



Charles N. Kahn III
President and CEO

September 27, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

SUBJECT: CMS-1717-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals (Vol. 84, No. 154), August 9, 2019

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching full-service community hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register (84 Fed. Reg. 39,398) on August 9, 2019.

EXECUTIVE SUMMARY

Disclosure of Payer-Specific Negotiated Rates

Although the FAH continues to support the Department of Health and Human Services' (HHS) goal of ensuring that patients have access to clear, accurate, and actionable cost-sharing information, the FAH strongly opposes HHS's proposal to expand section

2718(e) of the Public Health Service Act (PHSA), 42 U.S.C. § 300gg-18(e) (“Section 2718(e)”), to require disclosure of payer-specific negotiated rates.

HHS lacks the statutory authority to implement this proposal, the disclosure of competitively negotiated rates does not support the interests of consumers, and the proposal relies on operational assumptions that are untrue, resulting in a gross underestimation of the costs and unrealistic assessment of the feasibility of compliance with the Proposed Rule. Therefore, the FAH urges HHS to abandon the proposed price transparency rules and instead work with stakeholders—providers, health plans, employers, and consumers—to identify opportunities to improve consumers’ access to clear, accurate, and actionable cost-sharing information, which is what patients really need to make informed decisions.

OPPS Payment Methodology for 340B Purchased Drugs

The FAH fully supports CMS’s prospective budget-neutral 340B payment policy to continue to pay Average Sales Price (ASP) minus 22.5 percent for 340B-acquired drugs and agrees it is an appropriate action by the Secretary.

In addition to the continuation of the payment policy, CMS also seeks public comment on how to structure any potential remedy for Calendar Years (CY) 2018 and 2019, in light of ongoing litigation regarding the CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs. The FAH respectfully disagrees with CMS’s assertion that CMS must or may craft a budget neutral remedy for its CY 2018 and 2019 340B-acquired drug payment policy. To the contrary, the Medicare Act does not permit CMS to make any offsets to achieve actual or retrospective budget neutrality, and to the extent that CMS is ultimately required to provide relief to 340B hospitals through a prospective payment increase designed to compensate such hospitals for any past underpayments, that payment increase cannot be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made for non-drug outpatient prospective payment system (OPPS) items and services.

The FAH would strongly oppose any effort to offset any relief to 340B hospitals or to otherwise achieve budget neutrality by implicitly or explicitly recouping payments made for non-drug OPPS items and services in 2018 and 2019.

Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services

The FAH strongly advises that CMS reconsider its proposal regarding prior authorization for certain hospital outpatient services given the potential impact on payment to providers and the health and welfare of patients that would result from delays in receiving needed medical services.

Medicare data does not support that the increasing utilization of the identified procedures is solely or even primarily for cosmetic reasons as there are many instances where these services will be performed for medically necessary reasons. This is especially true for the large growth in Botox injections, which appears to be the basis upon which CMS is making its proposal. That growth is reasonably tied to expanding non-cosmetic medical indications over time, for example as a recognized treatment for migraines.

We are concerned that the policy could potentially delay treatment and seriously jeopardize a beneficiary's health or ability to regain maximum function. The policy will place providers in an untenable position of potentially providing the needed services immediately, without authorization, and risking payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations.

Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges (XVI.)

Although the FAH continues to support HHS's goal of ensuring that patients have access to clear, accurate, and actionable cost-sharing information, the FAH strongly opposes HHS's proposal to expand section 2718(e) of the Public Health Service Act (PHSA), 42 U.S.C. § 300gg-18(e) ("Section 2718(e)"), to require disclosure of payer-specific negotiated rates. *HHS lacks the statutory authority to implement this proposal, the disclosure of competitively negotiated rates does not support the interests of consumers, and the proposal relies on operational assumptions that are untrue, resulting in a gross underestimation of the costs and unrealistic assessment of the feasibility of compliance with the Proposed Rule. Therefore, the FAH urges HHS to abandon the proposed price transparency rules and instead work with stakeholders—providers, health plans, employers, and consumers—to identify opportunities to improve consumers' access to clear, accurate, and actionable cost-sharing information, which is what patients really need to make informed decisions.*

Section 2718(e) Does Not Give HHS Authority to Require the Disclosure of Payer Specific Negotiated Rates

Section 2718(e) requires each hospital to establish and update "*a list of the hospital's standard charges* for items and services provided by the hospital" (emphasis added). Congress also specified that hospitals must "make [this list] public (in accordance with guidelines developed by the Secretary)." Notably, in Section 2718(e), Congress only conferred the Secretary with authority to establish guidelines as to the manner in which the list of standard charges is made public, but did not provide broad authority to pursue price transparency policies by redefining "standard charges." Thus, in the fiscal year (FY) 2015 inpatient prospective payment system (IPPS)/long-term care hospital (LTCH) prospective payment system (PPS) proposed rule, HHS's guidelines only required that either the hospital's list of standard charges be made public or the hospital post policies specifying how members of the public can view that list of standard charges.¹ Last year, HHS changed these guidelines to require that the list of standard charges be posted online in a machine-readable format.² In doing so, HHS exercised its authority to specify the *manner* in which the list of standard charges was made public. The proposed price transparency regulations, however exceed this specified, limited grant of statutory authority by adopting a radical and expansive definition of "standard charges" instead of simply providing guidelines for making the required list of standard charges public.

¹ 79 Fed. Reg. 27,978, 28,169 (May 15, 2014).

² 83 Fed. Reg. 20,164; 83 Fed. Reg. 41,144.

Even if HHS had some degree of interpretive authority under Section 2718(e), the proposed price transparency regulations go far beyond and are inconsistent with the plain text of Section 2718(e) making them untenable. Critically, Congress chose to use the word “charges” in lieu of “price,” “rate,” “cost,” or any other similar term. Congress has referenced provider charges in health care statutes dating back to at least the Social Security Amendments of 1965, and the FAH is unaware of any instance where a reference to a provider’s or hospital’s “charges” in the Social Security Act or the Public Health Services Act has been interpreted by HHS or a court as including rates negotiated with private, commercial, third-party payers. Rather, Congress’ use of the term “charges” is a clear and unambiguous reference to what the Proposed Rule refers to as “gross charges” (*i.e.*, the charges reflected on the hospital’s chargemaster) rather than payer-specific negotiated rates.

When the word “charges” is read in context, it becomes even clearer that it refers only to gross charges. The statute specifies that the disclosure requirement applies to “*a list of the hospital’s standard charges for items and services provided by the hospital*” (emphasis added). This language describes a single set (“a list”) of non-discounted, regular (“standard”) charges. In other words, Congress unambiguously describes gross charges in Section 2718(e). The Proposed Rule, on the other hand, would require hospitals to make public two large data files consisting of complex matrices showing payer-specific negotiated rates, which are by definition non-standard, alongside gross charge data. The non-standard nature of the data encompassed by the Proposed Rule is clear from the proposed definition of standard charges, which references the rate for items and services “provided to a *specific group of paying patients*.”³ This patient- and payer-specific definition is at odds with the notion of “standard” charges and exceeds the authority delegated under Section 2718(e).

Moreover, Congress specified that hospitals would only be required to make public “a list” (singular) of its standard charges. In general usage, “list” means “a simple set of words or numerals (such as the names of persons or objects).”⁴ This is inconsistent with any disclosure requirement for payer-specific negotiated rates. An individual hospital may be contracted with tens of insurance carriers for any number of products, which may each have individual rates and even different rate methodologies (e.g., fee-for-service, per diem, diagnosis-related group (DRG), ambulatory procedure code (APC), percent of charges). And the hospital may be indirectly contracted with many more payers (including self-funded plans) that are contractually entitled to access the negotiated rates in another payer’s managed care agreement. Thus, under the Proposed Rule, a hospital would be required to make public any number of lists of payer- and plan-specific negotiated rates in the two data files, rather than the single list of standard charges required by statute. The Proposed Rule’s reference to each of these proposed “lists” of charges and payer-specific negotiated rates as data elements does not render these complex matrices a single list in accordance with Congress’ directive.

A review of state-level price transparency legislation adopted both before and after the passage of the Affordable Care Act further confirms that Congress did not intend to permit HHS to require disclosure of payer-specific negotiated rates. By 2006, Arizona, California, Florida, Maryland, and Massachusetts had public websites that included average hospitals

³ 84 Fed. Reg. at 39,641 (proposed 45 C.F.R. § 180.20) (emphasis added).

⁴ *List*, Merriam-Webster.com, at <https://www.merriam-webster.com/dictionary/list> (last visited Sep. 18, 2019). Alternative definitions likewise describe a simple list rather than a matrix of data fields. *Id.* (defining “list” alternatively as a “catalog, checklist” (e.g., a “hit list” of songs) or “the total number to be considered or included” (e.g., a “list of interests”).

charges per day and per stay for selected DRGs.⁵ California’s Assembly Bill 1627, passed in 2003, required hospitals to make *chargemaster* data public. In short, state-level price transparency initiatives focused on the disclosure of *chargemaster* data rather than payer-specific negotiated rates. In 2011, the Government Accountability Office released its report entitled “Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care.” The report only identifies two states—New Hampshire and Massachusetts—that provided price information rather than charge data, and neither state required hospitals to disclose their payer-specific negotiated rates. Rather, these states used historical claims data to determine payments made to providers and to roughly project future payment amounts.⁶ And neither state refers to this pricing data derived from historic claims as “charge” data. Although only legislative actions prior to enactment of the ACA on March 23, 2010 are probative of Congress’ intent, it is notable that even subsequent state-level transparency initiatives continue to consistently use the term “charges” to refer to *chargemaster* data.⁷ The FAH is unaware of any state that required hospitals to publicly disclose any pricing data other than *chargemaster* data when requiring the disclosure of “charges,” and HHS’s proposed interpretation of standard charges to include payer-specific negotiated rates appears to be unprecedented at both the state and federal level.

Consistent with the plain text of the statute, HHS guidelines to date have consistently interpreted Section 2718(e) to only require disclosure of a single list of standard charges but not payer-specific negotiated rates. The FY 2015 IPPS/LTCH PPS proposed rule stated as follows: “Our guidelines for implementing section 2718(e) of the Public Health Service Act are that hospitals either make public a list of their standard charges (whether that be *the chargemaster itself or in another form of their choice*), or their policies for allowing the public to view a list of those charges in response to an inquiry.”⁸ HHS reiterated this guidance in the IPPS/LTCH PPS final rule for FY 2015 as well.⁹ Last year, HHS updated its guidelines to require that standard charges be made available online in a machine-readable format.¹⁰ Subsequently, HHS clarified that the list of standard charges disclosed under Section 2718(e) must “represent[] the hospital’s current standard charges as reflected in its *chargemaster*.”¹¹ This consistent guidance has focused exclusively on gross (standard)

⁵ D. Andrew Austin, Jane G. Gravelle, Cong. Research Serv., RL 34101, Congressional Research Service Report to Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Healthcare Sector at p.24 (2007).

⁶ U.S. Gov’t Accountability Office, GAO-11-791, Health Care Price Transparency: Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care at pp. 18 – 19 (2011).

⁷ For example, in 2017, Colorado enacted S.B. 17-065, which requires hospitals to disclose their “health care prices” (charges) applicable to self-pay patients for their fifty most used inpatient DRG codes and twenty-five most used outpatient CPT or HCPCS codes. Colo. Rev. Stat. § 25-49-104. “Health care prices” is specifically defined to exclude payer-specific negotiated rates. Colo. Rev. Stat. § 25-49-102(4)(b). In order to minimize consumer confusion, the health care price list must include various disclosures, including one stating as follows: “If you are covered by health insurance, you are strongly encouraged to consult with your insurer to determine accurate information about your financial responsibility for a particular health care service provided at this health care facility.” *Id.* at § 25-49-104(2)(b). Those states that enacted non-charge based pricing transparency initiatives did not refer to this pricing data as “charges.” For example, Oregon’s S.B. 900 was enacted in 2015. It requires reporting of claims data and other data relating to price, cost, and quality, and that data is used to post “price information including the median prices paid by the reporting entities to hospitals and hospital outpatient clinics for, at a minimum, the 50 most common inpatient procedures and the 100 most common outpatient procedures” to a state-sponsored website. Or. Rev. Stat. § 442.466(5)(b). The statute does not use the word “charges,” and charge data is not included on the website.

⁸ 79 Fed. Reg. 27,978, 28,169 (May 15, 2014) (emphasis added).

⁹ 79 Fed. Reg. 49,854, 50,146 (Aug. 22, 2014).

¹⁰ 83 Fed. Reg. 20,164; 83 Fed. Reg. 41,144.

¹¹ HHS, Frequently Asked Questions Regarding Requirements for Hospitals to Make Public a List of Their Standard Charges via the Internet (October 2018), at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

charges and has properly excluded payer-specific negotiated rates. The FAH therefore urges HHS to decline to finalize the proposed definition of standard charges and to instead define “standard charges” as “gross charges,” consistent with HHS’s prior long-standing interpretation and the scope of HHS’s authority under Section 2718(e).

Finally, HHS’s proposed interpretation of the final rule is untenable and unreasonable because it is wholly inconsistent with other laws that protect payer-specific negotiated rates from disclosure or prohibit disclosure of this data. Congress has previously protected the disclosure of trade secrets and confidential commercial or financial information against broad public disclosure under the Freedom of Information Act (FOIA), and HHS’s proposed interpretation of “standard charges” to include payer-specific negotiated rates would impermissibly circumvent this statutory protection. Exemption 4 of the FOIA protects “trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.”¹² Payer-specific negotiated rates are a paradigmatic example of confidential commercial or financial information.¹³ If Congress intended to authorize disclosure of confidential commercial information protected from disclosure under FOIA, it would have said so plainly, and HHS’s proposed disclosure requirement for payer-specific negotiated rates is unreasonable and contrary to the purpose of this statute.

HHS’s proposed disclosure requirement is also inconsistent with the Sherman Act (and other state and federal trade regulation related statutes), which has protected competition since 1890 and has been interpreted for at least two decades to prohibit health care providers from disclosing fee-related information to competing providers. Because the matrices of payer-specific negotiated rates that would be required under the Proposed Rule would be publicly available, they would be available to competing providers. The Federal Trade Commission (FTC) and the Antitrust Division of the Department of Justice have concluded that the disclosure of prospective negotiated rates is “very likely to be considered anticompetitive” under the Sherman Act.¹⁴ In fact, the narrow safety zone for exchanges of price information among providers only applies to third-party surveys based on data at least three months old and where the data is aggregated such that it would not allow viewers to identify any particular provider’s negotiated rates.¹⁵ In short, if Congress intended to compel the disclosure of payer-specific negotiated rates when it required disclosure of provider chargemasters in Section 2718(e), it would have done so explicitly because such a policy stands in sharp contrast to long-standing policies and congressional enactments.

[Payment/AcuteInpatientPPS/Downloads/FAQs-Req-Hospital-Public-List-Standard-Charges.pdf](#). A second FAQ issued in December 2018 further clarified that the list of standard charges for subsection (d) hospitals should include charges by DRG, a requirement that could be satisfied using data in CMS’ Inpatient Utilization and Payment Public Use File (Inpatient PUF). HHS, Additional Frequently Asked Questions Regarding Requirements for Hospitals To Make Public a List of Their Standard Charges via the Internet (December 2018), at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/Downloads/Additional-Frequently-Asked-Questions-Regarding-Requirements-for-Hospitals-To-Make-Public-a-List-of-Their-Standard-Charges-via-the-Internet.pdf>.

¹² 5 U.S.C. § 552(b)(4).

¹³ Information is confidential for FOIA purposes if disclosure of the information is likely “to cause substantial harm to the competitive position of the person from whom the information was obtained.” *Nat’l Parks & Conservation Ass’n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974)

¹⁴ Department of Justice and FTC. Statement on Provider Participation in Exchanges of Price and Cost Information. Aug. 1996. Available at: <https://www.justice.gov/atr/page/file/1197731/download>.

¹⁵ *Ibid.*

The Compelled Disclosure of Payer-Specific Negotiated Rates is Unconstitutional

Even if Section 2718(e) could be interpreted to require the disclosure of payer-specific negotiated rates and if HHS had the authority to adopt such an interpretation, such a compelled disclosure would be unconstitutional. The First Amendment “imposes stringent limits on the Government’s authority to either restrict or compel speech by private citizens and organizations.”¹⁶ Under the *Central Hudson* test, government regulation of non-misleading commercial speech is unlawful unless it “directly advances” a “substantial” government interest, and is no “more extensive than necessary to serve that interest.”¹⁷

The disclosure requirement proposed here fails that test because HHS can identify no substantial government interest in the disclosure of all payer-specific negotiated rates. It is widely acknowledged that consumers’ interests in provider prices is focused on the consumer’s out-of-pocket costs, not the cost to their health plan. As HHS notes, “consumers of health care services simply want to know where they can get a needed health care service and what that service will cost them out-of-pocket.”¹⁸ The disclosure of payer-specific negotiated rates thus does not serve this consumer interest identified by HHS. Instead, the disclosure of negotiated rates is more likely to confuse consumers because their cost-sharing obligations will often be markedly different from the disclosed rates and the disclosed rates shown may by necessity reflect inconsistent assumptions necessary to reduce payment methodologies to set dollar amounts (*see* the discussion of typical managed care payment methodologies in Part D.3, below).

Even if the interest here were substantial, the proposed disclosure requirement would necessarily fail the *Central Hudson* test because it is not narrowly tailored to that government interest. The disclosure of all payer-specific negotiated rates for all items and services (including payer-specific service packages) and for 300 “shoppable” items and services (along with their associated ancillary services) is an extraordinarily broad and burdensome requirement with which hospitals may be wholly unable to comply.¹⁹ Moreover, hospitals and private payers alike rely heavily on the confidentiality of negotiated rates to permit them to negotiate arm’s length rates with other payers and providers. The resulting rates are confidential trade secrets that derive value from not being known to competing providers and payers, and the proposed disclosure requirement for payer-specific negotiated rates would infringe upon trade secret protections recognized by Congress, the common law, and many states.²⁰

¹⁶ *Am. Meat Inst. v. U.S. Dep’t Agric.*, 760 F.3d 18, 30 (D.C. Cir. 2014) (Kavanaugh, J., concurring).

¹⁷ *Central Hudson Gas & Electric Corp. v. Public Service Comm’n of New York*, 447 U.S. 557, 566 (1980).

¹⁸ 84 Fed. Reg. at 39,574.

¹⁹ *See* the discussion of the infeasibility of compliance with the Proposed Rule and the associated burdens in Parts 0 and 0, below.

²⁰ These rates constitute trade secrets under 18 U.S.C. § 1839(3) (defining trade secret to include “all forms and types of financial, business, scientific, technical, economic, or engineering information, including . . . compilations, . . . formulas, [or] methods . . . , whether tangible or intangible, . . . if (A) the owner . . . has taken reasonable measures to keep such information secret; and (B) the owner derived independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means, by another person who can obtain economic value from the disclosure or use of the information”), under the Uniform Trade Secrets Act (defining trade secret as “information, including a . . . compilation [or] method . . . that: (i) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use, and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy”), and the Restatement of Torts sec. 757, cmt. b (setting forth various factors to determine whether a trade secret exists, including the extent to which the information is known outside the business, the measures taken to guard the

Finally, we note that, even if the alternative test articulated in *Zauderer v. Office of Disciplinary Counsel* applied instead of the *Central Hudson* test, the proposed disclosure requirement would not pass muster.²¹ A disclosure requirement cannot be “unjustified or unduly burdensome” under *Zauderer*.²² But the disclosure requirement proposed here is not only burdensome, but also likely wholly infeasible, as explained further below. Moreover, *Zauderer* applies to disclosure requirements reasonably related to the State’s interest in preventing deception of consumers, an interest that is not applicable here. These sizable matrices of competitively sensitive information are not simple disclaimers or warning labels like those addressed by *Zauderer* and its progeny, and the proposed disclosures would fail under either *Zauderer* or *Central Hudson*.

Consumer Interests, Market Forces, and Payer-Specific Negotiated Rates

The FAH strongly believes that HHS’s Proposed Rule risks significant market disruption and unforeseen anticompetitive effects that offer few possible benefits and pose significant potential harms for consumers. Therefore, the FAH strongly urges HHS *not* to finalize the Proposed Rule.

Risks to Consumers of Disclosing Payer-Specific Negotiated Rates

The Proposed Rule notes that “the impact resulting from the release of negotiated rates is largely unknown.”²³ In fact, the profound risks posed by the public disclosure of payer-specific negotiated rates is established among those expert agencies charged with enforcing our nations antitrust laws. Longstanding guidance from the FTC and the Antitrust Division of the Department of Justice indicates that exchanges of current negotiated rates poses risks to competition.²⁴ These risks may manifest in different ways in various markets, depending on market-specific conditions, but might include higher prices in some markets or lower prices that threaten hospital viability in other markets. For example, as one payer observed in comments on the HHS Office of the National Coordinator for Health Information Technology (ONC) proposed rule information blocking, dominant health plans in local and regional markets can use disclosed rate information “to deter and punish hospitals that lower rates or enter into value-based arrangements with the dominant plan’s competitors, thus maintaining their dominance and fostering higher costs of care.”²⁵

The FTC has also explicitly warned against the disclosure of pricing information among competitors. For example, in 2015, the FTC wrote, “[T]ransparency is not universally good. When it goes too far, it can actually harm competition and consumers. Some types of information are not particularly useful to consumers, but are of great interest to competitors.”²⁶ In 2015 comments to the Minnesota legislature, the FTC counseled against disclosure of health plan terms and urged that transparency be limited to “predicted out-of-

secrecy of the information, the value of the information to the business and its competitors, and the ease or difficulty with which the information could be properly acquired or duplicated by others).

²¹ 471 U.S. 626 (1985).

²² *Id.* at 651.

²³ 84 Fed. Reg. at 39,579.

²⁴ Department of Justice and FTC. Statement on Provider Participation in Exchanges of Price and Cost Information. Aug. 1996. Available at: <https://www.justice.gov/atr/page/file/1197731/download>.

²⁵ UnitedHealth Group to HHS Office of the National Coordinator for Health Information Technology. RIN 0955-AA01. Available at <https://www.regulations.gov/contentStreamer?documentId=HHS-ONC-2019-0002-1855&attachmentNumber=1&contentType=pdf>.

²⁶ Koslov T, and Jex E, FTC. “Price Transparency or TMI?.” July 2015. Available at <https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi>.

pocket expenses, co-pays, and quality and performance comparisons of plans or provider.”²⁷ More recently, the FTC recommended against the inclusion of negotiated price information in the definition of “electronic health information” under proposed information blocking regulations in the interest of helping to “ensure that the final rule does not inadvertently distort competition.”²⁸

Although the Proposed Rule cites from the literature on price transparency, the cited articles provide little information as to the potential risks and benefits of the disclosure because HHS’s price transparency proposal is a radical experiment that is unprecedented in the health care sector. The HHS-cited studies concerning the market impacts of health care price transparency largely focus on the disclosure of hospital (gross) charges rather than payer-specific negotiated rates.^{29, 30} This data is already disclosed under Section 2718(e), and these studies are not probative of the potential impacts of disclosing payer-specific negotiated rates on markets and consumers. The remaining studies focus on a single state’s price transparency initiative.^{31, 32, 33} The New Hampshire price transparency initiative that is the subject of these analyses involves the centralized publication of *average* payer- and provider-specific “prices” for standardized bundles of services derived from *historic* claims payment data in a state-wide database, inflated by 5 percent. This is radically different, both in terms of burden and market impacts, from HHS’ proposal, and the limited studies of the price impacts of this distinct initiative in one very small state with fewer than forty hospitals and three main payers³⁴ does not call into question the robust literature on the importance of confidential third-party rates in a competitive marketplace.

Ultimately, the disclosures that would be required under proposed 45 C.F.R. Part 180 would be of little utility to patients because the disclosed rates would not enable apples-to-apples comparisons among providers (as described further below) and would not correlate to the patient’s expected out-of-pocket costs (or even historic averages of out-of-pocket costs). This misleading data, provided without any corresponding quality data, could also result in patients choosing higher cost, lower quality care, either because the patient perceives the higher cost to correlate with higher quality or because the payer-specific negotiated rate data

²⁷ Lao M, Feinstein D, and Lafontaine F to Hoppe J. and McCrery J. June 29, 2015. Available at: https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-regarding-amendments-minnesota-government-data-practices-act-regarding-health-care/150702minnhealthcare.pdf.

²⁸ FTC to HHS Office of the National Coordinator for Health Information Technology. RIN 0955-AA01. Available at https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-department-health-human-services-regarding-21st-century-cures-act-interoperability/v190002_hhs_onc_info_blocking_staff_comment_5-30-19.pdf.

²⁹ E.g., Christensen H.B., Floyd E., and Maffett M. “The Effects of Price Transparency Regulation on Prices in the Healthcare Industry.” Available at: <https://www.bakerinstitute.org/media/files/event/01ce2e80/HPF-paper-AHEC-Floyd.pdf>. (Cited at 84 Fed. Reg. 39,631.)

³⁰ Congressional Research Service Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in Other Markets for the Health Sector. July 24, 2007. Available at: <https://fas.org/sgp/crs/secretary/RL34101.pdf>.

³¹ Brown Z.Y. An Empirical Model of Price Transparency and Markups in Health Care. August 2018. http://www-personal.umich.edu/~zachb/zbrown_empirical_model_price_transparency.pdf.

³² Brown Z.Y. 2018. “Equilibrium Effects of Health Care Price Information,” *Review of Economics and Statistics*. Available at: https://www.mitpressjournals.org/doi/abs/10.1162/rest_a.00765.

³³ Tu H, and Gourevitch R. California HealthCare Foundation and Robert Wood Johnson Foundation. Moving Markets, Lessons from the New Hampshire Price Transparency Experiment. April 2014. Available at: <https://www.chcf.org/wp-content/uploads/2017/12/PDF-MovingMarketsNewHampshire.pdf>.

³⁴ New Hampshire’s website, NH Health Cost (nhhealthcost.nh.gov) only shows payer-specific *average, historic* data from group and non-group coverage offered by three payers: Anthem NH, CIGNA, and Harvard Pilgrim NH. Data based on claims from other payers, to the extent it is available for limited providers and procedures, is grouped under “Other Medical Insurance.”

is skewed by the typical acuity of a patient (discussed further below).³⁵ Thus, rather than contributing to improved consumer utilization of health care, the proposal would threaten harmful, irreparable, market-shifting, unintended consequences.

Identifying and Meeting Consumer Price Information Needs

Although the FAH strongly objects to proposed 45 C.F.R. Part 180 and the mandated disclosure of payer-specific negotiated rates, ***the FAH continues to be supportive of efforts to ensure that consumers have access to clear accurate, and actionable information concerning their copayment, coinsurance, and deductible obligations (collectively “cost-sharing obligations”) and urges CMS to work collaboratively with the industry to understand and foster these efforts.*** The FAH’s members are actively engaged in the development and implementation of improved price estimator tools, both independently and in coordination with payers. These initiatives focus on maximizing consumer benefit with actionable and understandable cost-sharing estimates while minimizing competitive harms by maintaining the confidentiality of payer-specific negotiated payment methodologies. The FAH is also concerned that onerous federal price-transparency initiatives may divert resources from these important initiatives and chill innovation that would ultimately be of far greater benefit to consumers. ***The FAH, therefore, urges HHS to provide an opportunity for providers and payers to address consumers’ interests in price transparency and to engage with stakeholders in meaningful ways rather than exceeding the bounds of its legal authority to adopt proscriptive, costly, and risky price transparency rules.***

In addition, we note the importance of including payers in efforts to promote meaningful, consumer-friendly price transparency while minimizing the risks to competition. As the Proposed Rule notes, payer-based price estimator tools are becoming more prevalent among insurers and self-funded employers and are well studied.³⁶ Payers can provide this information to their members and beneficiaries without disclosing data more broadly among competing providers or disclosing this data to competing payers. In addition, payers are uniquely qualified to provide patients with precise information concerning any limitations on their coverage, the scope of patient cost-sharing obligations (including out-of-pocket spending limits, deductibles, coinsurances, and any reference-based pricing strategies used by the plan). And, because an episode of care typically involves multiple providers and professionals rather than hospital care alone, the payer is uniquely situated to provide patients with accurate and actionable estimates of their potential financial exposure for an entire episode of care. Making hospitals’ payer-specific negotiated rate data available to consumers (and competitors) simply does not provide consumers with useful information as to their expected range of financial exposure or the quality of care provided in different settings.

The Disclosure of Payer-Specific Negotiated Rates in Either Matrix is Not Feasible

The Proposed Rule relies on the erroneous assumption that it is not only feasible for hospitals to generate comprehensive and comprehensible matrices of payer-specific negotiated rates for all hospital items and services (including each service packages, which will vary from payer to payer), but also that the burden of creating such matrices is minimal

³⁵ Health care pricing does not consistently correlate with quality. Hussey P, Wertheimer S., and Mehrotra A. Jan. 2013. “The Association Between Health Care Quality and Cost: A Systematic Review.” *Annals of Internal Medicine*. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4863949/>

³⁶ 84 Fed. Reg. at 39,573, 39,632-33.

because it merely involves the rote extraction of data from accounting and billing systems.³⁷ These assumptions are unquestionably incorrect. At most, sophisticated health systems may have the ability to model out appropriate payment *after* the delivery of services, but because of the complexity of payer-provider contracting and the resulting variability in reimbursement, this modeling capacity does not translate over to the ability to populate a matrix of *tens of thousands* items and services (including service packages) and a second set of matrices of hundreds of “shoppable” items and services plus hundreds of ancillary services provided at each hospital location in any rational or comprehensible manner, as discussed further below. The burdens faced by hospitals that do not have the resources and data systems to model out expected payment would be even more insurmountable.

Hospitals Bill Payers Based on Usual Charges, Not Negotiated Rates

The Proposed Rule appears to assume that hospitals maintain payer-specific negotiated rates in their accounting and billing systems and use these rates to bill third-party payers.³⁸ This is simply untrue. When a hospital bills a third-party payer, the claim form reports the hospital’s *charges, not negotiated rates*, along with codes identifying the services furnished and the patient’s diagnoses. The payer then adjudicates the claim, calculating the applicable payment amount and generating an explanation of benefits. Subsequently, the hospital bills the patient based on the payer’s adjudication of the claim and calculation of the patient’s cost-sharing obligations. Payers, not hospitals, are obligated to adjudicate claims and maintain the requisite processes and systems for doing so, and it is simply untrue that hospitals are required to or customarily bill third party payers on the basis of negotiated rates rather than usual charges.³⁹

³⁷ *E.g.*, 84 Fed. Reg. at 39,576 (“[H]ospital’s billing and accounting systems maintain the negotiated charges for service packages which are commonly identified in the hospital’s billing system by recognized industry standards and codes.”); 39,578 (Payer-specific negotiated rates “are already available, maintained, and in use in hospital billing systems.”); 39,580 (“Most (if not all) hospitals maintain [payer-specific negotiated rate] data electronically because these data are used routinely for billing, and therefore we believe it presents little burden for a hospital to electronically pull and displace these data online in a machine-readable format.”); 39,582 (“To inform this proposal, we considered what data elements are typically included in a hospital’s billing system and which of those elements would result in hospital standard charge data being most transparent, identifiable, meaningful, and comparable.”); 39,583 (“[M]any (if not all) hospitals already keep these data in electronic format in their accounting systems for purposes of, for example, ensuring accurate billing.”); 39,611 (“Additionally, hospitals maintain electronic data on charges they negotiate with third party payers for hospital items and services as well as service packages. As such, we believe that the burden for making this information publicly available is minimal.”); 39,612 (“We believe this will require minimal changes for affected hospitals because the standard charge information [including payer-specific negotiated rates] to be collected is already compiled and maintained as part of hospitals’ management practices and electronic accounting and billing systems.”); 39,360 (“[M]ost (if not all) hospitals actively review, update, and maintain all . . . payer-specific negotiated charges in electronic format in hospital billing systems.”); 39,360 (“[M]aintaining a set of negotiated charge data is part of normal operations for hospitals in order to work with payers and bill patients.”).

³⁸ *See* 84 Fed. Reg. at 39,580 (Payer-specific negotiated rates “are used routinely for billing.”); 39,583 (“[M]any (if not all) hospitals already keep these data in electronic format in their accounting systems for purposes of, for example, ensuring accurate billing.”).

³⁹ Some health systems maintain systems for verifying the accuracy of a payer’s payment, but this involves modeling the appropriate payment amount once all variables (length of stay, drugs and devices used, etc.) are known, and does not translate over to the creation of a simple matrix that assigns a dollar value to each item and service.

Variation in Service Packages Preclude Assigning a Negotiated Rate to Each Service Package

The matrices that would be required under the Proposed Rule would be enormously complex for providers to compile and for patients to navigate because, by and large, payer-specific negotiated rates do not simply map to the items and services found on the hospital's chargemaster (also known as the charge description master or CDM).⁴⁰ The composition of a hospital's inpatient and outpatient service packages will vary between payers and even between the lines of business offered by a particular payer.⁴¹ The differences between service packages are not merely differences between *types* of service packages (e.g., per diem versus a DRG-based payment methodology) but variations in the composition of seemingly comparable service packages.⁴² By way of example, a case rate for a particular procedure for one payer may include items and services A, B, and C, but the case rate for the same procedure with another payer (or with the same payer but a different line of business) may include items and services A, C, J, and K. This variation in the composition in service packages is common for both inpatient and outpatient case rates, including case rates for most "shoppable" services.

Developing a matrix that complies with the requirements of the Proposed Rule would be severely complicated if not impossible in light of the variability between service packages. It is unclear how any crosswalk between individual items and services and the composition of the various service package for particular payers and products could be devised and represented in the proposed matrices. Ultimately, the resulting matrices would be subject to extensive caveats, creating imprecision and consumer confusion. Moreover, disclosure of payer-specific negotiated rates along the lines in the Proposed Rule would not facilitate accurate rate comparisons by consumers given the complexity of any attempt to crosswalk service packages, variation between plan service packages, and inconsistencies in how hospitals endeavor to capture the data.⁴³

Typical Methods of Payer Contracting Preclude a Hospital from Identifying an Accurate Dollar Amount for Various Items and Services.

Even if service packages were comparable enough or could be consistently mapped to items and services in a consumer-friendly manner, certain rate methodologies in payer contracts would make it impossible to input accurate numbers into the matrix. In short, the Proposed Rule relies on the mistaken assumption that payer-specific negotiated rates can be expressed in a static matrix. Hospital's managed care agreements, however, do not typically

⁴⁰ The one exception would be in the rare instance in which the payer and provider have a percent of charges agreement. Under this arrangement, the payer and provider have established a flat percent of charges that will be reimbursed for covered services. Although such arrangements exist, they are anomalous and largely constrained to more rural markets.

⁴¹ It is not uncommon for a single managed care agreement with a payer to include three to seven appendices containing different rates and rate methodologies for different products or lines of business, each of which may change on an annual (or more often) basis, along with the potential for retractive adjustments in the amount due from one party to the other.

⁴² Along similar lines, the same payer may define service packages differently in agreements with different hospitals, with differences arising from variation in volume and typical patient acuity at different hospitals, as well as the parties' relative bargaining power.

⁴³ For example, a patient might mistakenly believe that the difference in payer-specific negotiated rates at two hospitals reflects a real difference in potential payment rates without understanding that one hospital's rate includes the associated high-cost drugs or implants and that the other hospital's managed care agreement provides pass-through or similar separate payment for high-cost drugs and implants. Such differences in service packages are complicated and likely to mislead patients undertaking to compare costs.

set forth simple dollar amounts for each service; instead, they specify payment *methodologies*, which are in essence *negotiated payment algorithms rather than static matrices*. In many cases, the appropriate payment amount for a particular service package cannot be calculated unless and until the delivery of care, and the assignment of any dollar amount prior to the delivery of care would risk overstating or understating the applicable payment amount for that case.

The following discussion provides but a few examples of negotiated payment methodologies that payers frequently include in managed care agreements, but that would preclude assigning a dollar value to a service package.

- ***DRG Tied to Days.*** Some agreements use a DRG-based payment system in which the amount of the payment is tied not just to the DRG but also to the length of stay. For example, for a particular procedure, the provider might receive \$10,000 for days one through three, \$5,000 for days four through six, and then \$2,000 for any additional days. The rationale for varying payment in this manner is that the intensity of care a patient will require declines over the course of the hospital stay. The number of days a patient stays is highly variable and turns on an individual patient's response to the procedure, which cannot be accurately predicted in advance. Furthermore, other hospitals might have a simple case rate for the procedure, precluding accurate price comparisons between the hospitals. For example, if another hospital has a case rate of \$15,000 for the procedure, then the hospital with the DRG tied to days would be \$5,000 less expensive for stays of three days or less, and \$2,000 more expensive for stays in excess of six days. An accurate prospective price comparison between these two hospitals is thus impossible. Moreover, the differences in the two hospitals' reimbursement methodologies with the payers may reflect very real differences in the acuity of patients that the hospitals typically treat, such that any attempt to reduce the DRG tied to days to a dollar amount based on historic data would better reflect the typical acuity mix at that hospital rather than any individual patient's likely cost.
- ***Stoploss.*** Many managed care agreements include a stoploss provision, under which the payment methodology shifts to a percentage of charges after a particular threshold (e.g., total charges or number of days) is met. Some procedures may be more likely than others to exceed the threshold for stoploss payment, and for certain procedures, stoploss may be triggered in the majority of cases. But in any individual case, whether stoploss will be triggered and the dollar amount associated with stoploss would be impossible to predict. It is unclear how this rate would be included in a matrix of rates, let alone reflected in a manner that is understandable to consumers and facilitates comparison shopping. Again, because the typical acuity mix can vary heavily between hospitals, any attempt to reduce the payment amount to a set dollar amount, even based on a median stoploss amount or similar, would reflect typical patient acuity at that hospital rather than any projection of likely cost for a typical patient more generally. This might result, for example, in a high-acuity patient choosing to receive care that is in fact of poorer quality and higher cost based on a misunderstanding that the matrices reflect objective price differences rather than differences in the hospitals' quality and experience with high-acuity patients.

- ***Hierarchy Provisions.*** In some cases, the payment methodologies incorporate a hierarchy provision, under which the payment rate varies depending on the highest hierarchy item or service. For example, the payment rate for a cardiac catheterization plus stent might be paid at a particular dollar amount for the placement of the first stent, a percentage of that dollar amount for the placement of the second stent, and the cost of each stent used, with no additional payment for the placement of the third or subsequent stents. The decision as to the number of stents that will be required and the precise type of stent(s) that will be used cannot be made until the time of the procedure. Because payment for each stent placement is based on the precise configuration of any other stents placed, it would be impossible to calculate any absolute dollar value for the placement of any cardiac stent in this example. Thus, any dollar amount published in a matrix for an item or service that is subject to a hierarchy provision would be misleading to the patient and would not be comparable between hospitals.

The foregoing provides only a few examples of typical managed care agreement rate terms that prevent hospitals from assigning a set dollar amount for items and services (including service packages). ***Because managed care agreements specify payment methodologies (algorithms), not fee tables (static matrices), the FAH understands it would be simply infeasible for hospitals to endeavor to create the static matrices that would be required by the Proposed Rule.*** Moreover, because different hospitals attempting to comply with the spirit of the Proposed Rule would apply different methodologies and input numbers based on differing mixes of patients, the resulting matrices could not be used by patients or referring physicians to compare payer-specific negotiated rates (let alone expected patient cost-sharing amounts) between hospitals.

The FAH also notes that, consistent with the goals of value-based care, hospitals and payers are increasingly negotiating risk-sharing agreements. The Proposed Rule provides no information as to how a hospital that accepts full or partial capitation, receives quality bonuses or is subject to withholds, participates in a clinically integrated network, or otherwise enters into a managed care agreement under which payment varies based on quality, volume, acuity, or a broad range of performance metrics that cannot be accurately projected in advance would be expected to comply with the Proposed Rule. For example, it is unclear if the rule would require disclosure of payer-specific negotiated rates that include both partial risk sharing or value-based payment in addition to a lower fee-for-service payment because no regular payment rate could be identified. Disclosure of only the fee-for-service rates would misleadingly suggest that the negotiated rates are artificially low, which might have unanticipated effects in provider-payer negotiations and might disrupt the marketplace.

Additional Feasibility Concerns for the Matrix of “Shoppable” Services

It is not feasible for hospitals to create and furnish the consumer-friendly matrix of “shoppable” services that would be required under proposed 45 C.F.R. § 180.60 for all the reasons set forth above and because (1) the requirement to identify and include ancillary services associated with “shoppable” services is unworkable, (2) it would be unduly burdensome or impossible to print the matrix within 72 hours of a consumer request, and (3) some hospitals do not furnish 300 “shoppable” services and would be wholly unable to comply.

Under the Proposed Rule, the consumer-friendly matrix of “shoppable” services would also be required to list payer-specific negotiated rates for all associated ancillary items and services customarily provided with each “shoppable” service at each hospital location.⁴⁴ Ancillary services to a procedure are highly individualized and based on specific patient characteristics and needs, thus for many procedures, it is impossible to determine which ancillary items and services are “customarily provided” to a hospital patient generally, let alone to a hospital patient at a particular practice location. This is particularly true for evaluation and management services because the ancillary services provided with the clinic visit at a particular practice location will vary both by the physician’s specialty as well as patient-specific characteristics. In addition, the volume of data points for a “shoppable” service provided at a particular hospital location might be so low as to preclude any assessment of ancillary services customarily provided with the shoppable service at that location. Lastly, the mix of associated ancillary services would vary between facilities based on methodological differences in how hospitals endeavor to comply with the rule, as well as natural variation in what ancillary services each patient requires, such that a patient who would receive nearly identical ancillary services at either hospital might mistakenly believe that there are meaningful differences in the ancillary services he or she would receive in one hospital compared to the other.

Proposed 45 C.F.R. § 180.60(c)(2) would also require a hospital to provide the consumer-friendly matrix of data for “shoppable” services “in written format upon request within 72 hours of the request.” Compliance with this requirement would necessitate printing a matrix with 300 “shoppable” services, plus the associated ancillary items and services for each of the “shoppable” services, along with all payer-specific negotiated rates for each item and service. The associated printing costs would be substantial, and given the size of the matrices, a hospital may need to have printed copies on hand in order to meet the 72 hour time-frame. Printing the entire matrix in response to a request would provide nominal value to the patient who, at best, is only looking at the data associated with a single payer and a single “shoppable” service.

In addition, proposed 45 C.F.R. § 180.20 would define “hospital” based on state licensure status. In addition to general acute care hospitals, this definition would encompass rehabilitation hospitals and long-term acute care hospitals. These hospital types may be licensed under state law as a hospital, but they do not offer 300 “shoppable” services, making compliance with § 180.60(a) impossible. Services provided by these post-acute care hospitals do not meet CMS’s definition of “shoppable” services “as a service package that can be scheduled by a health care consumer in advance. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient thus allowing patients to price shop and schedule a service at a time that is convenient for them.”⁴⁵ As an example, a patient who suffers a traumatic stroke, stays three to four days in the acute care hospital, and requires a 10 to 14 day stay in a rehabilitation unit or hospital immediately upon being discharged from the acute hospital, clearly does not have the time or opportunity to “price shop and schedule a service at a time that is convenient for them.” Put simply, rehabilitation hospitals and long-term acute care hospitals do not provide “shoppable” services, based on the underlying care and clinical trajectories of patients treated in these hospitals. As such, these hospitals cannot effectively report information for “shoppable” services or otherwise comply with proposed § 180.60, further underscoring why CMS should not finalize this proposal.

⁴⁴ 84 Fed. Reg. at 39,642 (proposed 45 C.F.R. § 180.60(b)(3)).

⁴⁵ *Id.* at 39,585.

The Inclusion of Data for Employed Physicians is not Permitted by Statute, Would Create Additional Burdens, and Would Confuse Consumers

The Proposed Rule would also require the disclosure of professional fees and payer-specific negotiated rates for physicians and non-physician practitioners employed by the hospital alongside data for hospital items and services, but Section 2718(e) is specifically limited to the disclosure of the “hospital’s standard charges” rather than professional fees. Since its inception, the Medicare program has distinguished between facility and professional services, and each hospital-employed physician (like all other Medicare-participating physicians) is enrolled separately in the Medicare program using Form CMS-855I (individual professionals) or Form CMS-855B (group practices) rather than being included under the hospital’s enrollment (Form CMS-855A). Section 2718(e) uses the word “hospital” four times, and it is unreasonable to interpret this unequivocal restriction of the disclosure requirement to *hospital* charges for items and services provided by the *hospital* as encompassing professional charges or rates, regardless of the nature of the relationship between the hospital and the physician.

In addition, the burden of expanding the requirements under Section 2718(e) to professional services would be substantial, but the Proposed Rule contains no discussion of the burden of gathering, synthesizing, and including this data. Although the employing hospital bills for the professional’s services, the process for doing so is separate than the process for billing hospital services. In fact, there may be no connection between employed physician/non-physician practitioner billing and hospital billing because the billing and accounting systems are separate, the bill types and data points are distinct, and different staff are responsible for billing for professional services. As a result, any requirement to include this data for employed physicians and non-physician practitioners would significantly increase the compliance costs associated with the price transparency regulations. In addition, the inclusion of this data would be of limited utility for patients because of variation between hospitals’ physician and non-physician practitioner employment practices in a given market and the ongoing turnover among a hospital’s employed physicians and non-physician practitioners. Patients comparing two hospitals may be confused or frustrated by the inclusion of rate information for anesthesiologists, but not radiologists, at hospital A and the converse at hospital B.⁴⁶

The Proposed Rule Grossly Understates the Burdens Associated with the Price Transparency Regulations

As the discussion above indicates, even if HHS had the legal authority to require hospitals to disclose information on payer-specific negotiated rates, which it does not, compliance with the Proposed Rule would be infeasible. Moreover, to the extent hospitals endeavored to comply with the Proposed Rule insofar as might be possible, the costs of doing so would far exceed CMS’ estimate, even for the most sophisticated health systems. The burdens faced by individual hospitals and smaller hospitals that do not have similar data systems and resources would be far greater.

Section 3506(c)(1)(A)(iv) of the Paperwork Reduction Act of 1995 requires HHS to evaluate fairly whether proposed collections of information should be approved and to review

⁴⁶ As HHS acknowledges, it is wholly infeasible for hospitals to report on rate information for non-employed physicians, and HHS lacks the legal authority to impose such a requirement. 84 Fed. Reg. 39,577.

“a specific, objectively supported estimate of burden.” The Proposed Rule, however, provides no objective support for its assumption that each hospital would, on average, only require a business operations specialist to spend eight hours gathering and compiling the required information and posting it to the web in the form and manner specified.⁴⁷ This assessment is based on the mistaken assumption that the gross charge and payer-specific negotiated rate data is “already compiled and maintained as part of hospitals’ management practices and electronic accounting and billing systems.” As discussed above, this is simply untrue. The Proposed Rule requires hospitals to produce tens of thousands of data points in matrices, but reimbursement methodologies are algorithms that are not amenable to production in a static matrix. Even for hospitals with robust data systems, endeavoring to reduce these payment methodologies to a set dollar amount for each item and service, to crosswalk service packages to items and services, to designate the ancillary services for a “shoppable” service at each hospital location, and to identify the charge and rate data for employed physicians, would require significant resources on the order of months of time from multiple full-time employees. Moreover, the Proposed Rule contains no discussion of the costs associated with collecting data for each hospital practice location or the costs of collecting data for the services of employed physicians.

CMS Lacks the Authority to Enforce Section 2718(e) Through Civil Monetary Penalties or Otherwise

In the Proposed Rule, HHS states, without any analysis, that it “interpret[s] section 2718(b)(3) of the PHS Act as authorizing [HHS] to enforce the provisions of section 2718(e).” The history of Section 2718, however, makes plain that HHS’s authority to impose civil monetary penalties under subsection (b)(3) is confined to enforcement of the medical loss ratio (MLR) provisions in subsection (a) and (b). Although subsection (b)(3) references “enforcing the provisions of this section,” it appears that the use of the word “section” is a scrivener’s error that arose when Congress consolidated a stand-alone MLR provision (including the enforcement provision) with other separate provisions into section 2718. What later became the ACA’s MLR provision was first introduced in the Senate and House on September 30, 2009 in stand-alone bills each containing a single substantive section with a subsection providing enforcement authority in language identical to Section 2718(b)(3).⁴⁸ Meanwhile, the “standard charges” language that ultimately was enacted at Section 2718(e) was first introduced in a Senate Finance Committee Bill with no enforcement language.⁴⁹

On December 4, 2009, the various stand-alone provisions were merged into Section 2718 of the ACA, but, through a scrivener’s error, no conforming amendment was made to the enforcement provision in Section 2718(b)(3) and the reference to “this section” remained. With the consolidation of these provisions, the text should have been revised to instead reference only the MLR provisions in subsection (a) and (b).⁵⁰ And, in fact, HHS implicitly

⁴⁷ 84 Fed. Reg. at 39,612.

⁴⁸ Fairness in Health Insurance Act, S. 1730, 111th Cong. § 2 (2009), available at <https://www.congress.gov/bill/111th-congress/senate-bill/1730/text>, and its companion bill H.R. 3681, 111th Cong. § 2 (2009), available at <https://www.congress.gov/bill/111th-congress/house-bill/3681/text>. Section 2(e) of each bill is identical to Section 2718(b)(3) and reads as follow: “The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.” Compare S. 1730 and H.R. 3681 with Public Health Services Act § 2718(b)(3), 42 U.S.C. § 300gg-18(b)(3).

⁴⁹ America’s Healthy Future Act of 2009, S. 1796, 111th Cong. § 1502(b) (Oct. 19, 2009).

⁵⁰ Notably, reading Section 2718(b)(3) as authorizing CMS to enforce the provisions of Section 2718 writ large would lead to absurd results. For example, Section 2718(c) addresses the establishment of uniform definitions by the National Association of Insurance Commissioners, but it would make little sense to read Section

recognized that its enforcement authority should properly be read as confined to enforcing the MLR requirements when it adopted Subparts D through F of 45 C.F.R. Part 158, stating that these provisions “implement enforcement authority in section 278(b)(3) and provide for enforcement of the reporting obligations set forth in section 2718(a) and rebate requirements in section 2718(b).”⁵¹

Calculation and Use of Cost-to-Charge Ratios (II.A.)

In the CY 2014 OPPS/Ambulatory Surgical Center (ASC) final rule with comment period (78 FR 74840 through 74847), CMS created distinct cost-to-charge ratios (CCR) for implantable devices, MRIs, CT scans, and cardiac catheterization. However, in response to public comment, CMS removed claims from providers that use a cost allocation method of “square feet” to calculate CCRs used to estimate costs associated with the CT and MRI APC (78 FR 74847) because of concerns about the accuracy of this cost allocation method. CMS indicated that it would provide hospitals with four years to transition to a more accurate cost allocation method and would use cost data from all providers, regardless of the cost allocation statistic employed, beginning in CY 2018. CMS later extended the transition policy through CY 2019. In the CY 2020 OPPS/ASC proposed rule, CMS is proposing to include those providers that use a “square feet” cost allocation method to estimate costs for CT and MRI beginning with CY 2020.

Including those hospitals that use a “square feet” cost allocation method will have significant impacts on the APCs 5521 through 5524, 5571 through 5573 and 8005 through 8008. While APC 5521 is estimated to increase by 2.0 percent, the decreases for the remaining APCs will range from an estimated 2.2 percent to 14.2 percent according Table 2 of the CY 2020 OPPS proposed rule (84 FR 39408). These reductions are particularly concerning because section 1848(b)(4) of the Act limits the technical component of the Medicare physician fee schedule (PFS) payment to the OPPS payment rate. Therefore, the large reductions in payment under the OPPS could further implicate payment for CT and MRI paid under the Medicare PFS raising concerns about adequate access to these diagnostic services in all settings.

Rather than implement these changes, the FAH requests that CMS examine its methodologies to determine if the OPPS payment methodology is accurately valuing CT and MRI services. Medicare’s Physician Fee Schedule (PFS) payments are determined based on an estimate of direct practice expenses for individual services and a methodology to allocate indirect expenses to individual codes based on surveyed costs of the specialties performing the services. Medicare’s OPPS payments are based on geometric mean costs reported by hospitals on the Medicare cost report using hospital charges from claims adjusted by CCRs. Logically, hospital costs would be expected to be higher than physician costs for the same service because of the higher overhead allocations associated with running a hospital than a non-hospital diagnostic practice due to such factors as hospitals providing a larger variety of services, being required to be in compliance with health and safety regulations, being open 24/7, etc.

2718(b)(3) as permitting HHS to penalize the National Association of Insurance Commissioners for failure to comply with the requirements of subsection (c).

⁵¹ 75 FR 74,864, 74,889 (Dec. 1, 2010).

While a search of the legislative history on the origins and purpose of section 1848(b)(4) of the Act is inconclusive, it is logical that the provision was enacted to address the potential for a flaw in the PFS payment methodology that results in the PFS payment being higher than the OPSS payment. However, the provision works as a one-way valve, e.g. it will reduce the PFS payment to the OPSS payment rate for imaging services implying that the methodological problem must be with the PFS payment being too high rather than the OPSS payment being too low. To our knowledge, the PFS payments for CT and MRIs have been subject to the same scrutiny as all other services evaluated under CMS's misvalued codes initiative. Thus, there is no reason to believe the PFS values for CT and MRI are overvalued relative to Medicare's OPSS payments. However, the FAH does have concerns that the OPSS payments for these services may be undervalued.

Table 3 of the CY 2020 OPSS/ASC proposed rule (84 FR 39408) shows extraordinarily low CCRs for the CT cost center irrespective of the cost allocation method used. The mean CCRs range from 0.0443 for those hospitals using a square feet allocation to 0.0609 for those using a "direct assign" allocation methodology. The median CCR is 0.0359 while the mean CCR is 0.0505. CCRs this low suggest that hospitals mark-up charges over costs by a factor of more than 20 for CT yet the national average CCR for radiology according to the FY 2020 IPSS rule is 0.140 (84 FR 42179). As CT equipment is higher cost than general radiology diagnostic equipment, the charge mark-up over costs for CT would be expected to be lower, not higher than for radiology. These data suggest a problem with the CCRs for the CT cost center and, to a lesser extent with the MRI cost center where Table 3 shows CCRs ranging from 0.0927 (for those using a square feet allocation methodology) to 0.1155. It also bears noting that the FY 2020 IPSS rule shows that MRI and CT have the lowest CCRs among the 19 in the table further suggesting potential problems with the data given that these cost centers would be expected to be high cost with lower than average charge markups.

The FAH recommends that CMS not further reduce the already low payments for CT and MRI under the OPSS by incorporating the CCRs for providers that use a square feet cost allocation methodology until CMS can further study why the CCRs for these cost centers are so low.

Proposed Wage Index Changes (II.C.)

The FAH applauds CMS's recognition of the negative feedback loop the wage index creates for low wage hospitals and supports CMS addressing this problem that disproportionately impacts rural hospitals through an increase to the wage index values of low wage index hospitals. The FAH, however, prefers that CMS implement this policy in a non-budget neutral manner.

Rural hospitals play a critical role in ensuring access to care for the approximately 60 million Americans that live in rural areas across the United States. Dependence on rural hospitals is particularly acute for Medicare beneficiaries—close to one-quarter of Medicare beneficiaries live in rural areas and depend on rural hospitals for care.⁵² Because Medicare beneficiaries disproportionately rely on rural providers to access care, Medicare reimbursement tends to have a greater influence on rural hospitals' revenue as compared to non-rural hospitals. The wage index, however, has aggravated rather than ameliorated

⁵² MedPAC June 2018 Data Book, Section 2: Medicare Beneficiary Demographics (July 20, 2018).

financial problems for many rural hospitals. As CMS noted in the FY 2020 IPPS rulemaking, the wage index has created a “downward spiral” whereby low wage index hospitals receive lower reimbursement, which decreases their ability to invest in recruiting and retaining employees, which then further depresses reimbursement. The FAH, therefore, supports CMS’s proposal to increase the wage index values for hospitals with a wage index value in the lowest quartile of the wage index values across all hospitals.

The FAH, however, prefers that the proposed increase in the wage index values for these hospitals be implemented in a non-budget neutral fashion. This would help ensure that hospitals in the top quartile remain able to respond to market conditions that are largely outside of their control. In addition, a non-budget neutral wage index fix for rural hospitals would ensure that hospitals in the middle two quartiles are not adversely impacted by the adjustment to the lowest quartile of wage index values. Further, the FAH supports CMS’s proposal to adopt a transition wage index to help mitigate significant decreases in the wage index values of hospitals due to the combined effect of the proposed changes to the FY 2020 wage index. While the proposed 5-percent cap on any decrease in a hospital’s wage index as compared to FY 2019 would appropriately limit what would otherwise be significant downward adjustments for certain hospitals in FY 2020, the FAH recommends a longer transition to support hospitals that may continue to experience a significant decrease.

Proposed Adjustment for Rural Sole Community Hospitals and Essential Access Community Hospitals (II.E.)

The FAH supports CMS’s proposal to provide this important payment adjustment. These hospitals are typically the chief, if not sole, source of community outpatient care for rural residents and this adjustment is vital to ensuring continued access to the care they need.

OPPS Payment Methodology for 340B Purchased Drugs (V.B.)

In the CY 2020 OPPS Proposed Rule, CMS proposes to continue to pay ASP minus 22.5 percent for 340B-acquired drugs. The FAH fully supports CMS’s 340B payment policy and agrees it is an appropriate action by the Secretary, as discussed in the FAH’s brief filed on September 10, 2019 with the Court of Appeals for the District of Columbia Circuit.⁵³

CMS notes in the proposed rule various beneficiary and Medicare program benefits arising from its policy, which as CMS has previously stated includes reduced copayments, especially for cancer patients, and a more efficient program that better aligns payment and cost. Our preliminary analysis also indicates a widespread benefit across a vast majority of hospitals paid under the OPPS. For example, some 2785 hospitals – 83 percent of all hospitals paid under the OPPS – would experience a net increase in payment in 2020 under CMS’s 340B payment policy, compared to only 583 hospitals that would experience a net reduction in payments, and 89 percent of rural hospitals would have higher payments. This is especially important as rural hospitals serve as a vital lifeline for outpatient care in the communities they serve, and struggle with Medicare OPPS payments that fall well below the cost of care.

⁵³ Brief of Amicus Federation of American Hospitals, *American Hospital Ass’n. v. Azar*, No. 0:2019-cv-05198 (D.C. Cir. Sep.10, 2019).

Payments increase for 75 percent of government hospitals, and almost half of 340B hospitals – 43 percent – would have higher payments from CMS’s decision to apply to the conversion factor the savings from the 340B payment adjustment. Accordingly, the FAH urges CMS to finalize its proposed policy regarding drugs purchased under the 340B program (and we also support continuation of the current ASP + 6 policy for drugs not purchased under the program).

CMS also seeks public comment on how to structure any potential remedy for CYs 2018 and 2019, in light of ongoing litigation regarding the CY 2018 and 2019 OPPS payment policies for 340B-acquired drugs. In requesting public comment on remedy in the event of an unfavorable decision on appeal, CMS states that “these types of changes to the OPPS must be budget neutral, and reversal of the policy change, which raised rates for non-drug items and services to the tune of an estimated \$1.7 billion for 2018 alone, could have a significant economic impact on the approximately 3,900 facilities that are reimbursed for outpatient items and services covered under the OPPS.” 84 Fed. Reg. at 39,504. The FAH respectfully disagrees with CMS’s assertion that CMS must or may craft a budget neutral remedy for its CY 2018 and 2019 340B-acquired drug payment policy. ***To the contrary, the Medicare Act does not permit CMS to make any offsets to achieve actual or retrospective budget neutrality, and to the extent that CMS is ultimately required to provide relief to 340B hospitals through a prospective payment increase designed to compensate such hospitals for any past underpayments, that payment increase cannot be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made for non-drug OPPS items and services.***

The Medicare Act requires that CMS prospectively adjust payment rates within OPPS in a budget neutral manner to account for the decreased payments for 340B drugs in advance of the commencement of each OPPS fiscal year. See 42 U.S.C. § 1395l(t)(9)(B). Importantly, however, while Congress very clearly intended that budget neutrality be reached within this *prospective* payment system, Congress only required that the Secretary make adjustments to achieve a *prospective* estimate of budget neutrality. To conceive of budget neutrality as a retrospective requirement would wreak havoc on Medicare’s payment systems.

The text of the Medicare Act provides support for the prospective-only nature of the budget neutrality requirement:

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the *estimated amount* of expenditures under this part for the year to increase or decrease from the *estimated amount* of expenditures under this part that would have been made if the adjustments had not been made.

42 U.S.C. § 1395l(t)(9)(B) (emphases added).⁵⁴ Paragraph (9) is entitled, “Periodic review and adjustments components of prospective payment system,” and subparagraph (A), which

⁵⁴ CMS’s statement that section 1833(t)(14)(H) of the Act [42 U.S.C. § 1395l(t)(14)(H)] mandates that “any adjustments made by the Secretary to payment rates using the statutory formula outlined in section 1833(t)(14)(A)(iii)(II) of the Act [42 U.S.C. § 1395l(t)(14)(A)(iii)(II)] are required to be taken into account under the budget neutrality requirements outlined in section 1833(t)(9)(B) of the Act [42 U.S.C. § 1395l(t)(9)(B)]” adds nothing new to and does not alter the prospective nature of the budget neutrality requirement. 84 Fed. Reg. at 39,505. Section 1833(t)(14)(H) of the Act simply refers back to subsection (t)(9)(B) in providing that “[a]dditional expenditures resulting from this paragraph shall not be taken into account in establishing the

triggers the budget neutrality provision, requires the Secretary to review and revise “the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)” not less than annually to take into account various factors and information. 42 U.S.C. § 1395l(t)(9)(A). These statutory provisions describe the OPSS prospective rulemakings CMS undertakes prior to the start of each calendar year. The budget neutrality provision cited above focuses on “estimated” amounts for the coming year. CMS similarly recognizes the prospective nature of this budget neutrality requirement. *See, e.g.*, the CY 2003 Final Rule, 67 Fed. Reg. 66,718, 66,754 (Nov. 1, 2002) (“With respect to budget neutrality, section 1833(t)(9)(B) of the Act [42 U.S.C. § 1395l(t)(9)(B)] makes clear that any adjustments to the OPSS made by the Secretary may not cause *estimated* expenditures to increase or decrease.”) (emphasis added). Thus, while budget neutrality remains a rate-setting requirement guiding adjustments *prospectively*, the law does not permit post-hoc reconciliation or recoupment to achieve budget neutrality *after* actual payments are made to providers. CMS’s statement in this Proposed Rule that the agency is seeking comments on the “best, most appropriate way to *maintain* budget neutrality” therefore misses the mark, as the budget neutrality adjustment authorized under section 1833(t)(9)(B) of the Act [42 U.S.C. § 1395l(t)(9)(B)] speaks in terms of *estimated* amounts of expenditures, and CMS historically has recognized its exclusively prospective purpose. *See* 84 Fed. Reg. at 39,505 (emphasis added).

Likewise, in setting OPSS rates for future years, it would be improper for the Secretary to attempt to recoup payments that resulted from CMS’s lawfully applied and unchallenged 3.2% budget neutrality adjustment. ***Put simply, the Secretary did not err in applying a positive adjustment to non-340B claims in order to achieve budget neutrality in CY 2018 based on estimates undergirding the CY 2018 OPSS Final Rule. Thus, any remedy must not explicitly or implicitly recoup non-340B payments, which were properly made under the CY 2018 and 2019 OPSS Final Rules.***

Critically, the Medicare Act does not generally permit reconciliation between anticipated aggregate payment amounts and actual aggregate payments to achieve budget neutrality in a given payment year under any prospective payment system. Thus, where changes to a prospective payment system produce alleged “overpayments,” these purported overpayments cannot be recouped absent specific statutory authorization. By way of example, the provisions of the Medicare Act establishing the IPPS and the OPSS each contain language authorizing the Secretary to adopt prospective adjustments to the IPPS or OPSS payment amounts to eliminate estimated *future* (but not past) changes in aggregate payments that are due to changes in the coding or classification of inpatient discharges or covered outpatient department services that do not reflect real changes in case mix or service mix. 42 U.S.C. §§ 1395ww(d)(3)(A)(vi), 1395l(t)(3)(C)(iii).⁵⁵ Although the Medicare Act permits CMS to implement prospective adjustments to eliminate anticipated overpayments in future years, 42 U.S.C. § 1395ww(d)(3)(A)(vi), the statute included no authority for CMS to recoup for purported overpayments in prior years until Congress passed the TMA, Abstinence

conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.”

⁵⁵ In relevant part, the statutory language provides as follows: “Insofar as the Secretary determines that [certain IPPS or OPSS] adjustments . . . for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the . . . year that are a result of changes in the coding or classification of [discharges or covered outpatient department services] that do not reflect real changes in [case mix or service mix], the Secretary may adjust [the average standardized amounts or the conversion factor] computed under this [paragraph or subparagraph] for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.”

Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–87 (2007) (TMA), which was later amended by the American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) (ATRA). *See, e.g.*, Hospital IPPS and FY 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any FY 2010 through 2012 “overpayments could not be recovered by CMS [prior to the passage of ATRA] as section 7(b)(1)(B) of Public Law 110–90 [TMA] limited recoupments to overpayments made in FY 2008 and FY 2009.”). No specific statutory authorization for recoupment by CMS of the prospectively set CY 2018 and 2019 OPSS rates exists here.

In addition, as CMS routinely has opined and various courts have agreed, the idea that payment will be made at a predetermined, specified rate serves as the foundation of the Medicare prospective payment systems, of which the OPSS is one. *See, e.g., Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232 (D.C. Cir. 1994); *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996). The D.C. Circuit has recognized these core principles of predictability and finality, finding that “the Secretary’s emphasis on finality protects Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates” and permits hospitals to rely on the predetermined rates and resulting payments made thereunder. *Methodist Hosp.*, 38 F.3d at 1232.

In line with the finality and predictability principles underlying the OPSS, the FAH’s members relied on and already have received reimbursement under the prospectively set payment rates for the outpatient non-drug items and services they provided to Medicare beneficiaries in CYs 2018 and 2019. Any error identified in CMS’s 340B reimbursement rate-setting in the CY 2018 or CY 2019 OPSS Final Rules cannot be imputed to all hospitals nationwide who properly relied on the prospectively set CY 2018 and CY 2019 OPSS payment rates. Likewise, the Secretary cannot remedy any purported CY 2018 or 2019 underpayments for 340B drugs by increasing payments for 340B drugs in a future payment year in a budget neutral manner (*i.e.*, by reducing payments for non-340B items and services) because this would amount to an unlawful retroactive recoupment of CY 2018 and 2019 payments that were properly made to all hospitals under the CY 2018 and CY 2019 OPSS Final Rules.

In sum, the FAH’s member non-340B hospitals relied on and were properly paid under an OPSS payment rate designed to be budget neutral based on CMS estimates. That the CY 2018 and 2019 OPSS payment rates may not ultimately have resulted in actual budget neutrality, whether due to a court decision, fluctuations in service volumes, or any host of other factors, should not (and does not, under the Medicare Act) jeopardize the payments that were made under the prospectively set payment rates. ***Therefore, the FAH would strongly oppose any effort to offset any relief to 340B hospitals or to otherwise achieve budget neutrality by implicitly or explicitly recouping payments made for non-drug OPSS items and services in 2018 and 2019.***

Proposed Payment for Partial Hospitalization Services (VIII.)

The FAH supports the CMS decision to institute a fact specific, data driven policy to establish a cost floor for CY 2020 in its development of hospital-based Partial Hospitalization Program (PHP) rates. As CMS correctly notes after calculating and reviewing its cost data, “we do not believe that is likely that the cost of providing hospital-based PHP services has

suddenly declined when costs generally increase over time. We are concerned with this fluctuation, which we believe is influenced by data from a single large provider that has low service costs per day.” CMS further notes that, “We believe this proposal for CY 2020 rate setting allows us to use the most recent or very recent hospital-based PHP claims and cost reporting data while still protecting provider services.” The FAH has members that provide significant levels of PHP services to Medicare beneficiaries and this proposed rate setting policy will:

1. help ensure that Medicare payment for PHP will more closely approximate the resources expended by hospitals when providing this critical service to Medicare beneficiaries and
2. most importantly, continue to ensure Medicare beneficiary access to this vital Medicare covered benefit that allows improved transition from an acute inpatient setting, which, absent access to the PHP benefit, could have the undesired result of increasing the instances of patient recidivism and acute psychiatric hospital readmissions.

Proposed Changes to the Inpatient Only List (IX.B.)

In the CY 2020 OPPS/ASC proposed rule, CMS proposes to remove total hip arthroplasty (THA; CPT code 27130) from the inpatient only (IPO) list. This proposal follows a solicitation in the CY 2018 OPPS/ASC rule inviting comments on the same subject. CMS summarizes prior comments both in support of and opposed to removing THA from the IPO list. After reviewing the clinical characteristics of the procedure, considering the past public comments, additional feedback from stakeholders and the opinions of its clinical advisors, CMS believes THA meets two of five criteria for being removed from the IPO list: criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments) and 3 (and the procedure is related to codes already removed from the IPO list). A procedure is not required to meet all of the established criteria to be removed from the IPO list.

The FAH opposes the removal of THA and Partial Hip Arthroscopy (PHA) from the IPO List for the same reasons we did two years ago in response to the comment solicitation on the CY 2018 OPPS/ASC proposed rule. First, the patient safety profile of outpatient THA in the non-Medicare population is not well-established. An extensive review and guidelines document about THA released by a large orthopedic professional association in March 2017, did not even examine THA in the outpatient setting as a patient safety/risk factor.⁵⁶ Second, an important subgroup of the THA group requires surgical intervention for treatment of fracture. The urgent surgery subgroup tends to be older and frailer and thereby not well suited to outpatient THA. Related to this finding, we think that evidence supporting the first criterion for removal from the IPO list – most outpatient departments are equipped to provide the services to the Medicare population – is important when considering removal of from the IPO list. Third, all the considerations involving the interface between outpatient total knee arthroplasty (TKA) and the Comprehensive Care for Joint Replacement and Bundled Payments for Care Improvement models also apply to outpatient THA. The combined effect of outpatient TKA and THA could be sufficient to reduce the impact of the CJR model and

⁵⁶ American Academy of Orthopaedic Surgeons, *Management of Osteoarthritis of the HIP Evidence-Based Clinical Practice Guideline*, March 13, 2017

make its evaluation difficult. *The FAH strongly recommends that CMS not finalize its proposal to remove THA from the IPO list.*

Removal of THA and (TKA before it) requires that CMS suspend these measures from relevant quality programs. Finally, the FAH notes that the Hospital Readmissions Reduction Program (HRRP), the Hospital Value-Based Purchasing Program (HVBP), and Inpatient Quality Reporting (IQR) Program include measures of hip and knee arthroplasty addressing readmissions, complications, and Medicare payment during a 30-day episode of care. CMS has already removed TKA from the IPO list. If CMS removes THA from the inpatient-only list, performance on these quality measures will change to reflect the increased complexity of the beneficiaries seen in the inpatient setting. The FAH requests, therefore, that should CMS remove hip arthroplasty in addition to knee arthroplasty from the inpatient only list, it should suspend the hip and knee arthroplasty measures from the HRRP and HVBP programs until performance levels can be recalibrated to reflect the change in patient mix. This is particularly important for the hip and knee arthroplasty measure included in the HVBP Program, where performance for both achievement and improvement points are assessed against benchmarks established during an earlier baseline period.

Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAH) (X.A.)

The FAH supports CMS's proposal to change the minimum required level of supervision for hospital outpatient therapeutic services from direct to general supervision for services furnished by all hospitals and CAHs. CMS discusses in the proposed rule its desire to end what is effectively a two-tiered system of supervision levels for hospital outpatient therapeutic services with a new policy that sets an appropriate and uniformly enforceable supervision standard for all hospital outpatient therapeutic services. We agree with CMS that the proposed policy is more appropriate and uniformly enforceable. Further, as noted in the proposed rule, general supervision has been in effect for small rural hospitals and CAHs, and there is not any data or other information indicating that this level of supervision has affected the quality of the services provided. This is reinforced by the fact that all services furnished to a beneficiary must be ordered by the responsible physician, which helps to ensure oversight and accountability. Also, hospitals remain subject to the conditions of participation (CoPs), and compliance with the CoPs complements the general supervision requirement.

In addition, permitting a general, rather than direct, level of supervision would alleviate undue burden for many hospitals that do not have sufficient staff available to furnish direct supervision, especially due to difficulties in recruiting physician and non-physician practitioners to practice in rural areas. We agree that with respect to critical specialty services, direct supervision by a hospital emergency department physician or non-physician practitioner is particularly difficult because of the volume of emergency patients or lack of specialty expertise. The proposed policy would appropriately address these difficulties.

Finally, we believe the proposed policy should apply across the board to all hospital outpatient services as this would achieve CMS's goal of creating a uniform and enforceable supervision policy. If future concerns were to arise about the level of supervision for certain specified services, we note CMS's discussion in the proposed rule that the Agency

will continue to have the Advisory Panel on Hospital Outpatient Payment (HOP Panel) provide advice on the appropriate supervision levels for hospital outpatient services, and CMS will retain the ability to consider a change to the supervision level of an individual hospital outpatient therapeutic service through notice and comment rulemaking.

Short Inpatient Hospital Stays (X.B.)

CMS is proposing to establish a one-year exemption from certain medical review activities for procedures removed from the IPO list under the OPPI in CY 2020 and subsequent years. As part of this proposal, procedures that have been removed from the IPO list would not be eligible for referral to recovery audit contractors (RACs) for noncompliance with the two-midnight rule within the first calendar year of their removal from the IPO list. These procedures would not be considered by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) in determining whether a provider exhibits persistent noncompliance with the two-midnight rule for purposes of referral to the RAC nor would these procedures be reviewed by RACs for “patient status.”

While CMS’s proposal for a one-year moratorium on RAC review of patient status for procedures removed from the IPO list may be a step in the right direction, the FAH urges CMS to impose a permanent moratorium in deference to physicians’ clinical judgment and in order to reduce rather than exacerbate the problematic and ongoing backlog of pending appeals of denied Medicare claims (that CMS is only beginning to clear).

When an IPO procedure – such as TKA – is removed from the IPO list, often the procedure will continue to be performed on an inpatient basis for clinical reasons. This is due to the physician’s judgment that the procedure should be performed on an inpatient basis for an individual Medicare patient, who may be older, frail, and have multiple complex comorbidities. In these cases, CMS should defer to the physician’s clinical judgment, as it would be inappropriate for RACs, which are paid on a contingency basis, to review these patient status cases and determine whether the physician’s judgment should be overruled.

Notably, with regard to the proposal to remove specific procedures from the IPO list, for example, THA, CMS acknowledges that most surgical procedures need to be tailored to the individual patient’s needs and that patients with multiple medical comorbidities would more likely require inpatient hospitalization and possibly post-acute care. This supports a permanent moratorium rather than the temporary suspension CMS proposes. The FAH urges CMS to defer to the physician’s clinical judgment in deciding on the most appropriate setting for a given patient and permanently restrict RAC reviews of patient status for procedures removed from the IPO list.

In addition, it would be inappropriate for CMS to allow RAC patient status reviews for procedures removed from the IPO list in light of the current backlog of administrative appeals of denied Medicare claims. In November 2018, the DC district court ordered HHS to address the appeals backlog by achieving targeted reductions established by the court between 2019 and 2022. CMS’s proposal to permit RAC review of procedures removed from the IPO list after just a one-year moratorium would exacerbate rather than ameliorate these efforts because it would undoubtedly lead to some increase in appeals of denied claims. In keeping with CMS’s commitment to reduce the appeals backlog and meet the court-ordered targets,

the FAH urges that CMS impose a permanent moratorium on RAC reviews for procedures removed from the IPO list.

Alternatively, at a minimum, CMS could review the data and technology related to a procedure removed from the IPO list, after at least five or more years, to determine whether the procedure is typically performed on an outpatient basis, rather than an inpatient basis. If so, CMS through notice and comment rulemaking could then determine whether to lift the moratorium.

Such a policy would be consistent with the intended purpose of the two-midnight rule which was to provide guidance to physicians and hospitals on when it is appropriate to admit patients as inpatients for services that are commonly performed on an inpatient or outpatient basis. While the FAH urges deference to physician judgment in all cases, the weight of that deference should be highest for procedures recently removed from the IPO list. In the case of THA, CMS proposes removing the procedure from the IPO list on the basis that the “simplest procedure described by the code may be performed in most outpatient departments.” Elsewhere in our comments, the FAH opposes removing THA from the IPO list. Nevertheless, a basis that removal from the IPO list that the simplest procedure can be done in an outpatient department is indicative that the procedure is commonly performed inpatient and only rarely is performed outpatient rendering the two-midnight rule inapplicable relative to the physician’s judgment of the most appropriate site of service.

In the event the moratorium is lifted, CMS should clarify that RACs would only be permitted to undertake such a review upon a referral by a QIO. At present, patient status reviews are initially conducted and managed by QIOs. Only in the event the QIO determines that a provider exhibits persistent noncompliance with Medicare payment policies does the QIO refer the provider to the RAC. The FAH requests clarification that in the event RAC reviews are permitted for patient status for procedures removed from the IPO list, RACs will only become involved in these reviews after a QIO completes the initial review process and determines that referral to a RAC is appropriate, consistent with the current process for patient status reviews.

Additions to the List of ASC Covered Surgical Procedures (XIII.C.)

In the CY 2020 OPPTS/ASC proposed rule, CMS proposes to add TKA to the list of covered surgical procedures in the ASC setting. CMS indicates that TKA meets its established regulatory requirements for being added to the ASC list of covered surgical procedures (e.g. it is a surgical procedure that is separately paid under the OPPTS that would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure). ***The FAH opposes CMS adding TKA to the ASC list. Among other reasons, the FAH notes that beneficiary coinsurance in ASCs will be higher than in hospital outpatient departments and the physician self-referral restrictions do not apply to physician-owned ASCs.***

While CMS is proposing to add TKA to the ASC list, CMS notes that TKA procedures were still performed predominantly in the inpatient hospital setting in CY 2018 (using professional claims data). CMS believes that limits are necessary to ensure that

Medicare Part B payment will only be made for TKA procedures performed when that setting is clinically appropriate. The proposed rule suggests such options as:

- Requiring a modifier that would indicate that the patient's physician believes the beneficiary would not be expected to require active medical monitoring and care at midnight following the procedure;
- Requiring each ASC to have a defined plan of care for each beneficiary following a surgical procedure; or
- Requiring the ASC to have a certain amount of experience in performing a procedure before being eligible for payment.

The FAH does not believe these are suitable options to limit performance of TKA in the ASC to only those situations where it is appropriate. If a physician schedules a surgical procedure in the ASC, by doing so, the physician is attesting to a belief that the procedure would not require active medical monitoring at midnight following the procedure. The modifier would be superfluous to merely scheduling the procedure at the ASC. Similarly, ASCs should already have a defined plan of care post-surgery for each patient that they treat as part of the ASC conditions for coverage (CFC). If those CFCs are insufficient for TKA, the solution is to not add TKA to the list of ASC-covered procedures rather than require additional CFCs that are specific to TKA. The FAH is further concerned about requiring a certain amount of experience in order for an ASC to be eligible for payment. Absent payment, the ASC will be unable to get experience doing surgical procedures. And absent experience, the ASC will be unable to obtain payment. The process of certifying the ASC is how an ASC becomes qualified to perform surgical procedures. Absent that certification, the ASC is unable to perform TKA or any other surgical procedure regardless of experience. ***Given CMS's concern about the propriety of performing TKA in the ASC, the FAH recommends not adding TKA to the ASC list at this time.***

The FAH would like to bring two other issues to CMS's attention that we believe may result in negative financial consequences for beneficiaries and TKA procedures being performed in ASC for patients not clinically appropriate for surgery in that setting: 1) patient coinsurance will be higher in the ASC setting than under the OPSS; and 2) physicians frequently own ASCs and there is no prohibition of physician self-referral to an ASC a physician owns.

Higher Coinsurance in an ASC than the Outpatient Department

Medicare's payment for TKA in an ASC according to Addendum AA of the OPSS proposed rule will be \$8,639.97. The 20 percent coinsurance would be \$1,727.99. While 20 percent of the OPSS payment will be higher than 20 percent of the ASC payment, section 1833(t)(8)(C)(i) limits the copayment for a procedure under the OPSS to the inpatient hospital deductible (\$1,364 in 2019). The beneficiary's copayment will be \$363.99 more in the ASC than in the outpatient department based on the 2019 inpatient deductible. In addition, Medicare's payment under the OPSS is determined under the comprehensive-APC methodology. Medicare's packages payment of all ancillary services into the OPSS payment resulting in no beneficiary coinsurance beyond the inpatient deductible cap. However, in the ASC, Medicare would pay separately for ancillary services that are integrally related to the surgical procedure potentially further raising beneficiary out-of-pocket costs. While the costs to Medicare may be less in the ASC than a hospital outpatient department for TKA, the costs to the beneficiary will be higher.

Physician Self-Referral in the ASC

Designated health services (DHS) are subject to the physician self-referral prohibitions. Services that are paid by Medicare as part of a composite payment for a group of services as a separate benefit (such as ASC services), are not DHS. (66 FR 923, January 4, 2001). As such, there is no prohibition on a physician referring Medicare beneficiaries for ASC services furnished by an ASC that the physician owns.

The combination of higher beneficiary coinsurance and no prohibition on physician self-referral to an ASC that the physician owns is concerning to the FAH. *Until such time as CMS can resolve these issues, the FAH remains opposed to adding TKA to the ASC list.*

Comment Solicitation on Coronary Intervention Procedures (XIII.C.)

The FAH has serious reservations about expanding the list of cardiac services that could be performed in the ASC, such as percutaneous coronary interventions (PCI), without better clinical understanding and evaluation of the adverse clinical consequences for the Medicare population.

CMS seeks comment on procedures that may be candidates for inclusion on the ASC surgical procedure list using a standard that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure ("overnight stay"). PCI involves opening stenotic or occluded arteries by expanding a balloon in the stenotic artery, usually followed by insertion of a stent. Patient monitoring following PCI is to identify and manage potential complications not apparent during the procedure, especially bleeding, vascular access complications, stent thrombosis, acute kidney injury, and arrhythmias. Overnight monitoring is reasonable for a subset of Medicare beneficiaries, who as a group are older and frailer than commercial populations and have significantly greater degrees of comorbid conditions. In addition, PCI procedural complications are often unpredictable, emergent and life-threatening (compared to other ASC procedures) including intervention for bleeding, ischemic or other procedural complications including conversion to an open heart procedure which would require emergent transport to an appropriate facility and place the patient at undue life-threatening risk due to delays, including that associated with transport.

The FAH recognizes that while technology is improving and same-day discharge rates are beginning to increase, same-day discharge rates for patients undergoing elective PCI cases is still the minority of procedures performed in the U.S. Furthermore, access-site and non-access-site-related bleeding complications remain a significant issue, despite the increasing use of radial access, due to the requisite use of potent anticoagulation regimens during the procedure. Lastly, pretreatment of patients undergoing PCI with oral antiplatelet agents is still inconsistent, which increases the risk of ischemic complications including acute stent thrombosis, which also carries life-threatening risk. Therefore, while the incidence of complications following elective PCI has decreased over the years, this is still an intervention of a major coronary artery(s), which is listed as a general exclusion under [42 CFR 416.166\(c\)\(3\)](#) as the intervention directly involves major blood vessels.

Other considerations include the extreme challenges in ensuring high quality outcomes, PCI procedural quality and procedural appropriateness in the ASC setting. ASC settings will likely have smaller clinical and physician teams than hospital-based catheterization laboratories, limiting staff and peer-to-peer oversight. This would also seem contrary to CMS's recent increased focus on a heart team approach to ensure appropriate decision-making by the care team in conjunction with the patient. Indeed, it would seem that a cardiothoracic surgeon would rarely, if ever, be in an ASC lab and therefore would not be able to opine on whether coronary artery bypass surgery (CABG) would be more appropriate than PCI for a given patient.

In addition, hospitals have made great strides in applying appropriate use criteria for PCI and hospital use of preoperative risk stratification derived from the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) CathPCI Registry. These data help to assess and mitigate bleeding risk and prevent acute kidney injury as well as other complications. Patient data entered into the ACC NCDR CathPCI Registry also provides the quality and outcome measures for improvement. We believe participation in the ACC NCDR CathPCI Registry is paramount, independent of procedural location. We are furthermore concerned with whether registry participation will be mandated as well as how the accuracy and completeness of registry data collection and data entry will be ensured in the ASC environment. Lastly, we are concerned as to how clinical performance improvement staff will be resourced in the ASC setting and how these data will be reviewed and incorporated into clinical care.

Although it does not necessarily preclude these proposed changes, the overwhelming majority of US cardiologists have not performed invasive cardiac procedures (diagnostic or interventional) in a non-hospital setting. Consequently, before further action is taken to expand ASC services to include PCI procedures for Medicare patients, CMS should convene expert panels and solicit scientific evidence to support the expansion of the ASC services to include invasive diagnostic and interventional cardiac procedures. Same-day discharge from a hospital setting following PCI is not equivalent to same-day discharge from an ASC setting. Given the inclusion of Diagnostic Cath on the ASC surgical procedure list has been in place less than one year, CMS should study data on quality and outcome measures for these patients prior to adding cardiac procedure types to the ASC surgical procedure list. With less than 5% of Medicare cardiac outpatient cases performed in an outpatient site of care (ASC, Outpatient Cath Lab) today, inclusion of PCI on the ASC surgical procedure list would seem premature without strong evidence and validation either by data from the diagnostic cath patient population or perhaps randomized trials, to suggest the absence of adverse impact on outcomes and impact on this patient cohort. ***Without defined criteria for preoperative risk stratification and standardized thresholds for discharge, the FAH strongly urges CMS to refrain from expanding cardiac services that are permitted in the ASC setting at this time.***

Requirements for the Hospital Outpatient Quality Reporting (OQR) Program (XIV.)

Removal of Quality Measures from the Hospital OQR Program Measure Set

CMS is proposing to remove one measure from the OQR program beginning with the CY 2022 payment determination. The measure OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) was proposed for removal based on removal factor 8: the cost outweighs the benefit of continued use of the measure.

The FAH supports removal of the measure as it requires significant burden to collect and report the data and does not provide substantial benefit. Furthermore, National Quality Forum (NQF) endorsement for this measure has been removed as the developer withdrew the measure from consideration for maintenance and endorsement in 2018.

Hospital OQR Program Measures and Topics for Future Consideration

CMS is asking for comments on the future proposal of the adoption of four patient safety measures that were previously adopted for the ASC quality reporting (ASCQR) Program and subsequently suspended due to concerns on reliance of quality data codes (QDCs) for data submission. The four measures are ASC-1 Patient Burn; ASC-2: Patient Fall; ASC-3: Wrong Site, Wrong Side, Wrong Procedure, Wrong Implant; and ASC-4: All-Cause Hospital Transfer/Admission.

While the FAH recognizes that rare events are important indicators of quality, the FAH cautions CMS to consider the substantial challenges identified in collecting and reporting these measures in the context of its Patients over Paperwork initiative. The FAH believes that clarification on how these measures would be specified for hospitals in order to determine the burden and feasibility of collecting this data is needed. In addition, it remains unclear how hospital outpatient departments (HOPD) can use these data for quality improvement and distinguishing meaningful differences in performance. The FAH notes that the lack of a performance gap was the reason why CMS initially proposed removing the measures from the ASC program beginning with the CY 2021 payment determination. While CMS determined that these rare events were still important to report and did not finalize their removal from the ASCQR program, the FAH cautions CMS in adding additional burden to HOPDs for measures that are known to be of limited usefulness and burdensome to collect. In addition, in consideration of its Meaningful Measures Initiative, the FAH suggests that CMS take into consideration how the current OP-36 measure, Hospital Visits after outpatient surgery, overlaps with ASC-4: All-Cause Hospital Transfer/Admission.

Finally, the FAH believes that the NQF provides a rigorous and thorough review of measures against the measure evaluation criteria as it involves a comprehensive assessment of the measure to ensure its currency with the evidence, ability to drive improvements in patient outcomes, feasibility, reliability, validity and current use. Decisions made by this endorsement body should be considered and prioritized by CMS in the proposal of all measures for the OQR Program.

Request for Information: Quality Measurement Relating to Price Transparency for Improving Beneficiary Access to Provider and Supplier Charge Information (XVII.)

CMS's RFI on Price Transparency in Quality Measurement seeks comment on the availability of and access to existing quality of health care information for third party and health care entities to use when developing price transparency tools and when communicating charges for health care services.

The FAH supports the concept that the presentation of quality and cost/affordability data in tandem is important to relay the value of healthcare provided to the patient, and we support helping consumers make informed decisions. However, despite great expectations placed on price transparency tools as harbingers of lower health care spending, there is little

evidence to support the claims.^{57,58} The health care community understands little about effective ways to present cost and resource use measures to consumers.⁵⁹ What is known is that consumers have expressed greater preference for information on their out-of-pocket costs, as opposed to the total cost of care for individual services.^{60,61,62,63,64,65}

In addition to concerns with price transparency tools, the quality measures used in CMS programs do not provide a clear picture of the care provided by clinicians, hospitals, and other providers. This is evidenced by the ongoing concerns with the CMS Star Ratings – from issues with the individual measures to the methodology used to compile the overall ratings.

For example, there are various issues with using measures that are currently available from the Medicare Quality Measures Inventory. Many of these metrics suffer from substantial validity, reliability, and attribution issues. CMS at times incorporates measures into programs that have not been tested for that care setting or have not been endorsed by NQF and have methodological deficiencies. Many of these measures are also not appropriately risk-adjusted. While the risk adjustment models often adequately address clinical factors, the vast majority do not sufficiently test or incorporate social risk factors. In addition, publicly reported measures can have lag times that render the data too old to be meaningful to a consumer.

Lastly, the association between costs and quality is poorly understood, and there is no consistent evidence of the direction of association between cost and quality.⁶⁶ Assumptions that higher costs indicate an undesirable care delivery experience are inherently flawed and could lead to negative unintended consequences including misleading clinicians and the public on what constitutes reasonable costs.

Convene a Technical Expert Panel (TEP) and Ask Patients What Matters

The concerns raised above are significant and will impede the utility of pricing and quality information for consumers. Prior to moving forward with the release of such information, the FAH urges CMS to convene the health care community for robust discussion and strategy development regarding how best to present this information without suffering the

⁵⁷ Bridges JFP, Berger Z, Austin M, et al. Public Reporting of Cost Measures in Health: An Environmental Scan of Current Practices and Assessment of Consumer Centeredness. AHRQ Comparative Effectiveness Technical Briefs. Mar 2015. Report No.:15-EHC009-EF.)

⁵⁸ Sunita D, Hatfield LA, Hicks AL. Associations Between Availability of a Price Transparency Tool and Outpatient Spending. JAMA. 2016;315(17):1874-1881. doi:10.1001/jama.2016.4288

⁵⁹ Greene J, Sacks RM. Presenting Cost and Efficiency Measures That Support Consumers to Make High-Value Health Care Choices. Health Services Research. 2018 Aug;53 Suppl1 1:2662-2681.

⁶⁰ Blumenthal D., Rizzo JA. Who Cares for Uninsured Persons? A Study of Physicians and Their Patients Who Lack Health Insurance. 1991 Medical Care 29;502-20

⁶¹ Mehrotra A., Hussey Ps, Milstein A, et al. Consumers' and Providers' Responses to Public Cost Reports, and How to Raise the Likelihood of Achieving Desired Results. Health Affairs 31(4);843-51.

⁶² Sommers R, Goold SD, McGlynn, et al. Focus Groups Highlight That Many Patients Object to Clinicians' Focusing on Costs. Health Affairs 32(2):338-46.

⁶³ Yegian JM, Dardess P, Shannon M et al. Engaged Patients Will Need Comparative Physician-Level Quality Data and Information about Their Out-of-Pocket Costs. Health Affairs. 2013; 32(2):328-37.

⁶⁴ Blumenthal-Barby JS, Robinson E, Canotr SB, et al. The Neglected Topic: Presentation of Cost Information in Patient Decision Aids. Medical Decision Making: An International Journal of the Society for Medical Decision Making. 2015; 35(4):412-8.

⁶⁵ Yegian JM, Dardess P, Shannon M, et al. Engaged Patients Will Need Comparative Physician-Level Quality Data and Information about Their Out-of-Pocket Costs. Health Affairs. 2013; 32(2):328-37.

⁶⁶ Hussey PS, Wertheimer S, Mehrotra A. The association between health care quality and cost: a Systematic Review. Ann Intern Med. 2013 Jan 1;158(1):27-34.

unintended consequences that result from 1) providing data that is not important to patients or at an inappropriate level of health literacy, 2) enabling the creation of pools of duplicative, and non-standardized information and 3) misleading through misinformation.

As such, the FAH strongly recommends that CMS convene a TEP to explore existing evidence on whether price information is beneficial to patients, evidence on whether quality information is useful to patients, how pricing and quality data should be combined, and what data should be used.

For example, the TEP should explore whether valid comparisons of quality and costs can be made and how best to make them, including a robust testing process. Evaluations of the value a clinician, hospital, or other provider delivers must accurately represent the quality of care associated with the cost of providing that care and will become increasingly important as CMS moves forward with any price transparency effort.

Leverage the CMS Meaningful Measures Framework; Develop a Framework of Criteria for Measure Selection

The CMS Meaningful Measures framework identifies the highest priorities for quality measurement. Within the set of measures aligned with framework there are basic characteristics that need to be considered. As mentioned above, the quality measures in CMS programs (which are stored in the Quality Measures Inventory), do not always provide a clear picture of the care delivered by clinicians, hospitals or other providers, nor are they always appropriately risk-adjusted – concerns that become even more pressing when linking that quality data to pricing information.

As part of the TEP recommended above, CMS and health care stakeholders should examine the types of quality measures that are best suited for this linkage. For example, patients might find quality information more useful if it is disease-specific and comparable on a regional level (rather than national comparisons). And measures and the resulting data need to be as close to real-time as possible to be reliable and valid and to enable patients to make informed decisions.

The FAH offers the following criteria that should be considered for such measures:

- Meaningful and understandable to patients and consumers;
- Closely linked to processes and structures that are within the control of clinicians and groups (i.e., do not rely on action by the patient);
- Produce a minimum reliability threshold of sufficient magnitude (e.g. 7.0 or higher);
- Represent valid assessments of quality at the attributed levels;
- Transparent and standardized;
- Yield variation in performance scores that would inform clinicians, practices, CMS, and patients on the quality of care provided;
- Capable of measuring and driving change toward meaningful improvements in patient care; and
- Appropriately risk-adjusted or segmented.

Regardless of the criteria used to select such measures, all the methodology, from measure design to risk-adjustment to any statistical weighting, must be transparent, non-proprietary, and standardized.

Volume and Complication Information

CMS also seeks comment on whether there is value in displaying volume and complications of procedures along with charge information for patients, as well as how such information should be displayed. ***The FAH believes the burden on providers to compile and report such data outweighs the utility of such information for patients.***

If CMS were to require this data to be displayed, the FAH believes that volume information would not be useful to patients without also providing them with context for what would be considered high volume or low volume specific to the service provided, based on peer-reviewed evidence. In addition, the reporting would need to be as concurrent or low-latency as possible. An appropriate timeframe would be a rolling 12 months accounting for reasonable variability and reporting a rate of change compared to the prior rolling 12 months; without sacrificing validity and reliability. The period from which the measure was taken must be identified on any dashboard for the public.

The FAH notes there is little evidence to inform on the association between price and complications rates. Current studies focusing on single outpatient procedures have shown modest associations between price and complication rates. Complication rates would need to be thoroughly risk-adjusted, as would the price information, or the data presented appropriately stratified. The reliability and validity of the diagnostic codes used to calculate these rates would need to be thoroughly established across each service line and population.

The FAH believes complication information could also be of limited utility – and could be misleading – to patients given the complexity and nuance of this information coupled with patient health literacy. For instance, complication rates do not inform on whether the procedure was successful, arguably a more important outcome for the patient.

Complication and volume data are not currently reported and would likely need to come from all payer data (not just Medicare data) to be valid and reliable. In keeping with CMS's Patients Over Paperwork Initiative, CMS must consider the additional burden this will place on providers – particularly when there is no evidence that this information will be of any use to patients.

Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); Communication of Cost of Care with Patients

CMS also seeks comment on developing HCAHPS question to assess hospitals and health care providers communication of the cost of care with patients. ***The FAH strongly disagrees with the use of the HCAHPS survey to evaluate provider and supplier communication of the cost of care with patients.***

The FAH, in conjunction with other hospital associations, recently performed an evaluation of the HCAHPS from the perspective of patient experience leaders and found that although experience with billing, such as a patient's out-of-pockets costs, is something about which patients care, it is not a top priority for inclusion in the HCAHPS.⁶⁷ In addition, the

⁶⁷ Salzberg CA, Kahn C, Foster N, et al. Modernizing the HCAHPS Survey; Recommendations from Patient Experience Leaders. Federation of American Hospitals, American Hospital Association, America's Essential Hospitals, Association of American Colleges, Catholic Health Association. July 2019. https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_-_Recommendations_from_PELs.pdf

HCAHPS already suffers from being too lengthy, contributing to the low response rates (e.g., 26% for 2017), which in turn bias the results.

During this evaluation, the FAH interviewed patients regarding their views on whether out-of-pocket costs should be presented in the HCAHPS. The key takeaway from those interviews is that out-of-pocket costs is a separate issue not factored into the hospital ratings of patient experiences as it is not seen as part of the experience of care. Thus, at a minimum, patient perspectives of the role out-of-pockets costs plays into their experience of care, in conjunction with how they prioritize it compared to other topics covered by the HCAHPS survey, should be studied prior to the addition of any additional measure to this survey.

Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy (XIX.)

Changing the Test Results Requirement

CMS proposes to revise the current date-of-service (DOS) policy to specify that the ordering physician would determine whether the results of the advanced diagnostic laboratory test (ADLT) or molecular pathology test are intended to guide the treatment provided during the hospital outpatient encounter. The test would be considered a hospital service unless the ordering physician decides that the test fails to guide treatment during the outpatient encounter. If it does not guide treatment, the test is not considered a hospital service and the billing is done by the lab that performs the test.

The FAH opposes any changes to the test results requirement. At the time the physician orders a test it is not always known if the test result would impact future treatment plans in a hospital outpatient. Whether or not the test will guide future outpatient treatment will depend on the results of the test, which may not be received until after the outpatient encounter is concluded. Given this sequence of events we believe the policy change CMS is considering would create unnecessary confusion and administrative burden in determining whether the performing lab or the hospital should bill for the test. For example, for the physician to provide proper documentation during a hospital outpatient encounter – she would ultimately be required to go back and document on a previous outpatient encounter whether or not the test guided future treatment plans. Because there are no regulatory requirements that the physician must document or provide this type of information, scarce resources and time will be spent trying to gather this information.

Limiting the Laboratory DOS exception to ADLTs

CMS proposes to limit the Lab DOS exception to only ADLTs and will exclude molecular pathology tests.

The FAH opposes the removal of molecular pathology from the Laboratory DOS exception. In general, molecular pathology tests do not guide or impact the care of the patient during the outpatient encounter when the specimen is collected and therefore would not be considered a hospital service. These tests are typically performed following the patient's discharge from an outpatient encounter and in some cases, it may take several weeks for a test result to be received. We agree that more hospitals now have access to and the competency to

perform molecular pathology testing; however, the fact that a hospital can now perform testing should not impact who bills for the test.

Excluding Blood Banks and Blood Centers from the Laboratory DOS Exception for ADLTs and Molecular Tests

CMS proposes to exclude blood banks and blood centers from the Lab DOS exceptions.

In general, we agree that blood banks and blood centers should be excluded, however, the exception should only apply to those tests that impact the blood transfusion within the outpatient encounter. If a blood bank performs molecular testing for diagnostic purposes on blood taken during an outpatient encounter and the testing will not change the outpatient encounter treatment plan, then the blood bank should bill those lab tests directly to Medicare.

Proposed Prior Authorization Process and Requirements for Certain Hospital Outpatient Department Services (XX.)

In the CY 2020 OPPTS/ASC proposed rule, CMS proposes to establish prior authorization for 5 categories of services: 1) blepharoplasty, 2) botulinum toxin injections, 3) panniculectomy, 4) rhinoplasty, and 5) vein ablation. (84 FR 39603). Under the prior authorization process, hospitals would request provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. The prior authorization request would have to include all relevant documentation necessary to show that the service meets Medicare coverage, coding and payment rules.

A claim submitted for a service subject to prior authorization list that has not received a provisional affirmation of coverage would be denied. This denial would include any claims associated with the service, including anesthesiology services, physician services, and/or facility services. Additionally, a service for which provisional affirmation was received may still be denied, based on technical requirements or information not available at the time that affirmation was provided.

Provisional affirmation or non-affirmation decisions would be made within 10 business days (2 business days in the case of an expedited review request where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function). A non-affirmation decision would not be appealable.

CMS indicates that it is establishing prior authorization for these 5 categories of services because the services are most often considered cosmetic and thus are only rarely covered by Medicare; the current volume of utilization far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries; and it is unaware of other factors that may contribute to the volume increases to indicate the services are increasingly medically necessary, such as clinical advancements or expanded coverage criteria.

Medicare Data Does not Support Increasing Utilization is for Cosmetic Reasons

While the procedures that CMS proposes to make subject are often considered cosmetic, there are many instances where these services will be performed for medically necessary reasons. For instance, the second category of services that CMS proposes to make subject to prior authorization is Botox injections. While Botox is frequently used for cosmetic purposes, the FDA approved label has been expanded in recent years to include non-cosmetic indications including: upper limb spasticity in adults (2010), chronic migraines (2010), certain forms of urinary incontinence (2011), overactive bladder (2013) and lower limb spasticity (2016). Source: <https://www.drugs.com/history/botox.html>. These additional FDA approved uses explain why utilization of Botox injections is increasing.

Botox dominates the 5 categories of codes for which CMS proposes prior authorization (57 percent of expenditures; \$94 of \$174 million according to data furnished by Watson Policy Analysis to the FAH). These data further show the leading diagnoses for use of Botox are the following: spasmodic torticollis (an extremely painful **chronic neurological movement disorder** causing the neck to involuntarily turn to the left, right, upwards, and/or downwards) in 2012 and 2013 followed by chronic migraines from 2014 through 2017. These conditions account for the top 3 diagnoses associated with Botox injections since 2015 and far exceed the next frequently appearing diagnoses. The remaining four categories of procedures that CMS proposes for prior authorization appear to have much lower utilization and slower growth than Botox injections. The FAH questions whether there has been uniform growth among these 5 categories of procedures or whether the large growth that is the basis upon which CMS is making its proposal can mostly be attributed to Botox injections for which there is strong evidence the growth is medically necessary and for non-cosmetic purposes.

Patient Health and Well-Being Will Be Affected by Delays in Medical Care

CMS indicates that provisional affirmation will be provided within 10 days of a request and 2 days where a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. The FAH is concerned about the potential for CMS's policy to delay treatment for 10 days where the request may not meet the requirements for expedited review but the patient is still suffering from a painful and debilitating condition such as involuntary neck movements and chronic migraines. In situations where a delay in receiving medical care could seriously jeopardize the beneficiary life, health or ability to regain maximum function, any responsible health care provider will furnish the needed services immediately and not wait 2 days for a response from Medicare. Absent the prior authorization, CMS's proposed policy would deny payment for all services related to the treatment even if the patient had an urgent need for the medical services. While the provider could request a reconsideration or appeal a denial, CMS's proposed policy would force significant administrative burden on a provider in order to receive payment, even in the most urgent of medical situations. *The FAH strongly advises that CMS reconsider its proposal given the potential impact payment to providers and the health and welfare of patients that would result from delays in receiving needed medical services.*

Burden Will Exceed CMS's Estimates

CMS estimates that the average time for office clerical activities associated with making a prior authorization request will be 30 minutes and postage costs will be \$5. The

FAH has concerns about the potential transfer of medical records and further delays that will occur as a result of the using a mail process to transmit records although CMS does acknowledge that most prior authorization requests will not be sent by mail. However, CMS does not indicate any process other than mail by which a prior authorization request would be made. The lack of detail on the mechanics of the prior authorization review process make it difficult to evaluate CMS' time estimates.

While the rule says that the 30-minute time estimate is equivalent to that for a normal prepayment or post-payment medical review, CMS provides no source or explanation for this conclusion. Prepayment review will take far longer than 30 minutes and involve more than \$5 in postage as it typically involves sending medical records for all claims within a certain time period (typically 3 months) to the contractor. The FAH does not believe that prepayment review provides a useful comparison upon which to base a time estimate for prior authorization.

Post-payment review may be similarly inapplicable for a comparison to the time that will be required to make a prior authorization request as post-payment medical review is a comprehensive review of individual beneficiary medical records, conducted either onsite at the hospital, or the Medicare contractor's medical review department. Such reviews take significantly in excess of 30 minutes and similarly not a basis for comparison to a prior authorization process.

Absent more information from CMS, the FAH cannot estimate how much time it will take to submit a prior authorization request. Nevertheless, it seems likely that compiling medical records and interacting with a contractor that will be undertaking the prior authorization is likely to take longer than the time estimates CMS provides and will distract a busy medical office from other activities necessary to provide ongoing patient care.

Comment Solicitation on Cost Reporting, Maintenance of Hospital Chargemasters, and Related Medicare Payment Issues (XXI.)

Use of Chargemaster Charges

In Part XXI of the Proposed Rule, CMS solicits “public comments on the continued value of the chargemaster charges in setting hospital payment and to other stakeholders.”⁶⁸ Notably, the hospital chargemaster is used outside the Medicare program, including for out-of-network and cash-pay patients as well as part of commercial payers payment methodologies. Although percent of charge payment methodologies are no longer common, they still exist, and many commercial payer agreements include stop loss or outlier provisions that convert to a charge-based payment methodology for certain high-cost cases. Moreover, hospitals are required to maintain a public list of the hospital chargemaster under Section 2718(e) (discussed in the context of price transparency, above) and various state laws. In light of the many varied purposes served by the hospital chargemaster, there does not appear to be a readily available path to move away from the maintenance and use of the hospital chargemaster.

CMS's request for comments does not indicate the problem or problems that could be addressed by considering an alternative to using chargemaster charges or the potential goals

⁶⁸ 84 Fed. Reg. 39,609.

of such a change. Without understanding CMS's goals and concerns, it is difficult for stakeholders to meaningfully respond to this comment solicitation. In the past the FAH and the HHS Office of the Inspector General have identified issues involving the increasing concentration of inpatient outlier payments among a relatively small number of providers, but this does not appear to arise from an inherent problem with the use of charges reduced to costs as opposed to other payment methodology issues.

In terms of possible alternatives, the FAH is aware of various exploratory proposals that have arisen around charge-based payment, but is concerned that these models may not in fact produce lower burdens and greater benefits compared to current payments based on charges reduced to costs. For example, one such model would require cost-reporting at the patient level, which would raise patient privacy concerns as patient-level information would be included in the hospital cost report. Moreover, such a model would require significant reconciliation activities, potentially eroding the prospective nature of our Medicare payment systems in favor of retrospective reconciliations. Instead of pursuing radically different alternatives to the current use of chargemaster charges in setting hospital payment in some areas, the FAH urges CMS to explore opportunities to improve the current system through incremental modifications to the rules that improve payment accuracy or otherwise address appropriate concerns without imposing additional operational burdens and costs on providers.

Modernizing the Cost Reporting Process

CMS further indicates it is “seeking public comments on whether it would be possible to modernize or streamline the Medicare cost reporting process, for example, by replacing it with other processes or if it could be modified in content, methodology, or approach.”⁶⁹ We believe that any effort to simplify the cost report should be designed to achieve the following goals: (1) reduce the cost and effort involved in its completion, (2) allow submission in a shorter time frame than currently provided by regulation, (3) allow providers and CMS to focus resources on creating and supporting systems that accurately report items that impact reimbursement areas that are actually settled in the cost report and (4) lower the costs to CMS in regulating and auditing the cost report function.

Consistent with the principles noted above, we believe CMS should consider taking the following steps in its efforts to simplify the acute care hospital cost report:

- A. Simplifying the cost report process will be a very technical and detailed process. CMS should assemble an expert panel to work through specific issues. The panel should include strong representation from the provider community;
- B. The initial focus on simplifying the cost report should focus on providers and programs that have limited reimbursement impact (e.g., IPPS hospitals versus Critical Access Hospitals) and require significant effort to complete in the current cost report;
- C. Cost report simplification should be budget neutral from a payment prospective at the provider level. A provider's budget neutrality factor could be developed by comparing the initial period of the simplified cost report data to the current cost-reporting forms; and

⁶⁹ *Ibid.*

D. CMS should look for opportunities to utilize one source of data for similar purposes. An example is Worksheet S-10 for UC DSH and Medicaid DSH payments.

We considered specific items for cost reporting simplification. For example, we believe that some cost centers (*e.g.*, various overhead cost centers) could be merged with little impact on payment accuracy, while otherwise satisfying the goals set forth above. CMS should consider reducing the number of revenue-producing cost centers, which CMS has increased by at least three over the last decade. The focus of cost reporting should be on significant revenue producing cost centers and a better alignment of revenue codes with those cost centers.

We also considered and rejected the notion of moving to financial and GAAP-based reporting instead of cost reporting. We rejected this approach because we know that hospital financial reporting systems are not as consistent between provider organizations as Medicare cost reporting principles. Such systems would need to be heavily audited by CMS to ensure consistency in data reporting as a useful tool in setting rates. We also rejected the elimination of cost reclassifications and A-8 adjustments because these are useful tools to ensure that non-program costs are not reported in Medicare program data used for rate setting or other payment mechanisms.

The FAH appreciates the opportunity to submit these comments. If you have any questions, please contact me at 202-624-1534, or Steve Speil, Executive Vice President, at 202- 624-1529.

Sincerely,

A handwritten signature in black ink, appearing to read "Steve Speil", written in a cursive style.