and approximately $4,800 to $20,000 per hospital; CMS believes that a total burden of 150 hours per hospital is reasonable for the first year of implementation.

Other comments highlighted ongoing costs after the implementation year; however, CMS says it did not receive specific estimates of the burden in succeeding years. It agrees that hospitals may incur maintenance costs in the outyears but notes that those costs should be less than those incurred in the first year of implementation. CMS believes hospitals will have made the necessary updates to their software and business operations during the first year, and they will become more acclimated to the rule. Thus, there should no longer be any need to consult with clinical professionals to select shoppable services or to determine associated ancillary services or to consult lawyers to review the requirements of the final rule.

CMS modifies the burden estimate by taking into account three additional types of standard charges a hospital must make publicly available: de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices. However, because the final rule permits hospitals to use Internet-based price estimator tools for shoppable services, which many hospitals currently offer, it reduces the impact of the additions.

Tables 5 and 6 in the final rule (reproduced below) show the final burden estimates for the first year and for succeeding years, respectively.

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

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

The regulatory impact analysis focuses on the burden estimates covered in section IV and generally repeats information found there. One item of note in the regulatory impact concerns Executive Order (EO) 13771 titled "Reducing Regulation and Controlling Regulatory Costs." EO 13771 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." CMS indicates that this final rule is considered an Executive Order 13771 regulatory action with $23 million in annualized costs. No further information is provided about these costs are offset.