AMA
AMERICAN MEDICAL ASSOCIATION

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

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

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I appreciate the opportunity to provide our comments on the draft "Lower Health Care Costs Act" and applaud your leadership in seeking solutions to improve our health care system and the process you have established to seek input from a broad spectrum of stakeholders.

Title I–Ending Surprise Medical Bills

The AMA has long been concerned about the coverage gaps that occur when patients unknowingly or without a choice receive care from an out-of-network provider. We believe that fair and workable solutions to unanticipated out-of-network care can come in many forms. As we evaluate proposals and determine their effectiveness and impact, the AMA believes that the best solutions have several common principles at their cores.

- **Protect patients**. The AMA supports solutions that keep patients out of the middle of payment rate negotiations. In situations where patients do not have the opportunity to select an in-network provider, they should not be charged any more than the in-network amount. Moreover, payments should count toward their deductibles and out-of-pocket maximums.
- **Network regulation**. Critical to any solution is a focus on increasing the adequacy of provider networks, especially when it comes to hospital-based providers. Network adequacy standards should require, at a minimum, an adequate ratio of physicians, including hospital-based physicians and on-call specialists and subspecialists, to patients, as well as geographic and driving distance standards and maximum wait times. Regulation should also include the active evaluation of networks to determine access to in-network, hospital-based care at participating hospitals.
- **Fair payment to providers**. To ensure that appropriate market incentives remain in place, any solution must incorporate a mechanism to ensure fair payment to providers. Such mechanisms could include a minimum payment standard based on physicians' rates and/or a binding arbitration process that requires the consideration of a number of market-related factors.
- **Transparency**. Any solution to address unanticipated medical bills must also require transparency so that all patients who choose in advance to obtain scheduled care from out-of-network physicians, hospitals, or other providers are informed prior to receiving care about their anticipated out-of-pocket costs, scope of their coverage, and breadth of their provider network.

> When scheduling services for patients, providers should be transparent about their own anticipated charges.

Components of this draft legislation provide a potential foundation for advancing a reasonable and workable solution. There are, however, several changes we believe are essential to achieve a truly balanced approach to resolve this complex issue and urge you to modify the bill to reflect our comments below.

The AMA agrees that the central tenet of legislation to address unanticipated out-of-network billing must be to protect the patients from the financial hardships associated with these coverage gaps. We strongly support provisions in the draft legislation that would ensure that patients are only responsible for in-network cost-sharing when a surprise coverage gap occurs, and that their cost-sharing count toward in-network deductibles and out-of-pocket maximums. We appreciate that the draft also includes some protections for physicians who mistakenly send a balance bill to patients whose out-of-network care falls under this legislation.

However, the AMA has serious concerns the draft legislation does not address an essential requirement to assuring patient access to in-network care—network adequacy requirements. We strongly recommend including legislative language aimed at stopping surprise billing before it happens via strong network adequacy requirements. While there has been a great deal of discussion about the growth of narrower provider networks, relatively little has been done to create or enforce network adequacy requirements, especially as they relate to hospital-based providers. Moreover, ensuring that patients have appropriate access to primary and specialty care will help prevent emergency department visits and other hospitalizations that may lead to unanticipated, out-of-network bills.

The basis of network adequacy standards should be quantitative, measurable requirements on the front-end, before insurance products are brought to market. The quantitative standards should include minimum time and distance requirements, maximum patient-to-provider ratios, and maximum wait times. In addition, and specific for hospital-based specialties, it is critical that standards also measure access to in-network physicians at in-network hospitals. Meaningful regulation of provider networks must also be ongoing. Consistent monitoring of the network's ability to provide in-network, hospital-based care is particularly important, given that patients may not evaluate access to these providers simply through a directory or other tool, as is normally the case when choosing a provider.

Some have recently attempted to separate the issue of network adequacy with that of surprise billing, suggesting that surprise billing solutions should solely be stopgap measures, retroactively addressing the network failure. However, we believe this is an oversimplified view and devalues the goal of reducing the frequency of surprise bills. Our views are shared by the nation's insurance regulators, who prominently addressed the issue of unanticipated out-of-network care in the National Association of Insurance Commissioners' (NAICs) recently revised model legislation on network adequacy regulation.[1] The NAIC noted that the revised model legislation "establishes strong standards for network adequacy, while balancing the need for states to establish specific standards that are effective for their markets and geography."[2] As such, we again strongly recommend a focus on network adequacy requirements in the final legislation.

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[1] https://www.naic.org/store/free/MDL-74.pdf.
[2] https://www.naic.org/cipr_topics/topic_network_adequacy.htm

Option 1

The AMA is very concerned about the wide-ranging impact that implementation of Option 1 in the proposed legislation would have on the health insurance market, contracting, and patient access to in-network providers. We encourage you to forgo inclusion of this option for the following reasons.

First, it is critical that federal proposals to solve the surprise billing issue not further undercut the contracting process, given the high level of health insurer market power already existing in most areas of the country.[3] Because hospital-based physicians have no choice but to practice within a hospital, this option will give insurers free rein to offer physicians practicing at contracted hospitals a take-it-or-leave-it contract, removing any remaining incentives for the insurer to negotiate a fair contract with these physicians. It is also important to recognize that many physicians, who otherwise practice outside a hospital, occasionally provide hospital-based care, potentially on an emergency or backup basis. This option would require those physicians to either accept a take-it-or-leave-it contract with the same plans as the hospitals they occasionally cover or stop providing that coverage. Additionally, this option would leave little incentive for insurers to incorporate these providers into their networks and every incentive for insurers to establish contract terms more favorable to themselves.

Moreover, this option transfers all responsibility to hospitals to create networks and negotiate non-employed physician payment rates—a role we believe hospitals are unprepared or qualified to do. Furthermore, in many states, stakeholders continue to express concern with hospital consolidation and the impact of such consolidation on contracting negotiations and costs. Increasing hospitals' control of the provider market by placing physician participation and payment rates within their purview would seem to only increase hospitals' market power.

Additionally, this option assumes that all insurers are willing to contract with all physicians, when in fact that is not the case. Under this option, should a physician be unable to secure a contract with an insurer, it becomes unlikely they can secure privileges to practice at a hospital that contracts with that insurer. In many cities and towns there are only a few insurers and hospital systems that dominate the markets, the implications of not being offered a network contract could be devastating to a physician's ability to practice medicine, create inadequate in-network access, and reduce patient access to in-network providers.

This option would also have the perverse effect of increasing the advantage of certain health insurers over others, which could harm patients. Building a network of providers is a basic component of establishing a health insurance product and involves establishing a level of trust by spending time educating providers on protocols, billing procedures, resources, etc. This investment can lead to productive communication between plans and providers and, frequently, a collaborative approach to treating patients. However, under Option 1, these plans would no longer have an incentive to invest such resources in developing a network because they would only need to contract with a hospital in order to establish a network of physicians. The AMA is very concerned that this option would give plans that do not invest in building

[3] The majority of health insurance markets are highly concentrated and characterized by insurers with high market shares of patients. This increases the risk of those insurers exercising monopsony power and paying physicians below competitive levels. Moreover, given that 56.5 percent of physicians providing patient care are in practices with 10 or fewer physicians, physicians are regularly in a weak bargaining position relative to commercial health insurers. American Medical Association. Competition in Health Insurance, A Comprehensive Study of U.S. Markets, 2018 Update. https://www.ama-assn.org/system/files/2018-11/competition-health-insurance-us-markets_1.pdf; Kane C. Updated Data on Physician Practice Arrangements: For the First Time, Fewer Physicians are Owners Than Employees. Policy Research Perspectives, 2019. https://www.ama-assn.org/system/files/2019-05/prp-fewer-owners-benchmark-survey-2018.pdf.

networks with a competitive advantage over those plans that do cultivate the network relationships, or even lead to a race to the bottom where all plans stop investing in building relationships with their network physicians that practice in their network hospitals.

Finally, the AMA has serious concerns with the use of the median in-network rate as a benchmark for emergency services provided at an out-of-network hospital. Such rates are negotiated by physicians and insurance plans during the contracting process where physicians agree to significantly discount their fees in exchange for contracted benefits, such as increased patient volume, being listed in the plan's provider directory, and prompt payment of claims. Setting out-of-network payments at those discounted rates would place physicians at a competitive disadvantage when they attempt to negotiate a fair contract. Further concerns about this minimum payment standard are outlined below.

Option 2

The AMA strongly supports the use of an independent dispute resolution (IDR) process to determine a fair payment when either party is dissatisfied with the initial payment for out-of-network care. We also believe a baseball-style arbitration process, as included in the draft legislation, holds potential given the positive results with New York's model.

In fact, a study released by Georgetown University Health Policy Institute and the Robert Wood Johnson Foundation found that New York state officials have seen a dramatic decline in consumer complaints about balance billing since enactment of their law in 2014, with one regulator stating to researchers that the law has "downgraded the issue from one of the biggest [consumer concerns our call center receives] to barely an issue."[4] Meanwhile, the study points to nearly evenly split numbers in IDR decisions among physicians and insurers and reports among stakeholders that physicians and insurers are incented to work out their payment disputes before filing with IDR. And, importantly, the study notes that regulators report there has not been any indication of an inflationary effect in insurers' annual premium rate filings.

We do, however, have concerns with the structure of this option as outlined in the draft legislation and suggest the following changes to ensure that the IDR process puts plans and providers on a more level playing field, with the goal of creating adequate networks and ensuring access to in-network care.

First, we suggest that all claims be paid at a fair minimum payment standard, regardless of the amount of the claim. Such a payment standard should include a percentile of charge-based data, as opposed to negotiated and discounted contracted rates. A fair payment standard over the long-term will create fewer claim disputes between payers and providers and, as a result, reduce the frequency of the IDR process.

If, however, no minimum payment standard is identified, it is important that all providers have access to an IDR process to resolve disputes with an insurer-determined payment. Successful implementation of this approach would require an arbitrator to have expertise in medical billing and the health care system. An IDR, including baseball style IDR, also has the potential to encourage parties to reach agreement outside of and before the arbitration process, if structured appropriately. Such structure includes clear guidelines on factors for the IDR to consider such as:

- The provider's training, education, experience, and usual charge for comparable services;
- The patient characteristics;

[4] https://georgetown.app.box.com/s/6onkj1jaiy3f1618iy7j0gpzdoew2zu9

- The special expertise required, comorbidities, and other extraordinary factors; and
- A market rate based on a percentile of charges for the particular service in the same geographic area as reported by an independent database.

Finally, we believe that frequency and cost of utilizing the IDR process would be even lower if the legislation (1) required that the initial charge by the provider and payment by the plan be the offers taken to the arbitrator; and (2) allowed providers to batch or bundle multiple claims into a single IDR.

Option 3

The AMA believes there are multiple means to establishing a fair payment rate for physicians, and setting minimum payment standards at levels that encourage physicians and payers to fairly negotiate is one option. However, the AMA urges you to consider combining a minimum payment standard with an IDR or arbitration process to be used as a backstop.

The AMA believes that establishing a minimum payment standard at the median in-network rate will have a negative effect on fair contracting and the adequacy of provider networks. Most health insurance markets are heavily concentrated making it difficult for physicians to negotiate fair contracts. While some suggest that physicians can simply not accept contracts they do not believe are fair, in areas where a single health insurer can hold 50, 60, or 70 percent of the market, physician contracts are largely take-it-or-leave-it. And, despite the popular but false narrative that physicians can choose to be in or out of networks, the decision more frequently rests with the insurers who are creating narrower and often inadequate networks. As such, it is very important that any solution to surprise billing not exacerbate the market imbalance that already exists.

The AMA strongly recommends the legislation be amended to include the use of charge-based data in setting a payment standard for out-of-network care, rather than the median in-network rate. As mentioned above, these in-network rates are negotiated by physicians and insurance plans during the contracting process and physicians agree to significantly discount their fees in exchange for contracted benefits. When a payment standard for out-of-network care is set at rates reserved for contracts and the relationship and benefits that come with it, physicians find themselves at a competitive disadvantage as they attempt negotiations. Insurers will also have a financial incentive to drop from their networks providers who have negotiated contracts with rates above the median, which means that patients end up receiving more care out-of-network and benefiting less from the efficiencies and protections that result when their insurer contracts with their physician.

The more effective solution is to incorporate charge data into the minimum payment standard, which would allow for consideration of physicians' fee schedules before the negotiation of rates and the discounting that occurs in exchange for network inclusion. In addition to establishing a fairer payment rate, this process should provide at least some incentive for health insurers to bring physicians into their network and develop collaborative relationships to benefit patients.

Additionally, as mentioned above, the AMA urges the addition of an IDR or arbitration process to supplement the minimum payment standard and to provide an option for parties to challenge the standard when the circumstances may deem it inappropriate.

Finally, the AMA is concerned that under this option and throughout Title I, data used to the set benchmarks could come from internal insurer data or data controlled by health insurance plans. Such proposals represent a significant step backwards in efforts to promote fairness and transparency in the health care system, especially with health care costs.

Moreover, using insurer-controlled data to determine out-of-network benchmarks opens the door for manipulation and consumer harm. For example, in 2009 a report from the New York Attorney General and a preceding settlement between UnitedHealth Group and the AMA, the Medical Society of the State of New York, and the Missouri State Medical Association, illustrated the dangers of using data controlled by insurers to set benchmarks for reimbursement rates. The New York Attorney General concluded that, because UnitedHealth Group owned Ingenix (the database used nationwide by health plans to set out-of-network benchmarks), there was an inherent conflict of interest. By using a flawed and conflicted database to determine reimbursement rates for out-of-network care, insurers were increasing profits at the expense of patients and physicians. In order to avoid this conflict, the report stated that "market rates for health care charges should be determined by an independent third party free of conflicts of interest, using a fair, objective, and reliable database."[5]

Given this history of data manipulation, the AMA urges the Committee to require that an independent data source be used for any benchmarking that is included in a surprise billing solution.

Title II–Reducing the Prices of Prescription Drugs

The AMA strongly supports the provisions of Title II that will increase transparency in the pharmaceutical supply chain and increase competition. The AMA has long urged modernization of the U.S. Food and Drug Administration's (FDA) requirement that ensure the safety and efficacy of drugs and biologics to prevent misuse that block competition and delay entry of affordable alternative treatments. The AMA urges, however, that the Committee consider including provisions to section 201 that would limit the enforceability of late-filed patents by biological manufacturers when a biosimilar application has already been filed by the FDA. Also, the AMA supports including language to section 202 that would specify that brand manufacturers should not list device patents in the Orange Book, but they should be required to share the device patents with the FDA to prevent efforts to delay generic drug competition. In addition, we have concerns with section 207, which may have unintended consequences impacting the quality of biologicals and biosimilars.

Title III–Improving Transparency in Health Care

The AMA is generally supportive of the provisions in section 301, but seeks clarification on whether the term "third-party administrator" was inadvertently not included in the language regarding "Group Health Plans" on page 65, lines 15-22. Such a term was included under similar provisions on page 69, line 2 and page 70, line 4. We urge the Committee to consider whether the term should be included to avoid a legal interpretation that opens a loophole around the application of section 301 in certain circumstances.

The AMA supports all claims databases with proper guardrails and input from the health care provider and patient perspective. Generally, health care databases, independent of private stakeholders, have the potential to advance not only price transparency as it pertains to benefits consumers purchase, but also

[5] https://ag.ny.gov/sites/default/files/pdfs/bureaus/health_care/FINALHITIngenixReportJan.13,%202009.pdf

assist policymakers in understanding price variation, trends in costs, and gaps in service. Additionally, as value-based contracting continues to grow and payers and providers explore alternative payment models, physicians and other health care providers, as well as payers, can benefit from aggregated independent data to evaluate the feasibility and impact of such contract arrangements. Furthermore, stakeholders, especially those in the states, may use the data to better evaluate the changes in spending, utilization, and quality that result from certain payment models. The AMA sees much promise in the availability of independent health care data to help move the needle on alternative payment models and value-based care. Such data can also be excellent tools for studying utilization trends, health care disparities, the impact of chronic conditions and more broadly, population health.

While supportive, we note that section 303 only allows employers, employee organizations, researchers, and policymakers access to the data and a specified position on the advisory council. Both the health care provider and patient perspectives are currently missing. The absence of these perspectives is concerning considering that the deidentified health care data is being used to inform patients about cost and quality, to assist providers to make informed choices about care, and to enable providers to improve services and outcomes for patients by benchmarking. Thus, while these data are being used with respect to patients and physicians, they have little insight or input into the process or the potential use of that data. For example, it is essential that any physician profiling be reviewed by the physician before being made public. As a part of AMA's data transparency principles, data need to be presented appropriately, depending on the objective and end-user. This should include transparently identifying what information is provided, for what purpose, and how it can or cannot be used to influence care choices. Currently, section 303 does not include any explicit recognition on what purposes the data cannot be used for. The AMA suggests that the information should not be used for other commercial purposes, to unnecessarily increase prior authorization, or to limit medically necessary care.

The AMA also welcomes the privacy and security protections placed on the entity. We appreciate that the entity is required to meet requirements "in accordance of HIPAA." However, if the entity is not a covered entity or a business associate, HIPAA will not apply to the entity and they have no obligation to follow HIPAA. Thus, section 303 should designate the chosen entity as a covered entity under HIPAA to remove any ambiguity.

The AMA supports timely billing and understands the importance of patients being able to financially plan for the costs of medical care. We are very concerned, however, with the negative impact section 305 would have on physician practices, especially smaller practices, of allowing nonpayment for bills sent after 30 days. There are a number of legitimate reasons a bill could be delayed more than 30 days, including the provider's inability to gather all the correct information from the payer and other third parties. To penalize physicians in such instances could significantly impact practices' financial stability. We also have concerns with the requirement that patients be provided a list of services received prior to discharge. We agree that this should be the general norm during discharge; however, such a requirement has the potential to delay patients' discharges if the provider is, for a number of reasons, unable to obtain all the information.

As mentioned above, the AMA strongly supports transparency so that all patients who choose in advance to obtain scheduled care from out-of-network physicians, hospitals, or other providers are informed prior to receiving care about their anticipated out-of-pocket costs, scope of their coverage, and breadth of their provider network. We are concerned, however, with the provisions in sections 304 and 309 that would

penalize providers when the health plan is at fault for not providing accurate directory information to patients (section 304) or place an unrealistic and unreasonable mandate on providers to provide certain information (section 309). We believe that it is impractical to hold physicians responsible for providing information that is the responsibility of the insurer to maintain, especially when this information may be incomplete, unreliable, inaccurate, and not timely. For example, section 304 requires a health plan to establish a business process to ensure that all enrollees receive proof of a health care provider's network status. If a health plan fails to establish this business process and a directory is not up to date, and a patient is inappropriately charged an incorrect rate, the health care provider—not the health plan—is subject to a civil monetary penalty of not more than $10,000. Moreover, the implementation of these provisions is impractical. At the time of scheduling an elective appointment, a physician—without seeing the patient—must identify the insurance of the patient, whether the physician has a contract with that patient's specific insurance plan, the services the patient will reasonably receive, the negotiated amount of those services, and whether the service is in- or out-of-network (which may require discussions with the health plan). On the other hand, the draft legislation provides that insurers—who actually have this information—must provide cost-sharing information to enrollees only when requested by the enrollee, within 48 hours (instead of immediately at the time of scheduling). We also raise the question as to why providers must give an "expected enrollee cost-sharing" while an insurer would only be required to provide an enrollee with a "good faith estimate of the enrollee's cost-sharing." We also believe that subsection (b) on page 127 of the draft legislation would need to be piloted, tested, and validated before considering whether the structure of subsection (a) could be applicable to health care providers.

The AMA supports section 306 regarding health plan oversight of pharmacy benefit manager services. Regarding section 307, we seek clarification on why the focus of the Government Accountability Office (GAO) study is on the relationships between hospitals and physician groups as it relates to financial relationships and profit-sharing. Many other relationships exist between hospitals and other entities and provider types that impact costs and should also be disclosed. For example, any relationship between a hospital and a group purchasing organization (GPO) should also be disclosed given that the hospital receives savings by aggregating purchasing volume. Often, GPOs are owned by their hospital members and may receive profits from their GPO activities.

Title IV-Improving Public Health

The AMA appreciates that the draft legislation includes in section 401 provisions to authorize a national campaign to increase awareness of the importance of vaccinations, combat misinformation, and disseminate scientific and evidence-based vaccine-related information. Given the current growing measles outbreak, the AMA believes a national public awareness campaign is very much needed. The overwhelming scientific evidence shows that vaccines are among the most effective and safest interventions to both prevent individual illness and protect the health of the public. The AMA has urged physicians to talk with their patients about the health risks associated with not being vaccinated and make a strong recommendation for vaccinations, unless medically inadvisable. Likewise, we support section 402, which authorizes grants for planning, implementation, and evaluation of activities to address vaccine-preventable diseases, and for research on improving awareness of scientific and evidence-based vaccine-related information. The AMA also supports section 403, which requires the Department of Health and Human Services (HHS) to develop and disseminate a guide on evidence-based obesity prevention and control strategies for state and local health departments, and Indian tribes and tribal organizations. The AMA recognizes that obesity remains a primary health concern impacting an

increasing number of Americans, yet many medical students and physicians are unaware of how to address obesity in their patients. We believe that the development and dissemination of such a guide will be helpful in ensuring that all health professionals have the tools and information they need to better understand obesity so they can provide their patients with the best care possible.

The AMA strongly supports building capacity and infrastructure to ensure access to medical services by leveraging new technologies with an established evidence base. We strongly support section 404, which would grow the evidence base concerning varied approaches to expanding access to specialty care using technology. We also support section 405 which would modernize public health data systems.

The AMA applauds the inclusion of sections 406, 409, and 410, which deal with the critical issues of maternal mortality and morbidity. The AMA has long-standing policy about the importance of addressing the issue of health disparities in maternal mortality, and supports working with the Centers for Disease Control and Prevention, HHS, and state and county health departments to decrease maternal mortality rates in the United States, encourages and promotes to all state and county health departments the development of a maternal mortality surveillance system, and supports working with stakeholders to encourage research on identifying barriers and developing strategies toward the implementation of evidence-based practices to prevent disease conditions that contribute to poor obstetric outcomes, maternal morbidity and maternal mortality in racial and ethnic minorities. Moreover, AMA policy supports the important work of maternal mortality review committees and endorsed legislation enacted into law last year that funds and supports state maternal mortality review committees. Sections 406, 409, and 410 of the draft legislation would help to improve maternal health care quality and eliminate preventable maternal mortality and severe maternal morbidity.

The AMA supports section 407 and applauds the Committee for including training and workforce provisions related to addressing the racial disparities that drive the incidence of maternal morbidity and mortality in the United States.

The AMA supports section 408. We recognize that implicit and explicit biases exist at both the provider and institutional level, negatively impacting the quality of health care equity and patient safety. Physicians, hospitals, and health care systems have made significant investments to improve care quality and safety for mothers and families around the time of birth. This has been accomplished through enhanced data tracking and analysis of maternal and pregnancy-related morbidity and mortality events in order to stop preventable complications, integrating structural competency, cultural sensitivity, and implicit bias training opportunities, and working with patients and varied health care stakeholders to better inform system changes and improvements. Medical education curricula also incorporate teaching and training on implicit and explicit biases and structural competency education, in order for physicians to build the necessary skillset to recognize and eliminate the harmful biases affecting patient care and health outcomes.

The AMA strongly believes that addressing current maternal mortality trends will require evidence-based policy solutions to be at the center of these efforts. Therefore, we would recommend that the bill language include language “training related to biases both implicit and explicit, in addition to the structural determinants of health.” Evaluating the barriers created by implicit bias is just one component of improving access to culturally-competent care training and workforce practices, with the ultimate focus of addressing the concerning disparities that exist in maternity care today.

Title V–Improving the Exchange of Health Information

The AMA appreciates the intent of section 501; however, we have concerns about the potential unintended consequences involved with third-party apps gaining access to this information and their potential secondary use of the information.

Section 501 (Sec 2715B) requires insurers to make claims data, directory information, and potential out-of-pocket costs available through APIs to enrollees, third-party apps authorized by the enrollees, providers under the insurer's contracts, and business associates of those providers at no charge. Section 501 does not involve payer APIs reaching into a clinician's electronic health record. The AMA has long heralded the benefit of APIs and apps. Together they can offer better information and usability by providing an enhanced view into claims, directory, and cost information. To be clear, the AMA supports patients' access to their entire record and apps can play an important role. However, even with enrollee authorization of a third party to access, use, and exchange this information, the AMA is concerned about how Section 501 might open the door for apps to access, use, and exchange copious amounts of health information. Once an enrollee authorizes another party to access this information, HIPAA and its protections no longer apply. In fact, Section 503 of the discussion draft calls for a GAO study examining the privacy and security risks of health information to and from entities not covered by HIPAA.

The AMA seeks clarification as to the term authorization and what it means for an enrollee to authorize a third-party application. Authorization can take many forms. Currently, it will happen without providing individuals with clear terms of use. These terms can be 6,000+ words in length, shielding activities such as granting app developers a "royalty-free, perpetual, and irrevocable license, throughout the universe" to "utilize and exploit" their de-identified personal information for scientific research and "marketing purposes." They may also "sell, lease or lend aggregated Personal Information to third parties."

If enrollees access this through a smartphone, they must have a clear understanding of the potential uses of that data by third parties. Most individuals will not be aware of who has access to this information, how and why they received it, and how it is being used. For example, an app may collect or use information for its own purposes, such as selling information to clients like employers or landlords. The AMA recommends that APIs shall provide mechanisms to maintain and protect the privacy of the information in subsection (b). This requirement could be additional subparagraph (6) under subsection (c).

Moreover, to assist in resolving this issue, the AMA has identified an opportunity for multiple coexisting components to empower patients with meaningful knowledge and control over the use of their data. We believe that individuals should be provided with a basic level of privacy and app transparency—especially since some apps deliberately hide their actions and make it difficult for individuals to learn about or control their data. The AMA urges policymakers to take the following steps to ensure health information is accessed, exchanged, and used pursuant with the goals outlined in Cures and the desires expressed by patients.

Policymakers should require insurers' APIs check an app's attestation to:

- Industry-recognized development guidance;
- Transparency statements and best practices; and

- The adoption of a model notice to patients.

One possible method to accommodate this would require an insurer's API to check for three "yes/no" attestations from any consumer-facing app. For example: 1) An app developer could choose to assert conformance to Xcertia's Privacy Guidelines; 2) An app developer could attest to the Federal Trade Commission's (FTC) Mobile Health App Developers: FTC Best Practices and the CARIN Alliance Code of Conduct; or 3) An app developer could attest to adopting and implementing ONC's Model Privacy Notice.

We do not believe that requiring an API check for an app developer attestation would be a significant burden on insurers. We recognize that a "yes" attestation would not ensure apps implement or conform to their attestations. However, we firmly believe this will provide a needed level of assurance to individuals and would be greatly welcomed by users.

Technical comments:

- Page 155, lines 22-25 "and any providers or third-party applications or services authorized by the enrollee."
    - The AMA seeks clarification as to who has to be authorized by the enrollee to access this information. We believe it is third-party applications and services because Page 158 lines 17-18 states that "third parties authorized by the enrollee" receive the data at no charge.
- Page 158, lines 12-14.
    - The AMA recommends that providers not under contract but are a part of the enrollee's care team to receive this information for no charge.
- Page 158, lines 19-21 "facilities and practitioners who are under contract with the plan or coverage."
    - The AMA seeks clarification as to how these entities would be identified. If it would be through the NPPES, the AMA recommends keeping the digital contact information visible to only the payer and provider community or, alternatively, utilize an industry-based solution.
- Page 159, lines 8-11 "permit persistent access by authenticated third-party applications."
    - The AMA seeks clarifications as to what authenticated means. Who does the authentication? Against what standards? Is this meant to be different than an enrollee's authorization?
- Page 59, line 18.
    - In addition to HIPAA and state privacy laws, we also suggest including Part 2, FERPA, and GINA.
- General: enforcement mechanism.
    - The AMA is concerned about the lack of a meaningful enforcement mechanism against an insurer who does not make this information available or provides information that is not in accordance with this section. For example, an enforcement mechanism should exist for failure to keep the provider directory accurate and up-to-date.

The AMA strongly supports section 502. To further promote the use of recognized security practices, the AMA recommends that section 502 create a cybersecurity Stark exception and anti-kickback safe harbor to allow parties to provide cybersecurity tools to promote recognized security practices.
The AMA support section 503. We would also support GAO reviewing federal-developed privacy standards and identify necessary funding and continuing support as needed as a part of this study. We also support section 504 to allow OIG to investigate non-Medicare and Medicaid information blocking allegations.

The AMA appreciates your commitment to seeking ways to lower the cost of health care in our nation, including addressing the problems associated with unanticipated out-of-network care. We welcome the opportunity to work with the HELP Committee and Congress to advance ideas to lower health care costs, protect patients from surprise bills, and promote greater access to in-network care.

Sincerely,

James L. Madara, MD