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The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health,
Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
U.S. Senate Committee on Health,
Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray,

The FAH appreciates the opportunity to comment on the bipartisan discussion draft on legislation to reduce health care costs released by the leadership of the Committee on Health, Education, Labor & Pensions (HELP) on May 23, 2019. The 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, short-stay, rehabilitation, long-term acute care, psychiatric, and cancer hospitals in urban and rural America, and they provide a wide range of acute, post-acute, and ambulatory services.

We appreciate the opportunity to comment on the policies set forth in the discussion draft and share your commitment to exploring ways to lower costs in America's health care system.

TITLE I: Ending Surprise Medical Bills

Patient Protection

We support a federal legislative solution and believe it should protect the patient financially, ensure patient access to emergency care, remove the patient from health plan/provider payment negotiations, preserve the role of private negotiation, ensure access to comprehensive provider networks, and support state laws that work.

To that end, policy solutions must have patients at their center, and we support the draft's intent to prohibit balance billing and hold the patient to in-network cost-sharing in circumstances where the patient has no reasonable control over the network status of the providers administering care. Additionally, we appreciate that the draft makes further provisions to ensure payments made by the patient are counted towards the patient's in-

network deductible and that it removes the patient from the health plan/provider payment negotiation by requiring the plan to make the payment directly to the provider. These provisions will provide the protections required to solve this problem for patients.

Provider/Health Plan Payment

Mediation/Arbitration

While we believe preserving provider/plan negotiation is the most appropriate process for solving payment disputes, we do believe there are other market-based solutions available to help determine provider/health plan payment in these instances. A number of states have implemented the use of mediation and/or arbitration to settle these payment disputes with great success.¹ We believe that such a dispute resolution process that allows a neutral third party to mediate or determine fair payment is far superior to the other two options provided in the draft.

Should the Committee move toward an arbitration process, such as those in Florida or New York, at a minimum, such process should include:

- Time limited private payment negotiation (e.g., mediation) between the provider and health plan prior to arbitration;
- Provider-initiated, voluntary arbitration with the losing party incurring the cost of the arbiter;
- Allow arbiter access to all appropriate information relevant to private sector negotiations;
- Aggregation (“batching”) of any claims between the same provider and health plan;
- An independent arbiter, free of conflicts of interest, with an understanding of health care and the local market;
- Confidentiality of payment amounts determined through the arbitration process; and
- No Judicial review of the payment amount determined through the arbitration process.

As demonstrated in the states where it has been implemented, such a system is an efficient means to settle disputes, will not result in increased health care costs, and will likely see diminished use as providers and plans understand the likely outcome of the dispute resolution process and settle disputes on their own.

Price Setting

We oppose policy options that include setting government prescribed prices. Such a policy will upend private payment negotiations between providers and health plans with ramifications far beyond the narrower issue the legislation seeks to cure.

¹ The recently-passed legislation in Texas is a good example of a hybrid approach – utilizing mediation for hospitals and arbitration for physicians. Florida utilizes provider-initiated, voluntary arbitration for hospitals and physicians, while New York utilizes arbitration for physicians.

Setting a payment through a plan driven, non-transparent process disincentivizes plans from creating comprehensive networks – contrary to the preferred outcome, and harmful to patients. The payment ceiling would allow plans to engage in inappropriate “gaming” by refusing to network or removing from networks providers with negotiated rates above the payment set by the draft. For example, if a provider has a negotiated rate above the set payment, the plan can save money by refusing to contract with that provider and paying the lower, out-of-network rate. Instead of incenting plans to negotiate network agreements with providers in good faith, the payment ceiling will be used as inappropriate leverage and have outsized influence not only on the small part of the market the legislation intends to address but on in-network payment and contracting across the country.

We also anticipate that costs will be shifted onto hospitals as we seek to ensure appropriate staffing of our facilities and meet our obligations to provide emergency medical care as required by the Emergency Medical Treatment & Labor Act (EMTALA). We strongly oppose any policy that includes such a set payment given the considerable harm it would impose on our hospitals and patients.

Network Matching/Bundled Payment

This is an overly complex, untested approach that will fundamentally change the relationship between hospitals and their physician partners and on its own, it will have no impact on protecting patients from surprise bills. It is, however, an approach that allows insurers to abdicate their fundamental responsibility – to design and build provider networks for patients.

Surprise bills are a direct result of a lack of negotiated contracts between the patient’s insurer and the hospital and/or physicians that provided their care. We support solutions that focus on arriving at a fair payment from an insurer to a provider while protecting patients from the consequences that can arise when an insurer lacks adequate contracted providers.

Such a policy prescription simply allows insurers to transfer to hospitals their responsibility for establishing comprehensive physician networks and managing the associated financial risk while also exposing hospitals to potential legal risk as they seek to impose network requirements on their non-employed physicians.

Notification

We are concerned that the draft policy’s notification requirements are misplaced. In the event that an individual seeks care at an out-of-network emergency department, we support protections for that patient from balance billing and from cost-sharing beyond that which the patient would pay in an in-network setting. At the point at which that patient may require post-stabilization services, it is imperative that the patient’s insurer fulfill its role and actively engage in finding and securing patient care at an in-network facility as is the case in states like California.² Should a patient choose to remain in the out-of-network facility, that choice should be informed by a good faith estimate of the patient’s expected responsibility.³

² Under California law, the health plan, once contacted by the hospital, is responsible for identifying an in-network facility to which the patient should be transferred and for arranging the transfer to such facility unless the health plan authorizes the post-stabilization care to be provided at the out-of-network hospital. Additionally, to the extent a health plan does not respond to a request by an out-of-network hospital within a specified period

In these situations, the hospital providing emergency care on an out-of-network basis is in no position to fully understand a patient's insurance network and those facilities that may be in- and out-of-network based on the patient's insurance coverage. We believe that a patient should have the choice to seek care at an in-network facility but oppose the draft's requirement that the hospital be the conduit for making that choice. A patient's insurer is in the best position, and has the responsibility, to assist the patient in successfully identifying and transferring to an in-network facility.

TITLE II: Reducing the Prices of Prescription Drugs

The price of prescription drugs has rapidly increased over the past several years. These price increases have negative impacts throughout the health care system. They not only threaten patient access to drug therapies, but also challenge providers' ability to provide the highest quality of care. Drug costs also are a major factor in the rising cost of health care coverage.

Hospitals bear a heavy financial burden when drug costs increase and must make tough choices about how to allocate scarce resources. Managing these rising costs forces difficult choices between providing adequate compensation to employees; upgrading and modernizing facilities; purchasing new technologies to improve care; or paying for drugs, especially when these price increases are not linked to new therapies or improved outcomes for patients.

With the American Hospital Association (AHA), the FAH completed a report this year that found that hospital budget pressures resulting from the continued dramatic increases in drug prices have negative impacts on patient care, with hospitals being forced to delay infrastructure investments, reduce staffing, and identify alternative therapies. Hospitals also struggle with drug shortages, which can disrupt typical work patterns and patient care, and often require significant staff time to address.⁴

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between FY2015 and FY2017.
- Outpatient drug spending per admission increased by 28.7% while inpatient drug spending per admission increased by 9.6% between FY2015 and FY2017. This 9.6% increase was on top of the 38% increase in inpatient drug spending between FY2013 and FY2015 included in the previous report.
- Very large percentage increases (over 80%) of unit price were seen across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in four hospitals had to cut staff to mitigate budget pressures.

of time (as described in the law) to transfer such plans enrollee, the post-stabilization care is deemed authorized and the plan is responsible for the hospital's charges. (California Health and Safety Code Section 1262.8)

³ See later comments to Section 309 to describe the parameters of such estimate which encompasses an estimate of those services typically expected to be delivered by the provider.

⁴ https://fah.org/fah-ee2-uploads/website/documents/AHA_Drug_Pricing_Study_Report_FINAL_01152019.pdf

- Almost 80% of hospitals found it extremely challenging to obtain drugs experiencing shortages, while almost 80% also said that drug shortages resulted in increased spending on drugs to a moderate or large extent.

We appreciate the Committee's leadership in developing the draft legislation and support its provisions. It is important that public policy continue to support the development and availability of generics and biologics and we appreciate the provisions in the legislation that seek to make these products more widely available.

Along with the provisions in the draft legislation, we encourage the Committee to consider inclusion of additional policies in the bill with broad bipartisan support – such as the CREATES Act.

TITLE III: Improving Transparency in Health Care

Section 301 – Increasing Transparency by Removing Gag Clauses on Price and Quality Information

The FAH urges the Committee to remove Section 301 as it is unnecessary in light of Sections 309 and 501 and current health insurance plan access to claims and encounter data and could have significant and unpredictable competitive impacts. First, regarding de-identified claims and encounter data, health insurance plans already have access to this information for each enrollee in the plan. Second, while the draft legislation states that a contract between a provider and health plan can restrict public disclosure of the information covered by this Section, prohibiting contractual clauses that restrict the disclosure of provider-specific cost information to the individuals (e.g., enrollees, eligible enrollees, referring providers) and entities (e.g., referring providers and business associates) described in the draft text amounts to a public disclosure – and could have the same negative effects. Such a practice would run contrary to guidance from the Department of Justice (DOJ) and Federal Trade Commission (FTC) concerning the sharing of pricing information. Economists and antitrust enforcers have long recognized that the disclosure of negotiated provider network rates could discourage and distort competitive price negotiations. In fact, the DOJ and FTC's antitrust safety zone for pricing surveys specifically cautions against the use of current pricing data.⁵

There is a distinct benefit to ensuring that patients only receive an estimate of their patient cost-sharing amounts and information concerning a provider's financial assistance and charity care programs rather than broader information, such as charges or allowed amounts. First, providing more generalized information concerning the payer-provider relationship instead of focusing on patient-specific information increases the likelihood that competitively sensitive pricing data will be aggregated from price estimator queries, creating unexpected and anticompetitive market distortions in the name of transparency. Second, in the experience

⁵ Department of Justice and Federal Trade Commission, Statement on Provider Participation in Exchanges of Price and Cost Information (Aug. 1996). Potential harm to competition might also arise from disclosures of pricing information in connection with referrals. ONC asks whether, for example, health IT developers should be required to include a mechanism for providers to have access to price information connected with referrals. This process, however, would create the potential for current rates to be shared between two competitors where, for example, the referring provider and the receiving provider offer some of the same services, but the receiving provider also offers some additional advanced diagnostic or treatment modalities. The creation of such a mechanism could be used by a competitor to gain access to confidential pricing information, to the detriment of competition.

of our member hospitals, relatively few patients indicate an interest in obtaining pricing information, and where they seek this information, patients are largely focused on obtaining cost-sharing estimates for financial planning purposes rather than comparison shopping purposes. Moreover, patients show little interest in the amount a third-party payer will reimburse the provider, and instead are focused on their own copayments, coinsurance, and deductible obligations. Therefore, there is little patient benefit to be derived from providing information other than an estimate of the patient's expected cost-sharing obligation, and the provision of additional, unnecessary information creates significant risks of market distortions and patient confusion. Hospitals and health systems support providing patients access to their estimated out-of-pocket cost-sharing and suggest doing so through the provisions in Sections 309 and 501. The FAH's comments on those Sections can be found below.

The FAH also has concerns about the accuracy and stringency of the quality of care information contemplated in the current draft. Every health plan uses different quality metrics, which often contain significant inaccuracies. This variation coupled with the inaccuracies would lead to individuals and entities receiving information that is not useful – and may be detrimental to their decision-making process.

The FAH urges removal of Section 301 given the considerations detailed above. Should the Committee move forward with this Section, however, the FAH strongly recommends the following minimum changes to the current draft. First, any provider-specific quality of care information must be accurate and based on nationally recognized standards. Second, the Committee should focus its efforts on accurate “cost-sharing information” rather than “cost information” to ensure patients receive the information they desire and are not confused by unnecessary additional information. Third, the FAH is concerned that health insurance plans could share information with a business associate or other individual or entity that is not held to the same confidentiality and/or deidentification requirements. This business associate or entity could then work to re-identify the data for its own purposes, essentially resulting in provider-specific cost data entering the public sphere thereby being shared with a competitor, with the associated anticompetitive effects. As such, the prohibition on public disclosure should also apply to business associates and any other individual or entity that is obligated by law or contract to maintain the confidentiality of any trade secrets or proprietary data. Lastly, the Section should clarify that the health care provider is not prohibited from charging a fee associated with the health insurance plan's electronic access to de-identified claims and encounter data to account for the infrastructure required for such transactions on the part of the health care provider.

Section 302 – Banning Anticompetitive Terms in Facility and Insurance Contracts that Limit Access to Higher Quality, Lower Cost care

The FAH urges the Committee to remove Section 302 as it is both unnecessary and a significant and unprecedented government intrusion into private negotiations and contracts. This draft provision incorrectly presupposes that certain terms in contracts are anticompetitive and detrimental to consumers. It is also particularly concerning in light of the proposed options to address surprise out-of-network medical bills, which would further incentivize health insurance plans to further narrow networks by not contracting with health care providers and instead paying those providers the out-of-network rate determined under the surprise billing provision.

The concerns that Section 302 are trying to address – predatory business practices and ensuring competition – are already more than adequately covered by existing law – namely Antitrust laws. These laws protect consumers from contracts that favor an entity over the consumer, and the Department of Justice (DOJ) and the Federal Trade Commission (FTC) already have the authorities and resources to investigate and pursue such arrangements. The basis for insurance networks are insurance plan and health care provider negotiations – and those negotiations must be permitted to continue to ensure that plans and providers can determine the scope and the pricing of the contracts, including volume-based discounts. For example, narrowing the scope of these contracts would require constant negotiations between health plans and hospitals and health systems for each provider type in each specific locale – an expensive, arduous, and unnecessary process.

The FAH also believes the “additional requirement for self-insured plans” contained in this draft Section is unworkable. This provision would enable self-insured group health plans (i.e., employers) to avoid financial responsibility for services provided to their enrollees/employees and for which the employer’s third-party administrator (TPA) negotiated a contract. If the contract between a health care provider and the TPA does not bind the employer’s self-insured group health plan, then the TPA could argue that it does not have to pay for the services provided because it was acting on behalf of the employer, while the employer could argue that it does not have to pay for the services provided because it cannot be bound by the terms of the contract. If a TPA is representing the interests of a self-insured group health plan, then the group health plan/employer should be bound by the terms of any contract between that TPA and a health care provider. To do otherwise would unfairly penalize health care providers who negotiated in good faith.

Given the significant concerns raised regarding this Section, the FAH urges its removal. Instead, the Committee should permit the market to work and recognize the current and appropriate DOJ and FTC authorities to investigate and pursue arrangements in which an entity inappropriately uses its market power in a way that negatively impacts consumers.

Section 303 – Designation of Nongovernmental Nonprofit Transparency Organization to Lower Americans’ Health Care Costs

The FAH recognizes the utility of All-Payer Claims Databases (APCDs) in collecting claims for purposes of quality improvement and certain deidentified pricing and payment information. The FAH urges caution, however, with the expectation that such an entity will lower health care costs. Experience with APCDs has been variable depending on participation in the APCD, comprehensiveness of the data included, and available uses and security of the data. Of the 18 states that have implemented APCDs, many have experienced data completeness and accuracy issues. The FAH is also concerned about the privacy and security considerations raised by APCDs, including the appropriate maintenance of and access to this sensitive patient information.

The discussion draft raises several questions regarding how the data collected would be used. For example, the requirements provision details how the database established under the legislation would be used to, among other things, improve quality and promote competition based in part on quality. Given claims data is not the only data source used for informing on quality, the FAH is interested in understanding if the intent was for the database also to hold quality data beyond that which can be found in claims data and by what nationally recognized standards any quality analysis undertaken by the entity would be

conducted. In addition, the FAH is unsure of the intent behind the uses for and authorized users of the data in the draft Section. For example, the language describes three uses – research, quality improvement, and cost-containment – but the language does not clearly limit the uses to those three. And, while the language describes several potential authorized users, it does not limit the types of authorized users. The FAH also seeks clarification on why the requirements section differs depending on whether data is used for research or for quality improvement and cost-containment. Lastly, the FAH seeks clarification on the extent to which the contracted entity would be required to create and make public additional reports outside of the annual report. For example, as drafted, it is unclear whether the contracted entity could make available or sell to authorized users reports generated by the contracted entity or whether all such reports would be made public.

The FAH notes that the current language does not include any health care provider representative on the Advisory Committee and urges the Committee to correct this oversight. The FAH also urges the Committee to add legislative text to ensure that the nonprofit entity selected by the Secretary is free of conflicts and does not have any relationship or affiliation with a health insurer.

Section 304 – Protecting Patients and Improving the Accuracy of Provider Directory Information

The FAH has long called for improvements in insurers’ provider directories and has commented on this issue in response to several annual Medicare Advantage Advance Notices and Call Letters. While the FAH appreciates the Committee’s attention to this issue and supports efforts for improvements in this area, we are concerned that the draft legislation significantly misplaces the responsibility and burden for those improvements and does not account for how insurers and hospitals already communicate regarding network status.

As currently drafted, the provision would penalize health care providers for inaccuracies on the part of the insurance plan and would do nothing to encourage insurers to make improvements to their directories. The responsibility for creating, maintaining, and updating insurers’ provider directories lies entirely with the insurers. Just as an insurer is responsible for having an adequate network – and that agreement is between the insurer and the insurer’s enrollees – so too is an insurer responsible for accurately conveying information about that network to its enrollees. As discussed in more detail below, insurers are always able to know the network status of and contact information for any providers with whom they contract. As such, it is inappropriate to place the requirements for providing refunds to insurance enrollees, as well as civil monetary penalties (CMPs), on health care providers.

As drafted, the legislation also mistakes how insurers and hospitals currently communicate regarding network status. The in-network contract between the hospital(s) or health system and the insurer contains the address and contract information of the hospital(s) or health system. Should the hospital’s or health system’s address or contract information change, that information would be communicated to the health insurer and reflected in an amended contract. There is no need for the hospital or health system to regularly check in with the insurer regarding the address and contact information because that information does not change unless the change is also reflected in the contract. Simply put, the insurer always has access to the current address and contact information via the contract and can reference it at any time. Creating a requirement that the health care provider verify its information in an insurer’s directory (which would amount to verifying that information in every insurer’s

directory in which the provider is listed) at least every six months places an unnecessary burden on the health care provider for information that is already easily accessible to the insurer.

The FAH urges the Committee to amend Section 304 to appropriately place the requirements and associated penalties for insurers' provider network directories with the responsible entities – the insurers. Specifically, the group health plan or health insurance issuer should be required to reimburse the enrollee for any amounts the enrollee pays beyond the in-network cost-sharing amount. In addition, because the enrollee relied on the insurer's inaccurate provider directory and inadvertently received an out-of-network service, the enrollee may face a situation in which the insurance plan refuses to pay the provider for the service. Thus, the group health plan or health insurance issuer should bear the responsibility for reimbursing the health care provider for any bill that may remain after the patient pays her in-network cost-sharing. Likewise, the group health plan or insurance issuer should also be the entity subject to CMPs for violating the provider directory, cost-sharing, and enrollee and health care provider reimbursement requirements. To do otherwise would financially penalize health care providers for the failures of insurers and would not achieve the Committee's goal of requiring insurers to maintain and update their provider network directories.

Section 305 – Timely Bills for Patients

List of Services Provided

The FAH appreciates the Committee's goals of providing patients with information about the care they have received and their cost-sharing obligations. The FAH does not believe, however, that requiring facilities and practitioners to provide patients a list of services rendered during a visit at the time of discharge will advance those goals. For years now, health care providers have worked to streamline and simplify bills to help consumers more easily understand the information they most want after receiving services – their cost-sharing obligations. Providing a list of services rendered during a visit or potentially lengthy hospital stay is the opposite of streamlined and simplified – leading to confusion for patients while not providing them the final cost-sharing information they desire.

In addition to resulting in patient confusion, as drafted, this provision is operationally infeasible for hospitals and health systems. Given the variety of services that can be provided by numerous practitioners during a hospital visit – particularly during inpatient hospital stays – hospitals and health systems do not have the information necessary at discharge to provide a list of services rendered during the visit. For example, it often takes several days for the physician services or other services (e.g., contracted dialysis services) to submit their information to the hospital. The FAH also believes this provision would delay patients being discharged from facilities while that information is compiled – resulting in patient frustration and increased health care costs.

The FAH recommends amending this provision such that health care providers would provide a list of services upon request from the patient, recognizing that fulfilling such requests would take at least a few days to ensure the necessary information has been received from the treating practitioners. This process would still provide the information to patients who desire it while not delaying patient discharges and recognizing hospitals' and health systems' operational considerations.

Timeline to Send Patient Bills

The FAH supports the Committee's intent to provide bills to patients in a timely manner. FAH members always strive to send bills to patients as soon as they have the necessary information to send an accurate bill, which is heavily dependent on prompt adjudication of the claim by the patient's insurance plan. As such, the FAH believes that the 30-days in the draft legislation is simply not enough time to ensure the complete and accurate adjudication of claims and the associated bills are sent to patients.

The first portion of the claims adjudication process is the responsibility of the health care provider and includes medical coding, which can only be completed once all of the clinicians involved in the patients' care – which could include non-employed, contracted practitioners who provide care – complete their medical records. As discussed above regarding the list of services at discharge, this information takes at least a few days – if not longer – to compile. For example, a final pathology or laboratory result may be relevant for coding purposes but may not be available for several days – or longer – depending on the types of services providers. There could also be unavoidable delays due to natural disasters (e.g., hurricane, wildfires) or man-made incidents (e.g., cyber attack, health IT system issues).

The second portion of the claims adjudication process is the responsibility of the health insurance plan. The plan must process the claim; determine the patient's cost-sharing responsibilities, such as deductibles and coinsurance; and remit the claim to the health care provider before the provider can send a bill to the patient. Only the health insurance plan can completely and accurately determine its enrollee's cost-sharing obligations. This process can take days or weeks – or even longer if the insurance plan reviews and/or denies the claim for medical necessity or there are coordination of benefits considerations (e.g., the patient is covered under multiple insurance plans). Medical necessity reviews often involve significant back-and-forth between the insurance plan and the health care provider, such as requests to send the enrollee's medical record that the plan then reviews. Coordination of benefits considerations also lead to delays in the final adjudication of the claims as the health care provider is working with and waiting for two or more insurance plans to determine the various plans' payment and the associated enrollee cost-sharing. For example, one plan may have significant enrollee cost-sharing that is partially or fully covered by the second plan. Thus, the health care provider does not know the patient's cost-sharing amount and cannot send the patient's bill until both health insurance plans have fully adjudicated the claim.

Given the significant role health insurance plans have in this process, the FAH was disappointed that the draft language places all the responsibility, including financial penalties for determining patient cost-sharing and sending patient bills on the health care provider. To address the important considerations raised in this Section, the FAH urges the Committee to revise the draft to instead require that patient bills be mailed at least 45 calendar days after final adjudication of the claim by the health insurance plan and remittance to the health care provider. In addition, as billing systems utilize calendar days, we encourage the Committee to use calendar days rather than business days (and extend the number of days provided) to reflect this operational consideration. Lastly, the FAH urges removal of penalties for late bills, as the sheer volume of claims and bills hospitals and health systems process daily means that mistakes are inevitable and that a threshold of ten late bills is far too low. Should the Committee determine the need for some sort of financial penalty, the FAH recommends that the Committee have the Secretary focus on outlier providers – those that routinely send late bills as compared to their peers.

Patient Payment After Billing

The FAH supports the draft provision that patients could not be *required* to pay a bill for services any earlier than 30 days after receipt of the bill. The language as currently drafted would provide patients time to pay their bill while ensuring that health care providers can still offer prompt pay incentives for un- and underinsured patients who remit payment more quickly.

Section 309 – Ensuring Enrollee Access to Cost-Sharing Information

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 (collectively, “cost-sharing”) obligations, and our members continuously engage with patients to provide them with good faith estimates of their expected out-of-pocket costs. Indeed, as discussed further below, hospitals currently engage with patients to assist them in understanding their cost sharing obligations at that particular hospital.

The FAH is concerned, however, that the Committee’s proposal underestimates the technical and operational challenges around providing price estimates and price estimator tools and fails to target the appropriate range of actors (*e.g.*, payers).

While hospitals work diligently to provide price estimate information to their patients, they often face significant technological and operational challenges. First, there are thousands of procedures, services, and items that might be provided during an inpatient or outpatient hospital stay in any number of potential combinations. Second, in most cases a hospital will not have adequate information to provide any reasonable price estimate unless and until the patient or referring provider supplies coverage information and details concerning the items and services requested and the payer responds to an eligibility verification request.

A provider’s ability to develop a reasonably accurate price estimate depends in part on the provider receiving: 1) accurate and complete coverage information from the patient; 2) an order or information concerning the anticipated hospital services; and 3) accurate and standardized cost-sharing information from the payer. Hospitals generally do not obtain the first two pieces of information until pre-registration for scheduled services and may not have this information until after services are furnished (in the case of unscheduled inpatient care). It is also worth noting that the anticipated services may differ substantially from the care ultimately received.⁶ The estimated patient cost-share for a particular inpatient hospital procedure may under- or over-estimate the length of stay and the actual bundle of services that will ultimately be provided to the patient. These differences can be particularly marked where a patient suffers an unforeseen complication that necessitates additional services and increases the patient’s cost-sharing liability. Regarding the second category of data needed to develop a patient cost-sharing estimate, if the patient provides accurate coverage information, the payer should respond to the provider’s inquiry with current data on the patient’s cost-sharing responsibilities and limits. Payers, however are not required to provide this

⁶ By way of example, there is enormous variation in the services provided to maternity patients, who may or may not ultimately require anesthesia, surgical intervention, an inpatient stay in excess of two midnights, and a wide range of other health care items and services. Any cost-sharing estimate offered during the pre-registration process (or prior to discharge) would necessarily rely on assumptions concerning the patient’s care that are unlikely to reflect the patient’s actual experience.

information to health care providers and, when they do provide such information, may not do so in a timely manner.

As discussed below regarding Section 501, insurers are in the best position to provide their enrollees with clear, accurate, and actionable cost-sharing information. Insurers are the only entity that has definitive information regarding their enrollees' coverage limitations, cost-sharing obligations (including out-of-pocket spending limits, deductibles, coinsurances, and any reference-based pricing strategies used by the plan), and any network tiering used by the plan. For example, as an episode of care typically involves multiple providers and suppliers, the payer is the only entity that can provide a patient with an accurate and actionable estimate of their potential financial exposure for the entire episode of care. As discussed below, placing the onus on hospitals to provide cost estimates for any service reasonably expected to be provided in conjunction with the specified service is inappropriate as the hospital cannot accurately know exactly what services would be provided in all instances and would not necessarily be privy to the patient's cost-sharing amounts for services provided by other providers that are not employed by the hospital (e.g., professional fees for contracted clinicians).

To address the concerns raised above while helping to provide patients with good faith out-of-pocket cost estimates, the FAH recommends that the Committee appropriately place the onus for providing good faith estimates for all expected services on the patient's insurance plan. Health care providers can also assist patients in understanding their cost-sharing information by providing a good faith overall estimate of services typically expected to be delivered by that provider, which could include a price range (e.g., cost-sharing for this service or procedure typically ranges from \$X to \$Y). For out-of-pocket cost estimates a hospital or health system cannot supply (e.g., non-employed contracted physicians), the hospital could the notify the patient that the procedure involves services provided by other providers or clinicians and recommend that the patient contact those providers and/or clinicians, as well as the patient's insurance plan.

The FAH also notes that the "good faith estimate" language contained in the draft legislation regarding insurer disclosures and in the section-by-section summary is not currently included regarding provider disclosures. The FAH urges the Committee to correct this matter by making the "good faith estimate" language applicable to provider disclosures. The FAH also urges the Committee to remove the 48-hour requirement and replace it at least three business days to recognize the complexity of providing some good faith out-of-pocket cost estimates and account for weekends and holidays. Lastly, the FAH notes that hospitals and health systems would be unable to comply with the proposed January 2020 effective date due to the technical and operational considerations discussed above. In addition, hospitals and health systems would need the time to review and possibly amend their current managed care contracts and possibly their internal policies and procedures, including staff training. The FAH instead recommends a January 2022 effective date.

TITLE IV: Improving Public Health

Section 401 - Improving Awareness of Disease Prevention

The FAH supports the creation of a national campaign to increase awareness around the use of vaccines for the prevention and control of disease. Additionally, we appreciate that the draft makes stipulations for the development of benchmarks and metrics to facilitate evaluation of the impact of the campaign.

Section 402 - Grants to Address Vaccine-Preventable Diseases

We support the authorization of grants for the research of strategies for improving awareness of scientific and evidence-based vaccine-related information and for planning, implementation, and evaluation of activities to address vaccine-preventable diseases.

Section 404 - Expanding Capacity for Health Outcomes

Technology-enabled collaborative learning and capacity-building models can help expand the capacity for health outcomes by connecting providers in remote or underserved areas with specialists who can help local providers, who may be lacking in specific expertise in particular conditions, through remote consultations. We support the authorization of grants to evaluate, develop and expand the use of technology-enabled collaborative learning and capacity-building models. It should be noted that standardized information collection of characteristics of the collaborative implementation and health outcomes targeted are necessary to facilitate research on the effectiveness of these models. We applaud the provision for information collection and evaluation and activities to identify best practices.

Section 405 - Public Health Data System Modernization

The FAH supports the requirement that HHS award grants to State, local, Tribal and territorial public health departments for the expansion and modernization of public health data systems. The capacity for public health departments to capture the data required to support the success of health care value initiatives remains limited. As the health care delivery system increases its focus on the collection and use of social determinants of health, the implementation of community-based programs, and the integration of social and medical services we increasingly rely on public health departments to capture data that can be used for research and integration with the medical system. For example, certain local public health data systems such as Prescription Drug Monitoring Programs (PDMPs) significantly need to be modernized so that they can be leveraged to combat the opioid epidemic. Currently public health departments face pressing demands to contend with legacy technology while data needs grow at an accelerated pace.

In particular, the FAH applauds awarding grants for the simplification of reporting by health care providers and the enhancement of interoperability of current public health data systems. Hospitals often bear substantial administrative burden and cost when publicly reporting data. The simplification of reporting and enhancement of interoperability will support provider burden reduction.

In addition, it is critical that interoperability be addressed as public health departments develop new IT strategies and that agencies consider information privacy and security, and infrastructure around data exchange. In particular, we support and stress the importance of the provision stating that applicants must support standards endorsed by the National Coordinator for Health Information Technology.

Finally, as a technical matter, the FAH requests that hospital associations be included as a consultative body under subsection (e).

Section 406 – Innovation for Maternal Health

The FAH supports awarding grants to support innovations for maternal health that help identify evidence-based practices.

Section 407 – Training for Health Care Providers

The FAH believes in health equity and supports activities that aid in the elimination of health disparities. The FAH supports the establishment of grants to support training for health care providers to reduce and prevent discrimination. Implicit bias can affect providers attitudes and behaviors towards patients that fall outside conscious awareness. Studies have shown that biases can influence diagnosis and care decisions. Although the FAH is concerned that there is a dearth of evidence of programs that effectively reduce implicit bias or provider behavior and attitude effects, the education of providers on the existence and effects of implicit bias is a first and important step towards attaining higher levels of health equity. The FAH encourages that the grant program authorized by the legislation contain clearly delineated outcome measures (measures of behaviors in health care delivery and patient outcomes) that may systematically inform the success or failure of the program.

Section 408 – Study on Training to Reduce and Prevent Discrimination

The FAH strongly supports the study and recommendations of best practices related to the training to reduce and prevent discrimination in the provision of health care services related to prenatal care, labor care, birthing care, and postpartum care. Currently there is a dearth of evidence on how to reduce implicit bias in the provision of health care services. In addition, current practices in cultural awareness training for health professionals has been shown to lack evidence, be over-general and impractical.⁷

Section 409 – Perinatal Quality Collaboratives

The FAH supports the establishment of grants to support the establishment of perinatal quality collaboratives.

Section 410 – Integrated Services for Pregnant and Postpartum Women

The FAH is supportive of efforts aimed at improving health outcomes for pregnant and postpartum women. To this effect, the FAH supports the establishment of grant awards to states for the purpose of establishing or operating evidence-based programs that deliver integrated health care services to pregnant and postpartum women. To ensure the facilitation of best practices, the FAH urges that grantees be required to specify methods of evaluation (including targeted outcomes) and specification of program characteristics to facilitate research on the effectiveness of these activities. The FAH also suggests that grantees have the ability to fulfill data requirements to inform on these outcomes.

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⁷ Shepherd, SM. Cultural awareness workshops: limitations and practical consequences. BMC Medical Education 2019; (19):14

Section 501 – Requirement to Provide Health Claims, Network, and Cost Information

As noted above, the FAH continues to be supportive of efforts to ensure that consumers have access to clear, accurate, and actionable information concerning their health insurance benefits, including adjudicated claims data, accurate listings of in-network providers, and their estimated copayment, coinsurance, and deductible (collectively, “cost-sharing”) obligations. Insurers are in the best position to provide their enrollees with their historical claims and encounter data as well as information regarding in-network facilities and practitioners. Insurers are also best suited to provide clear, accurate, and actionable cost-sharing information. They are uniquely qualified to provide patients with 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 any network tiering used by the plan. We encourage the Committee to work with stakeholders to ensure the requirements to provide estimates of cost-sharing information in Section 501 are operationally and technologically feasible.

The FAH appreciates the convenience for patients of having claims, provider directory, and estimated cost data available via a mobile application. As discussed at length below in response to Section 503, there are significant concerns with non-HIPAA-covered third-party applications having broad access to individuals’ protected health information, including claims data. The FAH recommends that such applications undergo a vetting process to ensure they meet appropriate security standards and are evaluated for their privacy practices. Patients should have convenient access to this data – and confidence that the data is both secure and protected in accordance with their expectations.

The FAH also has concerns about the proposal to permit third-party applications persistent access to an application programming interface (API). This provision raises privacy and security concerns, and the FAH instead recommends requiring reauthentication each time information is sought via the API. Reauthentication at each use is in line with industry standards for accessing other applications containing sensitive information, such as banking or credit card applications, and would not be unduly burdensome on the consumer.

Section 502 – Recognition of Security Practices

FAH members recognize the vital importance of robust cybersecurity practices to protect their electronic systems and their patients’ protected health information (PHI). As such, FAH members support the adoption of recognized cybersecurity practices and are constantly upgrading their systems and processes to defend against cybersecurity threats. However, even the most cutting-edge cybersecurity practices are not always enough to ward off increasingly sophisticated cyber attacks that result in breaches of patients’ PHI.

The FAH appreciates the Committee’s recognition of this reality and supports the intent of Section 502 of the draft legislation. Requiring the Secretary to consider whether a covered entity or business associate had recognized security practices in place when conducting audits or assessing fines under HIPAA will incent the adoption of those cybersecurity practices. It will also provide a fairer process for those entities potentially facing HIPAA-related fines or audits if they are the victim of a cyber attack despite their robust cybersecurity practices. To further strengthen the incentives for adoption, the FAH recommends replacing the “previous 12 months” language with language that the security practices were in place at the time of the incident in question.

Section 503 – GAO Study on the Privacy and Security Risks of Electronic Transmission of Individually Identifiable Health Information to and from Entities Not Covered by HIPAA

The FAH appreciates the Committee’s recognition that most third-party entities that collection individuals’ protected health information (PHI), including most mobile applications, are not covered by the HIPAA Privacy and Security Rules. As the Committee is aware, the recent CMS and ONC Proposed Rules implementing the *21st Century Cures Act* would permit third-party applications broad access to individuals’ health information with minimal vetting or oversight. The FAH’s comment letter in response to the CMS and ONC Proposed Rules raised significant concerns with such an approach and recommended an independent industry-backed vetting process to ensure these applications are: a) meeting all relevant security standards; b) using data appropriately and in line with consumer expectations; and c) clinically sound (for those applications that offer medical advice). As such, while the FAH supports a GAO study on the security and privacy gaps associated with these third-party applications, we believe the Committee should use its legislative authority to incentivize the use of an industry-led independent vetting process, as described in more detail below.

The FAH has long supported patients’ rights to access their health care information under HIPAA. Health care providers are familiar with the HIPAA Rules and believe they provide important protections for both patients and providers regarding the exchange of PHI. As most third-party applications are not governed by the HIPAA security and privacy requirements, FAH members are very concerned that these applications could expose their electronic health records (EHRs) to malware, hacking, and data mining. Hospitals must be empowered to protect their systems from unproven and potentially harmful applications and, as such, should not be considered “information blocking” for forgoing relationships with questionable applications.

In addition to security concerns, the FAH cautions against allowing these unvetted, non-HIPAA-covered, third-party applications fairly open access to patient digital health data without patients fully understanding how those applications might use that data and the implications of that usage. The FAH agrees that it is an individual’s prerogative to specify where and to whom to send their designated record set. The FAH does not agree, however, that individuals understand how the information they are sharing will be used and monetized. Most people routinely do not read the entire “terms of use” agreement on every application or website and often mistakenly believe their data is more private or secure than it really is. Recent consumer data privacy events highlight the gap between how companies are using data versus how their customers believe their data is being used. For example, millions of individuals were surprised and angry to learn how Facebook was using and selling their data, while other consumers were not even aware that all their financial information is funneled through three to four credit bureaus, two of which experienced major breaches in the last few years.

Digital data is the currency of the modern technology ecosystem and marketplace, and there are fortunes to be made in mining and monetizing personal digital health data. As such, the rules and processes that govern and protect digital health data must be sensitive to the reality that not all covered entities, business associates, and third parties are created equal. Particularly regarding entities that fall outside of the HIPAA requirements, it is imperative

that patients, their families, providers, and consumers can trust that these applications – and the data both sent to and received from them – are secure, private, and clinically sound.

The FAH believes it is possible to support innovation in the marketplace while ensuring the security, privacy, and clinical efficacy of third-party applications through both education and an industry-backed vetting process. In response to the FY19 IPPS Proposed Rule, the FAH urged ONC, CMS, the Office for Civil Rights (OCR), and the FTC to undertake a joint campaign to educate patients about the differences between HIPAA and non-HIPAA-covered entities and how those differences may affect the ways in which their data is used, stored, and shared with others.

Education alone, however, is not enough. Nor is an attestation-only requirement for applications. The FAH strongly believes there is a need for an industry-backed process to independently vet third-party applications to ensure they are: a) meeting all relevant security standards; b) using data appropriately and in line with consumer expectations; and c) clinically sound (for those applications that offer medical advice). The vetting process should be at the application level, not just at the entity level; the results of such vetting process should be made public in the form of an application “safe list”; and health care providers and API vendors should be able to refuse to connect to non-vetted applications without running afoul of the information blocking requirements.

Security

In order to “pass” the vetting process, an application must meet the most current security standards.

Privacy/Data Usage

The vetting should also examine applications’ data usage as compared to the more stringent HIPAA requirements and then publicly report those findings for consumers in an easy-to-understand format, such as a simple comparison chart. The FAH also recommends the assignment of an easy-to-understand letter grade (*e.g.*, A, B, C, etc.) to each application based on its data usage, with an “A” grade signaling HIPAA-level protections. The chart and the letter grade would appear to consumers prior to downloading the application or authorizing it to access their health information. The FAH believes this process would enhance consumers’ control over their designated record set by enabling them to make fully-informed decisions about where to send that data.

Clinical Soundness

Applications that contain a clinical component would undergo additional vetting to ensure they are clinically sound. The vision for the future includes health care providers pulling information from third-party applications used by their patients and then using that information to make treatment decisions. That vision is only possible if health care providers – and their patients – can trust the integrity of that information.

Publicly Reported “Safe List”

The vetting organization should publicly report the third-party applications that “pass” vetting for security (and clinical soundness, if relevant) as “safe” for vendors and health care providers to connect to their APIs.

Information Blocking Exception

The FAH strongly believes that all applications seeking to connect to a health care providers’ APIs must undergo this vetting process and that providers and API vendors that refuse to connect to non-vetted applications should not be considered “information blocking.”

The vetting and public reporting process detailed above will go a long way towards ensuring trust while removing the burden of vetting from consumers and health care providers, and the FAH urges the Committee to incentivize its development and use.

Thank you again for the opportunity to engage on these important topics. We look forward to continuing to work with you on them. Please contact us should you have any questions or require additional information.

Sincerely,

