Agenda Chapter 297 (2022 Acts of Assembly) Study September 7, 2022 Time 2:30 p.m. Board Room 2, Perimeter Center 9960 Mayland Drive, Henrico, VA 23233

- 1. Call to Order and Introductions
- 2. Review of Agenda
- 3. Legislative Mandate and Goals
- 4. Presentations and Discussion
 - 4.1. Overview of Current State and Federal Requirements about Hospital Price Transparency – Department of Health
 - 4.2. Discussion on Preliminary Recommendations for Implementation
 - 4.2.1. Recommendations to provide additional clarity or consistency to improve consumer utility of hospital pricing data
 - 4.2.2. Recommendations on compliance determination and enforcement
 - 4.2.3. What recommendations are regulatory, legislative, or other
- 5. Public Comment
- 6. Wrap Up and Next Steps
- 7. Meeting Adjournment

Chapter 297 (2022 Acts of Assembly) Workgroup

September 7, 2022







| Study Mandate and Goals | Ms. Allen |
|---|-----------------------|
| Current State and Federal Requirements for Hospital Price Transparency | Ms. Allen |
| Discussion on Preliminary Recommendations | Roundtable Discussion |
| Public Comment Period | |
| Wrap Up and Next Steps | |



Chapter 297 (2022 Acts of Assembly)

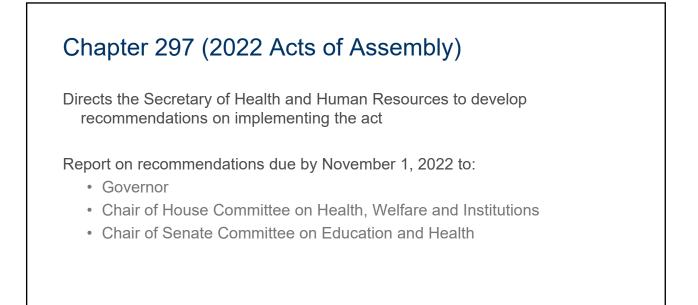
Effective July 1, 2023, every hospital shall:

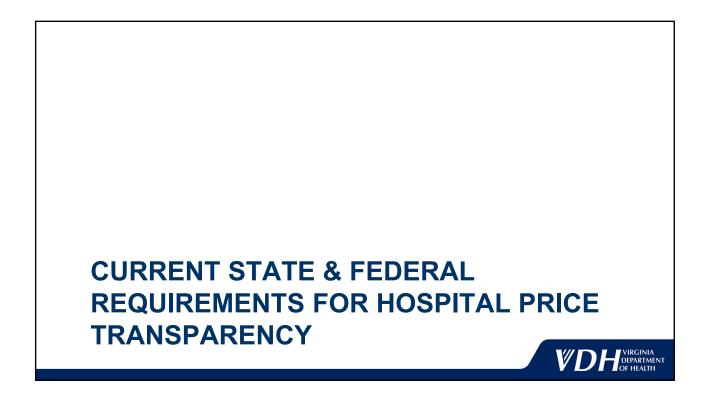
- 1) make available to the public
- 2) on its website
- 3) a machine-readable file
- 4) containing a list of all standard charges
- 5) for all items and services provided by the hospital

The terms "hospital," "items and services," "machine-readable," and "standard charge" have the same meaning as set forth in 45 C.F.R. § 180.20.



VDHOF HEALTH





Price Transparency: State

Effective July 1, 2023, every hospital shall:

- 1) make available to the public
- 2) on its website
- 3) a machine-readable file
- 4) containing a list of all standard charges
- 5) for all items and services provided by the hospital

The terms "hospital," "items and services," "machine-readable," and "standard charge" have the same meaning as set forth in 45 C.F.R. § 180.20

Enforcement: State

The State Health Commissioner can impose one or more of the following:

- Plan of correction
- Suspend hospital license
- Revoke hospital license

Determinations of noncompliance and penalties imposed can both be contested under the Virginia Administrative Process Act (§ 2.2-4000 *et seq.* of the Code of Virginia)



VDH DEPARTMENT OF HEALTH

<section-header> Drice Transparency: Federal Effective January 1, 2021, every hospital must make publicly available electronically via the internet: A machine-readable file containing a list of all standard charges for all items and services A consumer-friendly list of standard charges for a limited set of shoppable services Mospitals must make available the standard charges for each location it operates, if: The locations operate under a single license/approval The standard charges are not identical at all locations under the single license/approval

Minimum Data Elements for Item/Service: Federal

- Description
- Gross charge in inpatient and outpatient settings.
- Payer-specific negotiated charge in inpatient and outpatient settings
 - Each payer-specific negotiated charge must be clearly associated with third party payer's name and plan
- De-identified minimum negotiated charge in inpatient and outpatient settings
- De-identified maximum negotiated charge in inpatient and outpatient settings

- Discounted cash price in inpatient and outpatient settings
- Any code used by the hospital for purposes of accounting or billing, including:
 - Current Procedural Terminology (CPT) code
 - Healthcare Common Procedure Coding System (HCPCS) code
 - Diagnosis Related Group (DRG)
 - National Drug Code (NDC)
 - · Other common payer identifier



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Compliance Monitoring: Federal

CMS evaluates whether a hospital has complied with the requirements

- CMS has not authorized state survey agencies (e.g., VDH) to make compliance determinations of the *federal* requirements
- Federal hospital price transparency is not a condition of participation in Medicare or Medicaid

CMS can utilize the following to monitor and assess compliance:

- CMS' evaluation of complaints made by individuals or entities to CMS
- CMS review of individuals' or entities' analysis of noncompliance
- · CMS audit of hospitals' websites



Enforcement: Federal

CMS can impose one or more of the following:

- Written notice of violation(s)
- · Corrective action plan
- Civil monetary penalty, to be publicized on CMS website, for:
 - Failing to respond to CMS request for corrective action plan
 - Failing to comply with corrective action plan



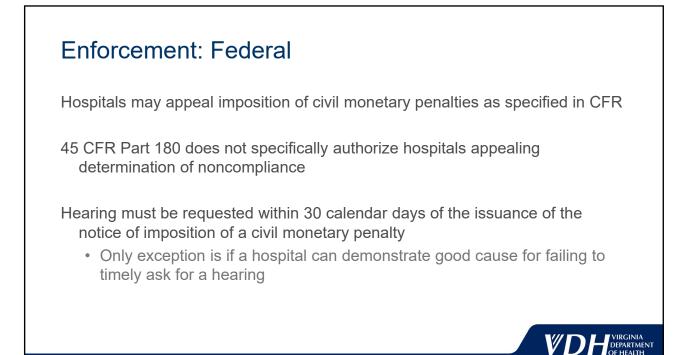
Enforcement: Federal

Schedule of civil monetary penalties based on maximum daily dollar amount

- CY2021: \$300
- CY2022 and thereafter:
 - Hospitals with 30 or fewer beds: \$300
 - Hospitals with 31 to 550 beds: # of beds X \$10
 - Hospitals with 551 or greater beds: \$5,500

Maximum daily dollar amounts will be adjusted annually using the multiplier determined by federal Office of Management and Budget







CMS auditing sample of hospitals starting January 2021, investigating complaints, and reviewing analyses of non-compliance

- · CMS has not indicated the size of the sample
- CMS has not indicated how the sample was determined (e.g., based on geography, population, etc.)
- VDH is not aware of any Virginia hospital being included in the sample

June 2022 - CMS imposes civil monetary penalties on:

- Northside Hospital Atlanta (GA) \$883,180
 - \$300/day x 121 days in 2021 = \$36,300
 - \$10/bed per day x 536 beds x 158 days in 2022 = \$846,880
- Northside Hospital Cherokee (GA) \$214,320
 - \$300/day x 114 days in 2021 = \$34,200
 - \$10/bed per day x 114 beds x 158 days in 2022 = \$846,880



DISCUSSION ON PRELIMINARY RECOMMENDATIONS

Observations from Sampled Machine-Readable Files

- Difficulty locating files on hospital websites, with some not being able to be located
- · Missing update dates or appear to be out of date
- · Filenames do not appear to match CMS specifications
- Inconsistent inclusion of medications
- Some file formats, though permitted by CMS, are harder to use than others
- · Prices not displayed in dollars
- Difficult to compare prices across hospitals because each hospital has discretion on description and coding for item/service
- Unclear if outpatient surgical hospitals are aware both federal and upcoming state hospital price transparency rules apply



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Questions to Consider

Should recommendations incorporate federal minimums for machine-readable files? If no, why? What recommendations would provide additional clarity or consistency to improve consumer/patient utility of hospital pricing data?

Should clarifying information from CMS's FAQ document be part of the regulatory recommendations? If yes, which ones?

How should the recommendations address price estimates vs. binding prices? How should compliance be monitored at the state-level?

Should the machine-readable file be submitted to VHI along with hospitals' annual filings?

What enforcement options should there be at the state-level?

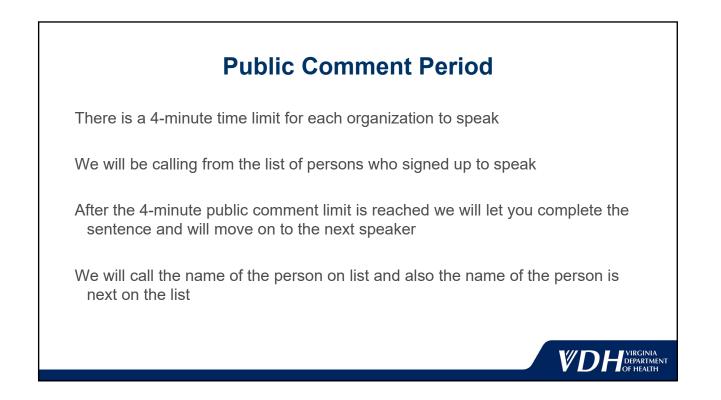
What recommendations, if any, could address outpatient surgical hospitals' knowledge of the new requirements?

What recommendations can be accomplished via regulation and what recommendations require a non-regulatory method?



PUBLIC COMMENT









VIRGINIA ACTS OF ASSEMBLY -- 2022 SESSION

CHAPTER 297

An Act to amend and reenact § 32.1-137.05 of the Code of Virginia, relating to hospitals; price transparency.

[H 481]

Approved April 11, 2022

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-137.05 of the Code of Virginia is amended and reenacted as follows:

§ 32.1-137.05. Information regarding standard charges; advance estimate of patient payment amount for elective procedure, test, or service.

A. Every hospital shall make available to the public on its website a machine-readable file containing a list of all standard charges for all items and services provided by the hospital in accordance with 45 C.F.R. § 180.50, as amended. As used in this subsection, "hospital," "items and services," "machine-readable," and "standard charge" have the same meaning as set forth in 45 C.F.R. § 180.20.

B. Every hospital shall, upon request of a patient scheduled to receive an elective procedure, test, or service to be performed by the hospital, or upon request of such patient's legally authorized representative, made no less than three days in advance of the date on which such elective procedure, test, or service is scheduled to be performed, furnish the patient with an estimate of the payment amount for which the participant will be responsible for such elective procedure, test, or service. Every hospital shall provide written information about the patient's ability to request an estimate of the payment amount pursuant to this section. Such written information shall be posted conspicuously in public areas of the hospital, including admissions or registration areas, and included on any website maintained by the hospital.

2. That the provisions of the first enactment of this act shall become effective on July 1, 2023.

3. That the Secretary of Health and Human Resources shall develop recommendations for implementation of this act, including any regulatory changes that may be necessary for implementation of this act, and shall report his recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2022.

This content is from the eCFR and is authoritative but unofficial.

Title 45 - Public Welfare Subtitle A - Department of Health and Human Services Subchapter E - Price Transparency

Part 180 Hospital Price Transparency

Subpart A General Provisions

§180.10 Basis and scope.

- §180.20 Definitions.
- §180.30 Applicability.
- Subpart B Public Disclosure Requirements
 - §180.40 General requirements.
 - §180.50 Requirements for making public hospital standard charges for all items and services.
 - §180.60 Requirements for displaying shoppable services in a consumer-friendly manner.
- Subpart C Monitoring and Penalties for Noncompliance
 - **§180.70** Monitoring and enforcement.
 - §180.80 Corrective action plans.
 - §180.90 Civil monetary penalties.
- Subpart D Appeals of Civil Monetary Penalties
 - §180.100 Appeal of penalty.
 - § 180.110 Failure to request a hearing.

PART 180 - HOSPITAL PRICE TRANSPARENCY

Authority: 42 U.S.C. 300gg-18, 42 U.S.C. 1302.

Source: 84 FR 65602, Nov. 27, 2019, unless otherwise noted.

Subpart A - General Provisions

§ 180.10 Basis and scope.

This part implements section 2718(e) of the Public Health Service (PHS) Act, which requires each hospital operating within the United States, for each year, to establish, update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. This part also implements section 2718(e). This part also implements section 2718(b)(3) of the PHS Act, to the extent that section authorizes CMS to promulgate regulations for enforcing section 2718(e). This part also implements section 1102(a) of the Social Security Act, which authorizes the Secretary to make and publish rules and regulations, not inconsistent with that Act, as may be necessary to the efficient administration of the functions for which the Secretary is charged under that Act.

§ 180.20 Definitions.

The following definitions apply to this part, unless specified otherwise:

- Ancillary service means an item or service a hospital customarily provides as part of or in conjunction with a shoppable primary service.
- *Chargemaster (Charge Description Master or CDM)* means the list of all individual items and services maintained by a hospital for which the hospital has established a charge.
- *De-identified maximum negotiated charge* means the highest charge that a hospital has negotiated with all third party payers for an item or service.
- *De-identified minimum negotiated charge* means the lowest charge that a hospital has negotiated with all third party payers for an item or service.
- *Discounted cash price* means the charge that applies to an individual who pays cash (or cash equivalent) for a hospital item or service.
- *Gross charge* means the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts.
- Hospital means an institution in any State in which State or applicable local law provides for the licensing of hospitals, that is licensed as a hospital pursuant to such law or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing.
 For purposes of this definition, a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.
- *Items and services* means all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. Examples include, but are not limited to, the following:
 - (1) Supplies and procedures.
 - (2) Room and board.
 - (3) Use of the facility and other items (generally described as facility fees).
 - (4) Services of employed physicians and non-physician practitioners (generally reflected as professional charges).
 - (5) Any other items or services for which a hospital has established a standard charge.
- Machine-readable format means a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include, but are not limited to, .XML, .JSON and .CSV formats.
- *Payer-specific negotiated charge* means the charge that a hospital has negotiated with a third party payer for an item or service.
- Service package means an aggregation of individual items and services into a single service with a single charge.

Shoppable service means a service that can be scheduled by a healthcare consumer in advance.

Standard charge means the regular rate established by the hospital for an item or service provided to a specific group of paying patients. This includes all of the following as defined under this section:

- (1) Gross charge.
- (2) Payer-specific negotiated charge.
- (3) De-identified minimum negotiated charge.
- (4) De-identified maximum negotiated charge.
- (5) Discounted cash price.
- State forensic hospital means a public psychiatric hospital that provides treatment for individuals who are in the custody of penal authorities.
- *Third party payer* means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021]

§ 180.30 Applicability.

- (a) *General applicability.* Except as provided in paragraph (b) of this section, the requirements of this part apply to hospitals as defined at § 180.20.
- (b) *Exception*. Federal and State hospitals are deemed by CMS to be in compliance with the requirements of this part including but not limited to:
 - (1) Federally owned hospital facilities, including facilities operated by the U.S. Department of Veterans Affairs and Military Treatment Facilities operated by the U.S. Department of Defense.
 - (2) Hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act.
 - (3) State forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities.
- (c) **Online availability.** Unless otherwise stated, hospital charge information must be made public electronically via the internet.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021]

Subpart B - Public Disclosure Requirements

§ 180.40 General requirements.

A hospital must make public the following:

- (a) A machine-readable file containing a list of all standard charges for all items and services as provided in § 180.50.
- (b) A consumer-friendly list of standard charges for a limited set of shoppable services as provided in § 180.60.

§ 180.50 Requirements for making public hospital standard charges for all items and services.

- (a) General rules.
 - (1) A hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in this section.
 - (2) Each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location.
- (b) *Required data elements*. A hospital must include all of the following corresponding data elements in its list of standard charges, as applicable:
 - (1) Description of each item or service provided by the hospital.
 - (2) Gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
 - (3) Payer-specific negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.
 - (4) De-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
 - (5) De-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
 - (6) Discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
 - (7) Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), the National Drug Code (NDC), or other common payer identifier.
- (c) *Format*. The information described in paragraph (b) of this section must be published in a single digital file that is in a machine-readable format.

(d) Location and accessibility.

- (1) A hospital must select a publicly available website for purposes of making public the standard charge information required under paragraph (b) of this section.
- (2) The standard charge information must be displayed in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated.
- (3) The hospital must ensure that the standard charge information is easily accessible, without barriers, including but not limited to ensuring the information is accessible:
 - (i) Free of charge;
 - (ii) Without having to establish a user account or password;
 - (iii) Without having to submit personal identifying information (PII); and

- (iv) To automated searches and direct file downloads through a link posted on a publicly available website.
- (4) The digital file and standard charge information contained in that file must be digitally searchable.
- (5) The file must use the following naming convention specified by CMS, specifically: <ein>_<hospitalname>_standardcharges.[json|xml|csv].
- (e) *Frequency of updates.* The hospital must update the standard charge information described in paragraph (b) of this section at least once annually. The hospital must clearly indicate the date that the standard charge data was most recently updated, either within the file itself or otherwise clearly associated with the file.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021]

§ 180.60 Requirements for displaying shoppable services in a consumer-friendly manner.

- (a) General rules.
 - (1) A hospital must make public the standard charges identified in paragraphs (b)(3) through (6) of this section, for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.
 - (i) In selecting a shoppable service for purposes of this section, a hospital must consider the rate at which it provides and bills for that shoppable service.
 - (ii) If a hospital does not provide 300 shoppable services, the hospital must make public the information specified in paragraph (b) of this section for as many shoppable services as it provides.
 - (2) A hospital is deemed by CMS to meet the requirements of this section if the hospital maintains an internet-based price estimator tool which meets the following requirements.
 - (i) Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.
 - (ii) Allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.
 - (iii) Is prominently displayed on the hospital's website and accessible to the public without charge and without having to register or establish a user account or password.
- (b) **Required data elements.** A hospital must include, as applicable, all of the following corresponding data elements when displaying its standard charges (identified in paragraphs (b)(3) through (6) of this section) for its list of shoppable services selected under paragraph (a)(1) of this section:
 - (1) A plain-language description of each shoppable service.
 - (2) An indicator when one or more of the CMS-specified shoppable services are not offered by the hospital.

- (3) The payer-specific negotiated charge that applies to each shoppable service (and to each ancillary service, as applicable). Each list of payer-specific negotiated charges must be clearly associated with the name of the third party payer and plan.
- (4) The discounted cash price that applies to each shoppable service (and corresponding ancillary services, as applicable). If the hospital does not offer a discounted cash price for one or more shoppable services (or corresponding ancillary services), the hospital must list its undiscounted gross charge for the shoppable service (and corresponding ancillary services, as applicable).
- (5) The de-identified minimum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).
- (6) The de-identified maximum negotiated charge that applies to each shoppable service (and to each corresponding ancillary service, as applicable).
- (7) The location at which the shoppable service is provided, including whether the standard charges identified in paragraphs (b)(3) through (6) of this section for the shoppable service apply at that location to the provision of that shoppable service in the inpatient setting, the outpatient department setting, or both.
- (8) Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, as applicable, the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the Diagnosis Related Group (DRG), or other common service billing code.
- (c) *Format.* A hospital has discretion to choose a format for making public the information described in paragraph (b) of this section online.
- (d) Location and accessibility of online data.
 - (1) A hospital must select an appropriate publicly available internet location for purposes of making public the information described in paragraph (b) of this section.
 - (2) The information must be displayed in a prominent manner that identifies the hospital location with which the information is associated.
 - (3) The shoppable services information must be easily accessible, without barriers, including but not limited to ensuring the information is:
 - (i) Free of charge.
 - (ii) Accessible without having to register or establish a user account or password.
 - (iii) Accessible without having to submit personal identifying information (PII).
 - (iv) Searchable by service description, billing code, and payer.
- (e) *Frequency*. The hospital must update the standard charge information described in paragraph (b) of this section at least once annually. The hospital must clearly indicate the date that the information was most recently updated.

Subpart C - Monitoring and Penalties for Noncompliance

§ 180.70 Monitoring and enforcement.

(a) *Monitoring*.

- (1) CMS evaluates whether a hospital has complied with the requirements under §§ 180.40, 180.50, and 180.60.
- (2) CMS may use methods to monitor and assess hospital compliance with the requirements under this part, including, but not limited to, the following, as appropriate:
 - (i) CMS' evaluation of complaints made by individuals or entities to CMS.
 - (ii) CMS review of individuals' or entities' analysis of noncompliance.
 - (iii) CMS audit of hospitals' websites.
- (b) Actions to address hospital noncompliance. If CMS concludes that the hospital is noncompliant with one or more of the requirements of § 180.40, § 180.50, or § 180.60, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:
 - (1) Provide a written warning notice to the hospital of the specific violation(s).
 - (2) Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements, according to § 180.80.
 - (3) Impose a civil monetary penalty on the hospital and publicize the penalty on a CMS website according to § 180.90 if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

§ 180.80 Corrective action plans.

- (a) *Material violations requiring a corrective action plan.* CMS determines if a hospital's noncompliance with the requirements of this part constitutes material violation(s) requiring a corrective action plan. A material violation may include, but is not limited to, the following:
 - (1) A hospital's failure to make public its standard charges required by § 180.40.
 - (2) A hospital's failure to make public its standard charges in the form and manner required under §§ 180.50 and 180.60.
- (b) *Notice of violation*. CMS may request that a hospital submit a corrective action plan, specified in a notice of violation issued by CMS to a hospital.
- (c) Compliance with corrective action plan requests and corrective actions.
 - (1) A hospital required to submit a corrective action plan must do so, in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital and must comply with the requirements of the corrective action plan.
 - (2) A hospital's corrective action plan must specify elements including, but not limited to:
 - (i) The corrective actions or processes the hospital will take to address the deficiency or deficiencies identified by CMS.
 - (ii) The timeframe by which the hospital will complete the corrective action.
 - (3) A corrective action plan is subject to CMS review and approval.
 - (4) After CMS' review and approval of a hospital's corrective action plan, CMS may monitor and evaluate the hospital's compliance with the corrective actions.
- (d) Noncompliance with corrective action plan requests and requirements.

45 CFR 180.80(d) (enhanced display)

- (1) A hospital's failure to respond to CMS' request to submit a corrective action plan includes failure to submit a corrective action plan in the form, manner, or by the deadline, specified in a notice of violation issued by CMS to the hospital.
- (2) A hospital's failure to comply with the requirements of a corrective action plan includes failure to correct violation(s) within the specified timeframes.

§ 180.90 Civil monetary penalties.

- (a) Basis for imposing civil monetary penalties. CMS may impose a civil monetary penalty on a hospital identified as noncompliant according to § 180.70, and that fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan as described in § 180.80(d).
- (b) Notice of imposition of a civil monetary penalty.
 - (1) If CMS imposes a penalty in accordance with this part, CMS provides a written notice of imposition of a civil monetary penalty to the hospital via certified mail or another form of traceable carrier.
 - (2) This notice to the hospital may include, but is not limited to, the following:
 - (i) The basis for the hospital's noncompliance, including, but not limited to, the following:
 - (A) CMS' determination as to which requirement(s) the hospital has violated.
 - (B) The hospital's failure to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan, as described in § 180.80(d).
 - (ii) CMS' determination as to the effective date for the violation(s). This date is the latest date of the following:
 - (A) The first day the hospital is required to meet the requirements of this part.
 - (B) If a hospital previously met the requirements of this part but did not update the information annually as required, the date 12 months after the date of the last annual update specified in information posted by the hospital.
 - (C) A date determined by CMS, such as one resulting from monitoring activities specified in § 180.70, or development of a corrective action plan as specified in § 180.80.
 - (iii) The amount of the penalty as of the date of the notice.
 - (iv) A statement that a civil monetary penalty may continue to be imposed for continuing violation(s).
 - (v) Payment instructions.
 - (vi) Intent to publicize the hospital's noncompliance and CMS' determination to impose a civil monetary penalty on the hospital for noncompliance with the requirements of this part by posting the notice of imposition of a civil monetary penalty on a CMS website.
 - (vii) A statement of the hospital's right to a hearing according to subpart D of this part.
 - (viii) A statement that the hospital's failure to request a hearing within 30 calendar days of the issuance of the notice permits the imposition of the penalty, and any subsequent penalties pursuant to continuing violations, without right of appeal in accordance with § 180.110.

- (3) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty, to conform to the adjudicated finding.
- (c) Amount of the civil monetary penalty.
 - (1) CMS may impose a civil monetary penalty upon a hospital for a violation of each requirement of this part.
 - (2) CMS determines the daily dollar amount for a civil monetary penalty for which a hospital may be subject as follows:
 - (i) For each day during Calendar Year 2021 that a hospital is determined by CMS to be out of compliance, the maximum daily dollar amount for a civil monetary penalty to which the hospital may be subject is \$300. Even if the hospital is in violation of multiple discrete requirements of this part, the maximum total sum that a single hospital may be assessed per day is \$300.
 - (ii) Beginning January 1, 2022, for each day a hospital is determined by CMS to be out of compliance:
 - (A) For a hospital with a number of beds equal to or less than 30, the maximum daily dollar civil monetary penalty amount to which it may be subject is \$300, even if the hospital is in violation of multiple discrete requirements of this part.
 - (B) For a hospital with at least 31 and up to and including 550 beds, the maximum daily dollar civil monetary penalty amount to which it may be subject is the number of beds times \$10, even if the hospital is in violation of multiple discrete requirements of this part.
 - (C) For a hospital with a number of beds greater than 550, the maximum daily dollar civil monetary penalty amount to which it may be subject is \$5,500, even if the hospital is in violation of multiple discrete requirements of this part.
 - (D)
 - (1) CMS will use the most recently available, finalized Medicare hospital cost report to determine the number of beds for a Medicare-enrolled hospital, for purposes of determining the maximum daily dollar civil monetary penalty amount under paragraph (c)(2) of this section.
 - (2) If the number of beds for the hospital cannot be determined according to paragraph (c)(2)(ii)(D)(1) of this section, CMS will request that the hospital provide documentation of its number of beds, in a form and manner and by the deadline prescribed by CMS in a written notice provided to the hospital. Should the hospital fail to provide CMS with this documentation in the prescribed form and manner, and by the specified deadline, CMS will impose on the hospital the maximum daily dollar civil monetary penalty amount according to paragraph (c)(2)(ii)(C) of this section.
 - (3) The amount of the civil monetary penalty will be adjusted annually using the multiplier determined by OMB for annually adjusting civil monetary penalty amounts under part 102 of this title.

(d) Timing of payment of civil monetary penalty.

(1) A hospital must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

- (2) In the event a hospital requests a hearing, pursuant to subpart D of this part, the hospital must pay the amount in full within 60 calendar days after the date of a final and binding decision, according to subpart D of this part, to uphold, in whole or in part, the civil monetary penalty.
- (3) If the 60th calendar day described in paragraphs (d)(1) and (2) of this section is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.
- (e) Posting of notice.
 - (1) CMS will post the notice of imposition of a civil monetary penalty described in paragraphs (b) and (f) of this section on a CMS website.
 - (2) In the event that a hospital elects to request a hearing, pursuant to subpart D of this part:
 - (i) CMS will indicate in its posting, under paragraph (e)(1) of this section, that the civil monetary penalty is under review.
 - (ii) If the civil monetary penalty is upheld, in whole, by a final and binding decision according to subpart D of this part, CMS will maintain the posting of the notice of imposition of a civil monetary penalty on a CMS website.
 - (iii) If the civil monetary penalty is upheld, in part, by a final and binding decision according to subpart D of this part, CMS will issue a modified notice of imposition of a civil monetary penalty according to paragraph (b)(3) of this section, to conform to the adjudicated finding. CMS will make this modified notice public on a CMS website.
 - (iv) If the civil monetary penalty is overturned in full by a final and binding decision according to subpart D of this part, CMS will remove the notice of imposition of a civil monetary penalty from a CMS website.
- (f) **Continuing violations**. CMS may issue subsequent notice(s) of imposition of a civil monetary penalty, according to paragraph (b) of this section, that result from the same instance(s) of noncompliance.

[84 FR 65602, Nov. 27, 2019, as amended at 86 FR 63998, Nov. 16, 2021]

Subpart D - Appeals of Civil Monetary Penalties

§ 180.100 Appeal of penalty.

- (a) A hospital upon which CMS has imposed a penalty under this part may appeal that penalty in accordance with subpart D of part 150 of this title, except as specified in paragraph (b) of this section.
- (b) For purposes of applying subpart D of part 150 of this title to appeals of civil monetary penalties under this part:
 - (1) Civil money penalty means a civil monetary penalty according to § 180.90.
 - (2) Respondent means a hospital that received a notice of imposition of a civil monetary penalty according to § 180.90(b).
 - (3) References to a notice of assessment or proposed assessment, or notice of proposed determination of civil monetary penalties, are considered to be references to the notice of imposition of a civil monetary penalty specified in § 180.90(b).

- (4) Under § 150.417(b) of this title, in deciding whether the amount of a civil money penalty is reasonable, the ALJ may only consider evidence of record relating to the following:
 - (i) The hospital's posting(s) of its standard charges, if available.
 - (ii) Material the hospital timely previously submitted to CMS (including with respect to corrective actions and corrective action plans).
 - (iii) Material CMS used to monitor and assess the hospital's compliance according to \S 180.70(a)(2).
- (5) The ALJ's consideration of evidence of acts other than those at issue in the instant case under § 150.445(g) of this title does not apply.

§ 180.110 Failure to request a hearing.

- (a) If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a civil monetary penalty described in § 180.90(b), CMS may impose the civil monetary penalty indicated in such notice and may impose additional penalties pursuant to continuing violations according to § 180.90(f) without right of appeal in accordance with this part.
 - (1) If the 30th calendar day described in this paragraph (a) is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.
 - (2) [Reserved]
- (b) The hospital has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this title, unless the hospital can show good cause, as determined at § 150.405(b) of this title, for failing to timely exercise its right to a hearing.

This document is designed as a resource for Hospital Price Transparency frequently asked questions (FAQs).

All FAQs presented in this document are current as of May 06, 2022.

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General Provisions

Where can I find the regulations that govern hospital price transparency and the final rules that implemented those regulations?

The regulations are found at 45 C.F.R. Part 180. CMS finalized hospital price transparency requirements under section 2718(e) of the Public Health Service Act, as well as a regulatory scheme under section 2718(b)(3) that enables CMS to enforce those requirements, in the Calendar Year 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates, Price Transparency Requirements for Hospitals to Make Standard Charges Public Final Rule (CMS-1717-F2) (Hospital Price Transparency Final Rule). The Hospital Price Transparency Final Rule was published in the Federal Register on November 27, 2019 (84 FR 65524) and is available at <a href="https://www.federalregister.gov/documents/2019/11/27/2019-24931/medicare-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and-medicaid-programs-cy-2020-hospital-outpatient-pps-policy-changes-and-payment-rates-and-

CMS amended some of the hospital price transparency requirements in the Calendar Year 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model Final Rule with comment period (CMS-1753-FC) (2022 Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges), which was published in the Federal Register on November 16, 2021 (86 FR 63458, 63941) and is available at <u>https://www.federalregister.gov/documents/2021/11/16/2021-24011/medicare-programhospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment#h-628 (New)</u>

What are hospitals required to do under the hospital price transparency regulations? When do hospitals have to comply with these requirements?

As of January 1, 2021, each hospital operating in the United States was required to provide clear, accessible pricing information about the items and services they provide in two ways:

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

What amendments did CMS finalize for the hospital price transparency regulations in the CY 2022 OPPS/ASC final rule?

CMS finalized the following amendments to the hospital price transparency regulation, which are effective January 1, 2022.

 Increase in Civil Monetary Penalties (CMP): CMS set a minimum CMP of \$300/day that applies to smaller hospitals with a bed count of 30 or fewer, and a penalty of \$10/bed/day for

hospitals with a bed count greater than 30, not to exceed a maximum daily dollar amount of \$5,500. Under this approach, for a full calendar year of noncompliance, the minimum total penalty amount would be \$109,500 per hospital, and the maximum total penalty amount would be \$2,007,500 per hospital. This approach to scaling the CMP amount retains the current penalty amount for small hospitals, increases the penalty amount for larger hospitals, and affirms the Administration's commitment to enforcement and public access to pricing information.

- Deeming State Forensic Hospitals as Having Met Requirements: CMS amended the regulations to deem state forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities as being in compliance with the requirements.
- Prohibiting Additional Specific Barriers to Access to the Machine-Readable File: CMS updated the regulation's prohibition of certain activities that present barriers to access to the machine-readable file, specifically requiring that the machine-readable file be accessible to automated searches and direct downloads.

Refer to <u>86 FR 63941</u>. (New)

What is the purpose of the Hospital Price Transparency regulation?

The Hospital Price Transparency Final Rule sets forth the requirements for complying with the law (PHS Act section 2718(e)) that requires hospitals to make public their standard charges. The public release of hospital standard charge information is important to ensuring transparency in health care prices for consumers, while working to address some of the barriers that limit price transparency. We note that while the rules we finalized are a required floor, they do not preclude hospitals from undertaking additional transparency efforts beyond making public their standard charges. (New)

How does Hospital Price Transparency support value-based care?

We believe hospital standard charge information will be useful to the public, including consumers who need to obtain items and services from a hospital, consumers who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making referrals, and other members of the public who may develop consumer-friendly price transparency tools or perform analyses and make policy to drive value-based care. Because the drive towards value depends on access to both quality and cost information, we believe that disclosure of hospital standard charges fully aligns with and supports our drive toward value care as one half of the value proposition Disclosure of hospital standard charge information will therefore complement quality information so that consumers can make high value decisions about their care. **(84 FR 65538-65539) (New)**

Will CMS ensure alignment between the Hospital Price Transparency final rule, the Transparency in Coverage (TIC) Final Rules, and the No Surprises Act?

As the federal government undertakes to implement these new laws and regulations over the next several years, we will continue to monitor and align the Hospital Price Transparency regulations, as necessary (86 FR 63942). (New)

Will hospitals be able to apply for a hardship waiver or exception to meeting the Hospital Price Transparency requirements?

No. The Hospital Price Transparency Final Rule contains no provisions that address waivers or hardship exemptions.

Definitions

How is hospital defined under the Hospital Price Transparency Final Rule? Does the rule apply to Critical Access Hospitals, other small or rural hospitals, state owned/operated institutions, and non-acute hospitals such as inpatient psychiatric hospitals and inpatient rehabilitation facilities (IRFs)?

Under 45 CFR § 180.20, hospital means an institution, in any State in which State or applicable local law provides for the licensing of hospitals, which is licensed as a hospital pursuant to such law or is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing. For purposes of this definition, a State includes each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. All hospital location(s) operating under the same hospital license (or approval), such as a hospital's outpatient department located at an off-campus location (from the main hospital location) operating under the hospital's license, are subject to the requirements in this rule. This definition includes all Medicare-enrolled institutions that are licensed as hospitals (or approved as meeting licensing requirements) as well as any non-Medicare enrolled institutions that are licensed as a hospital (or approved as meeting licensing requirements). Given this definition, this rule applies to every institution that meets the definition of 'hospital' established by the Hospital Price Transparency Final Rule including institutions such as critical access hospitals, specialty hospitals, and state owned or operated facilities other than those deemed compliant.

Federally owned or operated hospitals (for example, hospitals operated by an Indian Health Program, the U.S. Department of Veterans Affairs, or the U.S. Department of Defense) that do not treat the general public, except for emergency services, and whose rates are not subject to negotiation, are deemed to be in compliance with the requirements for making public standard charges because their charges for hospital provided services are publicized to their patients in advance (for example, through the *Federal Register*). In addition, beginning January 1, 2022,

state forensic hospitals that provide treatment exclusively to individuals who are in the custody of penal authorities are deemed to be in compliance with 45 CFR Part 180 because such hospitals are wholly funded through state general funds and treat patients who are not responsible for the cost of their care in such hospitals (86 FR 63941). (New)

Does the Hospital Price Transparency Final Rule apply to hospitals in the State of Maryland that are subject to global payments set by the Maryland Health Services Cost Review Commission?

Yes. If your institution meets the definition of 'hospital' as defined by the Hospital Price Transparency Final Rule, then your institution must comply. However, some required data elements for display may not be applicable to your hospital. For example, under the Hospital Price Transparency Rule, your hospital is obligated to make public the payer-specific negotiated charges as applicable for each item and service your hospital provides. The term "payerspecific negotiated charge" is defined as the charge that the hospital has negotiated with a third-party payer for an item or service. The term "third party payer" means an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service. If your hospital has not negotiated a charge with a third-party payer for an item or service your hospital provides, then your hospital would not have a "payer-specific negotiated charge" to display for that item or service.

What standard charges must hospitals make public?

A standard charge means the regular rate established by the hospital for an item or service provided to a specific group of paying patients. For purposes of complying with the Hospital Price Transparency Final Rule, this includes five types of standard charges:

- 1. The gross charge (the charge for an individual item or service that is reflected on a hospital's chargemaster, absent any discounts).
- 2. The discounted cash price (the charge that applies to an individual who pays cash, or cash equivalent, for a hospital item or service).
- 3. The payer-specific negotiated charge (the charge that a hospital has negotiated with a third-party payer for an item or service).
- 4. The de-identified minimum negotiated charge (the lowest charge that a hospital has negotiated with all third-party payers for an item or service).
- 5. The de-identified maximum negotiated charge (the highest charge that a hospital has negotiated with all third-party payers for an item or service).

Please refer to 45 CFR §180.20.

What hospital "items and services" are included by the Hospital Price Transparency Final Rule? What is a "service package"?

For purposes of complying with the hospital price transparency requirements, items and services are all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which a hospital has established a standard charge. Examples include supplies and procedures, room and board, and use of the facility and other items (generally described as facility fees), services of employed physicians and non-physician practitioners (generally reflected as professional charges), and any other item or service for which a hospital has established a standard charge. Please refer to 45 CFR <u>§180.20</u>.

A service package is an aggregation of individual items and services into a single service for which the hospital has a single standard charge. "Service packages" may have charges established on, for example, the basis of a common procedure or patient characteristic, or may have an established per diem rate that includes all individual items and services furnished during an inpatient stay. Please refer to 45 CFR <u>§180.20</u>.

The definition of "items and services" includes services of employed physicians and non-physician practitioners. How does CMS define "employment"?

Given the variation and complexity in employment models and possible contracting relationships that may exist between hospitals and physicians, we believe it is important to preserve flexibility for hospitals to identify employed physicians or non-physician practitioners under their organizational structure, and, for this reason, we declined to codify a definition of "employment" in the Hospital Price Transparency Final Rule. Refer to 84 FR <u>65535</u>. One resource that hospitals could consider reviewing for purposes of determining whether or not a physician or non-physician practitioner is employed by the hospital is: <u>https://www.irs.gov/newsroom/understanding-employee-vs-contractor-designation</u>.

Do these requirements apply to non-employed physicians and other practitioners who provide and bill for the same services at the hospital?

No. Services provided by physicians and non-physician practitioners who are not employed by the hospital are practitioners that are practicing independently, establish their own charges for services, and receive the payment for their services. Such services, therefore, are not services "provided by the hospital."

Do these requirements apply to the services of employed practitioners whose charges are not found in the hospital chargemaster?

Yes. The Hospital Price Transparency Final Rule does not limit the requirements to only hospital standard charges that are found within the hospital chargemaster, including standard charges

for items and services provided by practitioners employed by the hospital. The requirements apply to such charges that may be located elsewhere within the hospital accounting and billing system, or, in the case of payer-specific negotiated charges, in contracts and rate sheets that are specific to a particular third-party payer. Please refer to 84 FR <u>65535</u>.

Do the standard charges for services performed by physicians and/or nonphysician practitioners outside the scope of their employment by the hospital need to be included in the hospital's display of standard charges?

No, the Hospital Price Transparency Final Rule requires hospitals to post their standard charges for the items and services they provide. Items and services include, but are not limited to, the services of employed physicians and non-physician practitioners (generally reflected as professional charges). They do not include the services that physicians and non-physician practitioners perform outside the scope of their employment by the hospital.

Public Disclosure Requirements

Can hospitals choose between displaying standard charges in a machinereadable format and displaying standard charges for shoppable services in a consumer-friendly format?

No. Hospitals must make public both of the following: (1) A machine-readable file containing a list of all standard charges for all items and services as provided in 45 CFR §180.50 and (2) a consumer- friendly list of standard charges for a limited set of shoppable services as provided in 45 CFR §180.60. Please note that CMS will deem a hospital as having met the second of these two requirements if the hospital maintains an internet-based price estimator tool that meets the requirements provided in 45 CFR §180.60(a)(2).

Our hospital does not provide a discounted cash price for items and services. How should we reflect this in the display of standard charge information?

Some hospitals may not have determined a discounted cash price for self-pay consumers for the items and services it provides. In this case, the hospital must post the gross charge as reflected in the hospital chargemaster. Please refer to 84 FR <u>65553</u>.

Some of the hospital items or services we offer do not have an associated HCPCS or CPT code. Are we required to list such services? If so, what should be indicated next to the item or service?

Yes. The Hospital Price Transparency Final Rule requires hospitals to disclose the standard charges for each item or service it provides, therefore, all hospital items and services for which the hospital has established a standard charge must be listed regardless of whether all the

required corresponding data elements are available. Corresponding common billing and accounting codes must be included, <u>as applicable</u>. Please refer to <u>Table 1</u> (84 FR <u>65558</u>) for an example of a display of gross charges which includes this scenario. When an item or service does not have a corresponding standard charge or diagnosis code associated with an item or service, we strongly recommend your hospital use an indicator, such as N/A, or other method to communicate to the public that there is no corresponding code. Please refer to <u>Table 1</u> (84 FR <u>65558</u>) for an example of a display of gross charges which includes this scenario.

Is there a limitation on the number of third-party payers for which we have to make negotiated charges public? For example, does this requirement apply to contracts with our top payers only?

No. Hospitals are required to list their standard charges, as applicable, including all payerspecific standard charges, for all items and services with respect to all third-party payers. Please refer to 84 FR <u>65567</u>.

What is a "base rate" for a service package?

The base rate is the payer-specific charge the hospital has negotiated for a service package. Base rates for service packages are typically not found in the hospital chargemaster but can be found in other parts of the hospital's billing and accounting systems, or in what are known as 'rate sheets' found in hospital in-network contracts with their third-party payers. The base rate is **not** the final payment or reimbursement rate for the service package received by the hospital for individual patients.

My hospital has established a gross charge for an individual item or service (as found in our chargemaster) but it has not established a payer-specific negotiated charge for that same item or service. In this case, does the hospital price transparency rule require our hospital to establish a payer-specific negotiated charge for that item or service?

The Hospital Price Transparency regulations require hospitals to make public a list of the standard charges the hospital has established for the items and services it provides and to make these data elements available in a single machine-readable file *as applicable*. We recognize that a hospital may have established one type of standard charge (for example a gross charge) for a particular item or service without having established other types of standard charges (for example, a payer-specific negotiated charge with a particular payer/plan) for the same item or service. When an item or service does not have a corresponding standard charge associated with an item or service, we strongly recommend your hospital use an indicator, such as N/A, or other method to communicate to the public that there is no corresponding standard charge.

How should my hospital display a payer-specific negotiated charge when no standardized dollar amount applies to all the members of a payer/plan, for example, when the contract with the payer/plan specifies that the reimbursement for members covered under the plan will be determined as a standardized algorithm?

It is possible that a hospital may have established a payer-specific negotiated charge that cannot be displayed as a standardized dollar amount. In these situations, the hospital may indicate the standardized algorithm as its payer-specific negotiated charge in the machine-readable file. Note that estimates and averages do not meet the definition of a 'payer-specific negotiated charge,' and, therefore, cannot be displayed by themselves as payer-specific negotiated charges, however, the hospital may choose to include such information (for example, an average reimbursement amount for a procedure that is derived from historical claims data) in addition to the payer-specific negotiated charge for the procedure. Examples can be found in Appendix 1.(New)

My hospital has not established or negotiated a standard charge for an item or service. How should I display the lack of standard charge in the machine-readable file? Should I leave it blank?

The rule at 45 C.F.R. 180.60 requires that hospitals make public several data elements, including all five types of standard charges, <u>as applicable</u>, in the machine-readable file. We believe the "as applicable" reference is reasonable and necessary, given differences across hospitals that are subject to the regulations. We encourage hospitals to consider taking steps beyond the display requirements of the Hospital Price Transparency regulations to improve the public's understanding of the data the hospital has posted in its machine-readable file, and, in particular, to clarify why there may appear to be data missing from the machine-readable file. For example, using "N/A" to indicate that a data element is not applicable could clarify the displayed information for some formats, avoid consumer confusion and complaints, and could help avoid raising compliance concerns during a CMS comprehensive review. (New)

How should my hospital display charges for service packages that vary based on severity of illness?

Base rates for service packages are sometimes adjusted by a multiplier to address severity of illness (SOI) or adjustments for other factors. For example, a joint replacement may have a payer-specific negotiated base rate at \$2,000 with multipliers for various SOIs: intermediate complexity at \$3,000 (\$2,000 x 1.5); high complexity at \$4,000 (\$2,000 x 2); or very high complexity at \$5,000 (\$2,000 x 2.5). The Hospital Price Transparency Final Rule does not limit hospitals from displaying additional clarifying information for patients, for example, providing a base rate for each severity level within a DRG or other clarifying information to patients related to how a service package base rate may change depending on severity of illness (SOI). Please

refer to 84 FR <u>65547</u> and <u>65551</u>.

In the machine-readable file, can my hospital post an average charge based on historical claims as the payer-specific negotiated charge for an item or service?

No. As we explained in the CY 2020 Hospital Price Transparency final rule, average charges based on prior years are not acceptable because an 'average charge' is not one of the types of standard charges finalized in the rule (84 FR 65571) (New)

If a hospital has not provided a service in the previous 12 months, is it required to post the standard charge for that service?

Yes. CMS finalized the proposal to define hospital "items and services" to mean all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission or an outpatient department visit for which the hospital has established a standard charge. In other words, hospitals must post the standard charge (as applicable) for each item/service for which the hospital has established a standard charge.

Should Medicaid plan rates be considered part of the de-identified minimum charge and payer-specific charge if a state is a fully managed care Medicaid state?

Hospitals are required to make public the payer-specific negotiated charges that they have negotiated with third party payers, including charges negotiated by third party payer managed care plans such as Medicare Advantage plans, Medicaid MCOs, and other Medicaid managed care plans. Therefore, a state's Medicaid managed care contracts may fall within this description, if such managed care contracts include rates negotiated with the hospital. Please refer to 84 FR <u>65551</u> where we finalized our definition of "third party payer" as an entity that, by statute, contract, or agreement, is legally responsible for payment of a claim for a healthcare item or service.

In cases where the hospital has negotiated a payer-specific negotiated charge based on the Medicare or Medicaid FFS rate, can the hospital simply indicate that the price of the hospital item/service is set to the Medicare or Medicaid rate instead of reporting a specific dollar value?

No. The payer-specific negotiated charge is defined for purposes of the Hospital Price Transparency Final Rule as the charge that a hospital has negotiated with a third-party payer for an item or service, including a service package, and the hospital should list that standard charge. For example, if your hospital has negotiated a payer-specific negotiated charge for a service package that equals 200% of the Medicare FFS reimbursement rate for MS-DRG 123, then your hospital should determine the Medicare reimbursement rate for DRG 123, multiply it

by 2, and indicate the resulting amount as its payer-specific negotiated charge for that service package.

We believe displaying payer-specific negotiated rates publicly would violate the confidentiality clause of the hospital's contract with our third-party payers. Has CMS addressed this issue?

Even if a contract between a hospital and a payer contained a provision prohibiting the public disclosure of its terms, it is our understanding that such contracts typically include exceptions where a particular disclosure is required by Federal law. Refer to 84 FR <u>65544</u>.

Can you give examples of how to determine the de-identified minimum and maximum negotiated charges for an item or service?

Once your hospital has listed each item and service it provides, along with the corresponding payer-specific negotiated charges the hospital has established for each one, you must identify the minimum and maximum amount. The following illustrations provide simple examples of how a hospital can determine the de-identified minimum and maximum negotiated charges for each item or service across all their payers. Each example assumes one plan per payer.

Example 1: A hospital negotiates the following payer-specific charges with three payers for an individual item or service, for example, an imaging test identified by billing code '12345'.

| Item/service description | Billing Code | Payer 1negotiate d charge | Payer 2 negotiated charge | Payer 3 negotiated charge | De-identified minimum negotiated charge | De-identified maximum negotiated Charge |
|-----------------------------|-----------------|---------------------------------|---------------------------------|---------------------------------|--|--|
| Imaging test | 12345 | \$125 | \$300 | \$550 | \$125 | \$550 |

Example 2: A hospital negotiates the following payer-specific charges with three payers for two different service packages. The hospital has negotiated a payer-specific charge with Payer 1 for a procedure based on an APR-DRG. With Payers 2 and 3, the hospital has negotiated a payer-specific charge based on the number of days the patient spends in the hospital, that is, a *per diem* charge.

| Item/service description | Billing Code | Payer 1 negotiated charge | Payer 2 negotiated charge | Payer 3 negotiated charge | De-identified minimum negotiated charge | De-identified maximum negotiated charge |
|-----------------------------|-----------------|---------------------------------|---------------------------------|---------------------------------|--|--|
| Procedure | 999 | \$1250 | N/A | N/A | \$1250 | \$1250 |
| Per diem | XXX | N/A | \$500 | \$450 | \$450 | \$500 |

What are the similarities and differences of the requirements for the two ways that each hospital must make public a list of the hospital's standard charges for items and services it provides?¹

| | Comprehensive Machine-readable File | Consumer-friendly display of Shoppable Services ² |
|--|--|--|
| General requirement | Single comprehensive machine- readable file containing a list of standard charges, as applicable, for all items and services. | Some standard charge information, as applicable, for at least 300 shoppable services including 70 CMS-specified services presented in a consumer- friendly manner. ³ The primary shoppable service must be grouped with any ancillary services the hospital customarily provides as part of or in conjunction with the primary service. |
| Standard Charges | Gross charge Discounted cash price Payer-specific negotiated charges De-identified minimum negotiated charge De-identified maximum negotiated charge | Discounted cash price (or gross charge, where the hospital has not established a discounted cash price) Payer-specific negotiated charges De-identified minimum negotiated charge De-identified maximum negotiated charge |
| Description of item or service and billing codes | A description of each item or service along with, as applicable, any code used by the hospital for purposes of accounting or billing for the item or service. | A <u>plain-language</u> description of each |

| | Comprehensive Machine-readable File | Consumer-friendly display of Shoppable Services ² |
|---------------------------------------|--|--|
| Service not offered by hospital | No requirement. CMS recommends using an indicator when one or more of the services are not offered by the hospital (for example, N/A). | Use an indicator when one or more of the CMS-specified shoppable services are not offered by the hospital (for example, N/A). |
| Format | A single digital file that is machine- readable | No requirement |
| Naming Convention | Must adhere to the CMS naming convention: <ein>_<hospital- name>_standard charges. [json xml csv]</hospital- </ein> | No requirement |
| Location of information | Displayed prominently on a publicly- available website and in a prominent manner that clearly identifies the hospital location with which the information is associated. | Displayed prominently on a publicly- available website and in a prominent manner that clearly identifies the hospital location with which the information is associated. |
| Access to information | Must be free of charge and may not require a log-in, password, and/or the submission of any personal identifying information (PII) in order to access. In addition, the information must be accessible to automated searches and direct downloads. | Must be free of charge and may not require a log-in or password, other barriers, and/or the submission of any personal identifying information (PII). |
| Search Capability | Digitally searchable | Searchable by service description, billing code, and payer |
| Updates | Annually – with date of last update clearly indicated | Annually – with date of last update clearly indicated |

¹A complete overview of requirements can be found at <u>Subpart B-Public Disclosure Requirements</u>.

² A hospital is deemed by CMS to meet the requirements of this section if the hospital maintains an Internetbased price estimator tool which meets the following requirements:

- Provides estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.
- Allows 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.
- Is prominently displayed on the hospital's website and accessible to the public without charge and without having to register or establish a user account or password.

³ If a hospital does not provide 300 shoppable services, the hospital must make public its standard charges for as many shoppable services as it provides.

Machine-Readable File

What is a 'machine-readable' file format?

A machine-readable file format is 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 this format include, but are not limited to, .XML, .JSON, and .CSV formats. Refer to 45 CFR § 180.20.

What updates did CMS make to the accessibility requirements of the machinereadable file in the CY 2022 OPPS/ASC final rule?

As of January 1, 2022, CMS requires that the machine-readable file must be accessible to automated searches and direct downloads through a link posted on a publicly available website (45 CFR §180.50 (d)(3)(iv)). Specific examples of barriers to automated searches and direct downloads that CMS identified include, but are not limited to, lack of a link for downloading a single machine-readable file, using "blocking codes" or CAPTCHA, and requiring the user to agreement to terms and conditions or submit other information prior to access. Refer to 86 FR 63952. (New)

How can my hospital ensure that its machine-readable file is "prominently displayed"?

The Hospital Price Transparency final rule states "displayed prominently" means "the value and purpose of the web page and its content is clearly communicated, there is no reliance on breadcrumbs to help with navigation, and that the link to the standard charge file is visually distinguished on the web page." Additionally, "easily accessible" means "the 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" (84 FR 65561). We recommend that hospitals do the following to ensure the machine-readable file is prominently displayed: (New)

- Review and use, as applicable, the HHS Web Standards and Usability Guidelines (available at: <u>https://webstandards.hhs.gov/</u>), which are research-based and are intended to provide best practices over a broad range of web design and digital communications issues.
- Post a link to the machine-readable file on a website where the value and purpose of the web page and its content is clearly communicated, for example, a dedicated price transparency webpage or a webpage devoted to patient billing or financing healthcare services.
- While "breadcrumbs" (e.g., secondary navigation aids) can be useful for navigating a website, they should not be relied upon in order for consumers to find the link to the machine-readable file. Instead, facilitate user navigation by including searchable terms on the webpage such as "price transparency," "standard charges," or "machine-readable file."

Ensure that the link to the machine-readable file is visually distinguished on the web page, and that its purpose is to open the single machine-readable file for a particular hospital location. **Refer to 45 CFR** § 180.50(d)(2)

What naming convention should hospitals use when making public the machinereadable file? How can I find the EIN and associated hospital legal name?

Hospitals must use the following CMS naming convention as specified in the regulations at 45 CFR <u>180.50(d)(5)</u> for the machine-readable file: <ein>_<hospital-

name>_standardcharges.[json|xml|csv] in which the EIN is the Employer Identification Number of the hospital, followed by the hospital name, followed by "standardcharges" followed by the hospital's chosen file format (84 FR 65562). It is important that you follow the rule's naming convention. Specifically, hospitals must use the following schema:

- Write out "standardcharges" as a single word, without capitalization.
- Finish by using the. json, .xml, or .csv as applicable to the file format you have chosen.
- Separate the EIN, hospital name, and "standardcharges" by using an underscore: 12345678_example-hospital-name_standardcharges.csv

In addition, hospitals may do the following:

- Exclude dashes from the EIN (use "12345678", not "12-345678")
- Use the legal name of the hospital without capitalization and include dashes between words (use "example-hospital-name", not "Example Hospital Name")

Hospital EINs and legal names can be found using lookups hosted by the IRS (<u>https://apps.irs.gov/app/eos/</u>) and SEC (<u>https://www.sec.gov/edgar/search/</u>)

We have multiple facilities and locations, each with its own list of standard charges, functioning under the same EIN and legal name. CMS regulations require 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." In this case, what naming convention should we use for these machine-readable files?

Hospitals must use the CMS naming convention as specified in the regulations at 45 CFR <u>180.50(d)(5)</u> but may also add "-<NPI>" following the EIN (where "#" is the National Provider Identifier that corresponds to the hospital location). NPIs and hospital names can be found using this lookup: <u>https://npiregistry.cms.hhs.gov/</u>. For example, "Example Hospital Name" with EIN of 12345678 has two locations with NPIs of "1011121314" and "1516171819", each with its own set of standard charges. This hospital could name its two csv-formatted machine-readable files as "12345678-1011121314_example-hospital-name_standardcharges.csv" and "12345678-1516171819_example-hospital-name_standardcharges.csv", respectively.

In the machine-readable file, are hospitals required only to display the payerspecific negotiated charges for each item/service that is found in the hospital chargemaster, even when the hospital has negotiated rates with some payers based on 'service packages'?

The machine-readable file posted online by the hospital should include not only the items and services listed in the chargemaster but also list any service packages for which the hospital may have established a standard charge. For example, some payer-specific negotiated rates are for 'service packages' (for example, per diem or based on a procedure). Such 'service packages' are not typically found in the hospital chargemaster which is a list of itemized items and services, but a hospital is still required to display the payer-specific negotiated charge (and all other standard charges applicable) for which the hospital has established a standard charge regardless of whether it appears in the chargemaster. Please refer to 84 CFR <u>65534</u> for further discussion.

Consumer-friendly Display of Shoppable Services

What is a shoppable service? Are medications considered shoppable services?

A shoppable service means a service that can be scheduled by a healthcare consumer in advance. Procedures such as joint replacements and services such as physical therapy are examples of shoppable services. Hospital administration of a medication could be considered a shoppable service if it can be scheduled in advance. Examples of administration of a medication that could be considered a shoppable service are the administration of flu shots or medication infusions for chronic conditions. The definition of 'shoppable service' can be found at 45 CFR §180.20.

What if a hospital does not provide one or more of the 70 CMS-specified shoppable services or provides less than 300 shoppable services in total? How can requirements of this regulation be met?

If a hospital does not provide one or more of the 70 CMS-specified shoppable services, the hospital must select additional shoppable services such that the total number of shoppable services is at least 300. If a hospital does not provide 300 shoppable services, the hospital must list as many shoppable services as they provide. The hospital must clearly indicate any CMS-specified shoppable service that it does not provide. The hospital may use "N/A" for the corresponding charge or use another appropriate indicator to communicate to the public that the shoppable service is not provided by the hospital. Refer to 84 FR <u>65569</u> and <u>65574</u> for further discussion.

What is an 'ancillary item and service'?

Ancillary services, defined at 45 CFR §180.20, are any item or service a hospital customarily provides as part of, or in conjunction with, a shoppable primary service and may include laboratory, radiology, drugs, delivery room (including maternity labor room), operating room (including post-anesthesia and postoperative recovery rooms), therapy services (physical, speech, occupational), hospital fees, room and board charges, and charges for employed professional services. Ancillary services may also include other special items and services for which charges are customarily made in addition to a routine service charge. For example, an outpatient procedure may include many services of employed professionals, supplies, facility and/or ancillary facility fees, imaging services, lab services and pre- and post-op follow up. To the extent that a hospital customarily provides (and bills for) such ancillary services as a part of, or in conjunction with, the primary service, the hospital should group the ancillary service charges along with the other standard charges that are displayed for the shoppable service. For further discussion of ancillary services refer to 84 FR <u>65564</u>.

How should a hospital display charges for a shoppable service in a consumerfriendly manner when the hospital offers it as a service package or when the hospital already includes all ancillary services as part of the service package charge?

To the extent that a hospital includes in its public display a shoppable service that it commonly provides as a service package, the hospital must display the charge the hospital has established for the service package as a whole. In other words, if the hospital has established a standard charge for a service package, the hospital must display that standard charge as opposed to displaying a manufactured charge for each of the individual items and services that make up the service package. For example, when displaying the charge for a shoppable service identified by a DRG, the hospital would display the payer-specific negotiated charge (the "base rate") negotiated with a third-party payer for the DRG. To be consumer friendly, the hospital may elect to communicate the individual items and services included in the standard charge for the service package, but this is not required under the Hospital Price Transparency Final Rule.

However, should a hospital customarily provide any items or services beyond those already included in a service package, the rule does require hospitals to list any such <u>additional</u> ancillary services the hospital customarily provides with the shoppable service. In other words, the hospital must provide a description of the ancillary service along with its standard charge(s) and other required data elements, as applicable.

What does CMS consider to be a plain-language description for purposes of the consumer-friendly display?

The regulations at 45 CFR § 180.60(b)(1) require hospitals to include a plain-language description for each of the 70 CMS-specified and 230 hospital-selected shoppable services

in its consumer-friendly display. We invite hospitals to review the Federal plain language guidelines that can be found here: <u>https://plainlanguage.gov/guidelines/</u>. Refer to 84 FR <u>65573</u>.

Examples that we would consider plain-language descriptions:

- Direct Admission to the Hospital from Observation Status
- CT of the Head or Brain with Contrast
- MRI of Orbit, Face, or Neck with and without Contrast

Examples that we would *not* consider plain-language descriptions:

- OBSRV ASMT DIRECT ADMIT1
- CT HEAD/BRAIN W/CON 42
- MRI ORB/FACE/NK W/WO CON 43

Can a price estimator tool be used to meet the requirement to display shoppable services in a consumer-friendly format? If yes, what requirements must the price estimator tool meet?

Yes. In the Hospital Price Transparency Final Rule, we stated that we had been persuaded by commenters' suggestions that hospitals offering online price estimator tools that provide real- time individualized out-of-pocket cost estimates should receive consideration. For further discussion on the requirements of a price estimator tool, please see 45 CFR $\frac{§180.60(a)(2)}{2}$.

Although we recognize that some hospital price estimator tools may not display consumerfriendly standard charge information in the precise ways we are requiring under the rule, they do appear to accomplish the goal and intent of ensuring such information is available in a consumer-friendly manner by allowing individuals to directly determine their specific out-ofpocket costs in advance of committing to a hospital service. We emphasize, however, that hospitals must still publish their standard charges for the items and services they provide in a comprehensive machine-readable file (refer to 45 CFR §<u>180.50</u>). In other words, offering a price estimator tool can satisfy the requirement to post shoppable service information in a consumer-friendly format but does not satisfy the requirement to display hospital standard charges in a comprehensive machine-readable file.

Further, if a hospital chooses to exercise this option, the hospital Internet-based price estimator tool must meet the following criteria to be deemed in compliance:

 Provide estimates for as many of the 70 CMS-specified shoppable services that are provided by the hospital, and as many additional hospital-selected shoppable services as is necessary for a combined total of at least 300 shoppable services.

- Allow healthcare consumers to, at the time they use the tool, obtain an estimate of the amount they will be obligated to pay the hospital for the shoppable service.
- Is prominently displayed on the hospital's website and accessible to the public without charge and without having to register or establish a user account or password.

Refer to 84 FR <u>65577</u> for further discussion on this topic.

If a hospital chooses to use a price estimator tool as an alternative to meeting the requirements for making public the standard charges for shoppable services in a consumer-friendly manner, may hospitals collect patient insurance information or other PII in order to generate a real-time out-of-pocket estimate for the patient?

Yes. In the Hospital Price Transparency Final Rule, we specifically did not include a requirement that no PII be collected because we recognize that insurance information may be necessary to provide patients with real-time personalized OOP price estimates. In order to ensure there is flexibility for the data elements, format, location and accessibility of a price estimator tool that would be considered to meet the requirements of 45 CFR 180.60, we established minimum data and functionality requirements at 45 CFR §180.60(a)(2). Refer to 84 FR 65578 for further discussion on this topic and to 45 CFR §180.60(a)(2) for the requirements.

For the price estimator tool, would a display of an estimated range across all commercial payers for each of the 300 shoppable services meet the requirements?

No. As clarified in the CY 2022 OPPS/ASC final rule, if a hospital chooses to offer a price estimator tool in lieu of displaying standard charges in a consumer-friendly manner, the hospital must ensure (among the other requirements at 45 CFR 180.60(a)(2)) that the tool allows healthcare consumers to, at the time they use the tool, obtain an estimate of the amount that the hospital anticipates the individual would be obligated to pay. This means that the estimated amount is a personalized estimate of "the amount" the individual would be obligated to pay, and is therefore represented as a single out-of-pocket dollar amount that takes into account the individual's insurance status (see 86 FR 63954). We note, however, that Hospital Price Transparency final rule is not prescriptive regarding the method by which a hospital's price estimator tool estimates the individual's single out-of-pocket dollar amount, and nothing in the rule prevents a hospital from developing an accurate and reliable cost estimate using prior claims information or from providing additional information that may be useful to the end-user, such as the range of out-of-pocket costs for the population to which the individual belongs.

Does CMS have an example of disclaimer language that a hospital could use on its price estimator tool?

No. Each hospital is unique and serves a unique patient population. We encourage, but do not require, hospitals to provide disclaimers as applicable and appropriate in their price estimator tools, including disclaimers acknowledging the limitation of the presented standard charge information and advising the user to consult, as applicable, with his or her health insurer to confirm individual payment responsibilities and remaining deductible balances. Similarly, we encourage, but do not require, that hospital standard charge information include the following:

- Notification of the availability of financial aid, multiple procedure discounts, payment plans, and assistance in enrolling for Medicaid or a state program.
- An indicator for the quality of care in the healthcare setting.
- Making the standard charge information available in languages other than English, such as Spanish and other languages that would meet the needs of the communities and populations the hospital serves.

We discussed the flexibility to provide disclaimers in hospital price estimator tools at 84 FR <u>65578-65579</u>.

Can CMS provide a list of internet-based price estimator tool vendors?

No, we do not have an available list of vendors who provide price estimator tool application software.

Can hospitals provide additional consumer-friendly resources?

Yes. Hospitals are encouraged to embrace a patient-centered approach to care in all forms, including providing consumer-friendly resources related to cost of care that will empower patients with pricing information to help them make healthcare decisions that work best for them.

Do contracts with non-payer companies, i.e., local employers for drug screening, need to be included in the list of payer-specific negotiated rates?

The term "payer-specific negotiated charge" is defined as the charge that the hospital has negotiated with a third-party payer for an item or service. The term "third party payer" is defined as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service. Therefore, if a local company meets the definition of "third party payer" and your hospital has negotiated a payer-specific negotiated charge for an item or service, along with the other required data elements, as applicable. These definitions can be found at 45 CFR §180.20.

Monitoring and Penalties for Noncompliance

What happens if a hospital does not comply?

CMS has the authority to monitor hospital compliance with section 2718(e) of the Public Health Service Act, by evaluating complaints made by individuals or entities to CMS, reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may provide a warning notice to the hospital, request a corrective action plan (CAP) from the hospital if its noncompliance constitutes a material violation of one or more requirements, and may assess on a hospital a civil monetary penalty, and publicize the penalty on a CMS website, should the hospital fail to respond to CMS' request to submit, or comply with the requirements, of a CAP. Please refer to amended 45 CFR § 180.90 for adjusted penalty amounts under <u>Subpart C- Monitoring and Penalties for Noncompliance</u>.

Is CMS enforcing the Hospital Price Transparency rules?

Yes. CMS expects hospitals to comply with these legal requirements, and is actively enforcing these rules to ensure people know what a hospital charges for items and services. The public is invited to <u>submit a complaint</u> to CMS if it appears that a hospital has not posted information online.

<mark>(New)</mark>

What is CMS' process for enforcing the Hospital Price Transparency rules?

The enforcement process is established in the Hospital Price Transparency regulations and occurs in a phased manner. The process typically involves a comprehensive compliance review in response to CMS audit or a complaint received through the Hospital Price Transparency website. If CMS concludes a hospital is noncompliant with one or more of the requirements to make public standard changes, CMS may take any of the following actions, which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s)
- Request a Corrective Action Plan (CAP) if noncompliance constitutes a material violation of one or more requirements
- Impose a civil monetary penalty

In accordance with 45 CFR 180.80(c), if CMS issues a request for a hospital to submit a CAP, it must be submitted by the date specified in the request and must specify the process the hospital will take to address the deficiency(ies) identified by CMS and the timeframe by which the hospital will complete the corrective action. A CAP is subject to CMS review and approval. For reference, CMS has developed a <u>CAP Response Sample</u> as an optional format for submitting a CAP. Should a hospital that CMS has identified as noncompliant fail to respond to CMS' request to submit a CAP or comply with CAP requirements, CMS may impose a CMP in accordance with 180.90(a). Once CMS issues a CMP, CMS will post the notice of imposition of a CMP on a CMS website (45 CFR 180.90(e)). (New)

How does CMS assess compliance?

During a comprehensive compliance review, CMS assesses whether the hospital's disclosure of standard charges meets the requirements specified at 45 CFR Part 180. Specifically, CMS assesses whether the hospital has displayed standard charges in a machine-readable file in accordance with the criteria established at 45 CFR §180.50 and shoppable services in a consumer-friendly manner in accordance with the criteria established at 45 CFR §180.60. (New)

What is CMS doing to educate hospitals and assist them with compliance?

CMS has, to date, engaged in a number of education and outreach activities to help prepare hospitals for compliance:

• held several National Open Door Forums to review the requirements of the Hospital Price Transparency final rule;

• established a dedicated <u>hospital price transparency website at</u> <u>https://www.cms.gov/hospital-price-transparency;</u> and

• established an inquiry email box (<u>PriceTransparencyHospitalCharges@cms.hhs.gov</u>). (New)

Transcripts of National Open-Door Forums can be found here: <u>https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts</u>. The hospital price transparency website includes the following resources to assist hospitals in meeting compliance:

- A link to the Hospital Price Transparency final rule in the Federal Register (<u>https://www.govinfo.gov/content/pkg/FR-2019-11-27/pdf/2019-24931.pdf</u>);
- A link to the CY 2022 OPPS/ASC final rule (<u>https://www.govinfo.gov/content/pkg/FR-2021-11-16/pdf/2021-24011.pdf</u>)
- August 11, 2021 Hospital Price Transparency Stakeholder Webinar Presentation (PDF): <u>https://www.cms.gov/files/document/august-11-2021-hospital-price-transparency-odf-slide-presentation.pdf</u>
- An extensive FAQ document that is continually updated to provide guidance and address common inquiries (<u>https://www.cms.gov/files/document/hospital-price-transparency-frequently-asked-questions.pdf</u>);
- Two step-by-step documents designed to assist hospitals in implementing each of the two main requirements: 8 Steps to a Machine-Readable File (https://www.cms.gov/files/document/steps-machine-readable-file.pdf) and 10 Steps to a Consumer-Friendly Display (https://www.cms.gov/files/document/steps-making-publicstandard-charges-shoppable-services.pdf); and
- A Quick Reference Checklist to assist hospital review of the Hospital Price Transparency regulatory requirements (<u>https://www.cms.gov/files/document/hospital-price-transparency-final-rule-quick-reference-checklists.pdf</u>).

I received a warning notice from CMS. How do I contact CMS with questions about the deficiencies outlined in the notice?

The CEO/President of the hospital or their authorized representative may contact CMS via email at: <u>PriceTransparencyHospitalCharges@cms.hhs.gov</u>. When contacting CMS for technical assistance regarding the Hospital Price Transparency warning letter you received, please submit detailed questions in writing. CMS cannot offer anything that could be construed as legal advice, and recommend that individuals consult with hospital counsel and/or compliance officials. (New)

How do I authorize a representative to talk to CMS about my hospital's warning notice?

As a policy matter, CMS will only discuss the hospital's compliance status with the recipient of the warning notice (specifically, the addressee of the warning notice) or the authorized representative. The CEO/President of the hospital may appoint a designee if he/she will not be the official representative communicating with CMS regarding the Hospital Price Transparency program. To appoint a representative the CEO :

- Should notify CMS by emailing PriceTransparencyHospitalCharges@cms.hhs.gov from the CEO's corporate e-mail of the intent to appoint someone other than the CEO as the official representative of the organization for Hospital Price Transparency.
- Should include in the email the designee's name, title, e-mail, and phone number to ensure any confidential information will be shared only with the hospital's official representative.
- Should send the email to <u>PriceTransparencyHospitalCharges@cms.hhs.gov</u>. (New)

Do I need to notify CMS when my hospital has corrected any deficiencies identified in the warning notice?

. If your hospital receives a warning notice, CMS will indicate the date by which the hospital must take action to correct the deficiency or deficiencies identified by CMS. CMS will review the hospital website after the close of the indicated period to determine if the deficiencies have been remedied or if further compliance actions are warranted. (New)

My hospital is part of a larger hospital system. If one of the hospitals in the system received a warning notice from CMS outlining deficiencies, does this mean that all other hospitals in my system are compliant?

No. A warning notice or request for corrective action sets forth CMS's determination of noncompliance with respect to the specific hospital receiving the letter. Nothing in the warning letter sent to a hospital in a system of hospitals implies a determination of non-compliance for other hospitals in the system. The warning notice, however, may serve as a helpful compliance indicator for other hospitals within a hospital system that have followed similar (or identical) reporting methods. Refer to <u>Subpart C- Monitoring and Penalties for Noncompliance</u>. (New)

How will CMS calculate the Civil Monetary Penalty (CMP), beginning January 1, 2022 and with respect to that timeframe forward? What is the CMP calculation?

The maximum daily CMP amount for hospitals with 30 or fewer beds is \$300, even if the hospital is in violation of multiple discrete requirements. The maximum daily CMP amount for hospitals with at least 31 and up to 550 beds is the number of beds times \$10. For hospitals with greater than 550 beds, the maximum daily CMP amount is \$5,500, even if the hospital is in violation of multiple discrete requirements. Refer CFR 180.90(c)(2). (New)

Ex. A noncompliant hospital with a bed count of 200 would be assessed a maximum daily CMP of \$2,000/day (\$10*200/day) or \$730,000/year.

| Number of Beds | Maximum Penalty Applied Per Day | Total Maximum Penalty Amount for full Calendar Year of Noncompliance |
|----------------|---|--|
| 30 or fewer | \$300 per hospital | \$109,500 per hospital |
| 31 up to 550 | \$310 - \$5,500 per hospital (number of beds times \$10) | \$113,150 - \$2,007,500 per hospital |
| >550 | \$5,500 per hospital | \$2,007,500 per hospital |

Note: In subsequent years, amounts will be adjusted according to 45 CFR 180.90(c)(3).

Why is a scaling factor being used?

A scaling factor is being used to address a trend towards a high rate of hospital noncompliance identified by CMS through sampling and reviews to date, and the reported initial high rate of hospital noncompliance with 45 CFR part 180. Several factors informed our decision to use a scaling factor to determine the CMP, including: the ability to penalize based on a sliding scale method that relates to the hospital's characteristics, such as using the hospital's number of beds as a proxy for the size of the patient population;; the use of scaling factors in other Federal programs to determine CMP amounts; and the availability of a reliable source of data that can be used to establish a CMP amount across most hospitals. We believe a scaling factor approach strikes an appropriate balance and provides for the assessment of a CMP that is commensurate with the level of severity of the potential violation. Refer to 86 FR <u>63948</u>. (New)

What is the source of data used to determine bed count for scaling the CMP and where is that information located?

The scaling factor for the CMP amount uses hospital cost report data. This data is routinely submitted by Medicare-enrolled hospitals, is certified by a hospital official, and is reviewed by a Medicare Administrative Contractor (MAC) to determine acceptability and is submitted annually. The cost report contains provider information such as facility characteristics and financial statement

data. CMS maintains the cost report data in the Healthcare Provider Cost Reporting Information System (HCRIS). Further, the chief financial officer or administrator of the provider certifies the content of the submitted cost report is true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions.¹ The website is available here: <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports</u>. Refer to 86 FR <u>63944</u> (New)

How will CMS determine the bed count for a hospital that is not a Medicare-enrolled hospital?

If the bed count information cannot be determined using Medicare hospital cost report data, CMS will specify the conditions for CMS' receipt of documentation from the hospital to determine its number of beds, and if the hospital does not provide CMS with such documentation (in the prescribed form and manner, and by the specified deadline), CMS will impose a CMP on the hospital at the highest, maximum daily dollar amount (\$5,500 per day). Refer to 45 CFR §180.90(c)(2)(ii)(D)(2). (New)

Where will the public list of non-compliant hospitals that are assessed a CMP be located?

The public list of non-compliant hospitals that are assessed a CMP will be located on the CMS Price Transparency website: <u>https://www.cms.gov/hospital-price-transparency</u>. (New)

Appeals of Civil Monetary Penalties

Can a hospital appeal a civil monetary penalty related to hospital price transparency?

Yes. A hospital upon which CMS has imposed a penalty may request a hearing before an Administrative Law Judge (ALJ) in accordance with <u>45 CFR part 180, subpart D.</u> In deciding whether the amount of a civil monetary penalty is reasonable, the ALJ may only consider evidence of record related to the following: hospital's posting(s) of standard charges, if available; material the hospital timely previously submitted to CMS (including with respect to corrective actions and corrective action plans), and material CMS used to monitor and assess the hospital's compliance.

How long does a hospital have to request a hearing?

A hospital must request a hearing within 30 calendar days after the date of issuance of the notice of imposition of a civil monetary penalty. The "date of issuance" is no more than five (5)

¹ 42 CFR 413.24(f)(4)(iv). See also, Form CMS-2552-10. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935, Chapter 40-(T16)-- Hospital & Hospital Health Care (Form CMS-2552-10) (ZIP), file "R16P240f.pdf", Part II – Certification.

days after the filing date postmarked by the U.S. Postal Service, or deposited with a carrier for commercial delivery, unless there is a showing that the document was received earlier. Please refer to 45 CFR §<u>150.401</u>, <u>150.405(a)</u>.

Can a hospital request an extension of time for filing a request for a hearing?

A request for an extension of time must be made promptly by written motion. The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the hospital was prevented by events or circumstances beyond its control from filing its request within 30 calendar days after the date of issuance of the notice of imposition of a civil monetary penalty. Please refer to 45 CFR § 150.405(b).

What happens if a hospital does not request a hearing within the required timeframe?

If a hospital does not request a hearing within 30 calendar days of the issuance of the notice of imposition of a CMP, CMS may impose the CMP indicated in such notice and may impose additional penalties pursuant to continuing violations according to 45 CFR 180.90(f) without right of appeal. 45 CFR §180.110(b) provides that the hospital has no right to appeal a penalty for which it has not requested a hearing in accordance with 45 CFR §150.405, unless the hospital can show good cause, as determined at §150.405(b), for failing to timely exercise its right to a hearing.

In the CY 2022 OPPS/ASC final rule, CMS indicated a belief that it was necessary to increase the penalty amount as a result of an internal analysis in early 2021. What were the findings from the CMS analysis?

Beginning January 1, 2021, CMS initiated audits of the websites of hospitals subject to the hospital price transparency rule and determined that the noncompliance rate with one or more of the requirements was approximately 75%. As a result, we proposed and finalized an increase to the penalty for noncompliance, beginning January 1, 2022.

What were the most frequent "deficiencies" seen by CMS during a comprehensive compliance review in 2021?

- Of hospitals that received warning notices in CY 2021, approximately 70% had deficiencies associated with the machine-readable file, while just under 30% were cited for deficiencies in both the machine-readable file and the consumer-friendly display. Very few hospitals were cited for deficiencies related only to the consumer-friendly display. Of hospitals found to be noncompliant with the machine-readable file display, the most common deficiencies included:
- Failure to make public a single machine-readable file.
- Missing one or more of the five types of standard charges.
- Including all five types of standard charges but failing to clearly associate the payer-specific

negotiated charges with the name of the third-party payer and plan.

Of hospitals found to be noncompliant with the consumer-friendly display, the most common deficiencies included:

- Failure to make available a consumer-friendly list of standard charges for shoppable services or to offer a price estimator tool
- Failure to include all corresponding data elements (such as the required types of standard charges, ancillary services, and relevant billing codes).

Appendix 1: Machine-Readable File Display Recommendations

Example 1: For Payer A/Plan 1, the hospital has established a payer-specific negotiated charge for a procedure that is based on a percent discount off the total gross charges generated during a patient's stay, and the total gross charges generated during a patient's stay will vary from patient to patient.

Display recommendation: In this case, for Payer A/Plan 1, the hospital could provide a description of the procedure and indicate a payer-specific negotiated charge of "50% off total gross charges".

Example 2: For Payer A/Plan 1, the hospital has established a payer-specific negotiated charge for a procedure that includes both a standardized dollar amount (such as a base rate of \$5,000) and an amount that is variable (such as a 50% percent discount off the gross charge for the implanted device chosen by the surgeon).

Display recommendation: The preferred approach is to display each standard charge as a standardized dollar amount. For example:

| Description | Code | Gross Charge | Payer A/Plan 1 |
|------------------------|--------|--------------|----------------|
| [procedure] | [code] | N/A | \$5,000 |
| [implantable device 1] | [code] | \$1,500 | \$750 |
| [implantable device 2] | [code] | \$2,000 | \$1,000 |

In some cases, the standardized dollar amount for an implantable device may not be available, for example, when the device is purchased on an as-needed basis and the cost of the device is dependent on the prevailing market rate at the time of purchase. In this example, for Payer A/Plan 1, the hospital could provide a description of the procedure and indicate a payer-specific negotiated charge of the base rate (\$5,000) and a separate charge of "50% off the gross charge" for the implantable device.

| Description | Code | Gross Charge | Payer A, Plan 1 |
|------------------------|--------|--------------|----------------------|
| [procedure] | [code] | N/A | \$5,000 |
| [implantable device 1] | [code] | Market price | 50% off gross charge |

In other cases, the same implantable device may be used in different procedures, and the payer-specific negotiated charge for the device varies for each procedure. For example, the payer-specific negotiated charge for the implantable device is 50% of the gross charge when used for procedure X and the payer-specific negotiated charge for the same implantable device is 60% of the gross charge when used for procedure Y. The preferred approach would be to describe the procedure and provide the standardized dollar amount as the base rate (\$5,000) and ensure that the description of each implantable device reflects its use in each procedure along with their associated standardized dollar amount (discounted rate) as

follows:

| Description | Code | Gross Charge | Payer A, Plan 1 |
|--|--------|--------------|-----------------|
| [procedure X] | [code] | N/A | \$5,000 |
| [procedure Y] | [code] | N/A | \$5,000 |
| [implantable device 1 when used for procedure X] | [code] | \$1,500 | \$750 |
| [implantable device 1 when used for procedure Y] | [code] | \$1,500 | \$600 |

As an alternative, for Payer A/Plan 1, the hospital could provide a description of procedure X and indicate a payer-specific negotiated charge as the base rate (\$5000) + the established percent discount off the gross charge for the implantable device as follows:

| Description | Code | Gross Charge | Payer A, Plan 1 |
|------------------------|--------|--------------|---|
| [procedure X] | [code] | N/A | \$5,000 + 50% off the gross charge of the |
| | | | implantable device |
| [procedure Y] | [code] | N/A | \$5,000 + 60% off the gross charge of the |
| | | | implantable device |
| [implantable device 1] | [code] | \$1,500 | |

Example 3: For Payer A/Plan 1, the hospital has established a payer-specific negotiated charge for all medications of 50% off the gross charge when administered in one setting (such as the emergency department identified by revenue center code 0450) and 60% of the gross charge when administered in another setting (such as the general medical inpatient ward, identified by revenue center code 0150).

Display recommendation: As noted above, we recommend that hospitals display the payerspecific negotiated charge for each medication in each setting as a standardized dollar amount by listing each one separately.

The preferred approach is for hospitals to display the payer-specific negotiated charges for each medication as a standardized dollar amount like this:

| Description | Quantity | Code 1 | Code 2 | Gross Charge | Payer A, Plan 1 |
|----------------|----------|---------|---------------|--------------|-----------------|
| [medication 1] | [X] | [NDC 1] | | \$3.00 | N/A |
| [medication 1] | [X] | [NDC 1] | Rev code 0450 | \$3.00 | \$1.50 |
| [medication 1] | [X] | [NDC 1] | Rev code 0150 | \$3.00 | \$1.20 |
| [medication 2] | [X] | [NDC 2] | | \$4.00 | N/A |
| [medication 2] | [X] | [NDC 2] | Rev code 0450 | \$4.00 | \$2.00 |
| [medication 2] | [X] | [NDC 2] | Rev code 0150 | \$4.00 | \$1.60 |
| [medication 3] | [X] | [NDC 2] | | \$5.00 | N/A |

| | | · · · · · · · · · · · · · · · · · · · | | | |
|----------------|-----|---------------------------------------|---------------|--------|--------|
| [medication 3] | [X] | [NDC 2] | Rev code 0450 | \$5.00 | \$2.50 |
| [medication 3] | [X] | [NDC 2] | Rev code 0150 | \$5.00 | \$2.00 |

However, we recognize that doing so could exponentially increase the data in the file which may present a challenge for some hospitals and a barrier to consumer access. Therefore, the hospital could also display payer-specific negotiated charge established by the hospital as a standardized algorithm if the standardized algorithm (e.g., 50% off gross charges) and the description of the item/service (e.g. all medications provided in the emergency department) is sufficient for the public to determine what the payer-specific negotiated charge would be and under what conditions:

| Description | Quantity | Code 1 | Code 2 | Gross Charge | Payer A, Plan 1 |
|-----------------------------|----------|--------|---------------|-----------------|----------------------|
| [medication 1] | [X] | [NDC] | | \$3.00 | N/A |
| [medication 2] | [X] | [NDC] | | \$4.00 | N/A |
| [medication 3] | [X] | [NDC] | | \$5.00 | N/A |
| All medications provided in | [X] | [NDC] | Rev code 0450 | N/A | 50% of gross charges |
| the emergency department | | | | | |
| All medications provided in | [X] | [NDC] | Rev code 0150 | N/A | 60% of gross charges |
| the general medical ward | | | | | |

Example 5: In this example, the hospital has established gross charges for all itemized items/services. With Payer A/Plan 1, the hospital has established a payer-specific negotiated charge for Procedure X of "60% off the total gross charges" and for Procedure Y of "75% off the total gross charges." The hospital has also established a gross charge of "50% of gross charges" when the same items and services are not provided in the context of any procedure that is otherwise specified in the contract. In this case, the display recommendation is as follows:

| Item/service | Code | Gross Charge | Payer A/Plan 1 |
|-----------------------|--------|--------------|----------------------------|
| Room & board (each | | \$500 | \$250 |
| day) | | | |
| OR time (each 15 min) | | \$100 | \$50 |
| Procedure X | [code] | N/A | 60% of total gross charges |
| Procedure Y | [code] | N/A | 75% of total gross charges |

Example 6: The hospital has established a payer-specific negotiated charge for a procedure as an algorithm that includes two standardized dollar amounts, specifically, the base rate (\$5000) multiplied by an adjustment factor (for example, the hospital's case mix of 3.4).

Display recommendation: In this case, the hospital could display a standardized dollar amount as the payer-specific negotiated charge by multiplying the procedure's base rate by the case mix adjustment factor and display the resulting payer-specific negotiated charge.