American College of Physicians
Leading Internal Medicine, Improving Lives

June 5, 2019

The Honorable Lamar Alexander
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chairman Alexander and Ranking Member Murray:

On behalf of the American College of Physicians (ACP), I am writing to share our input about your collaborative efforts to protect health care consumers/patients and lower health care costs. The College appreciates this opportunity to comment on your bipartisan discussion draft, as released on May 23rd, entitled the Lower Health Care Costs (LHCC) Act of 2019, which addresses the issues of surprise medical bills, lowering the cost of prescription drugs, promoting transparency, improving public health, and bolstering the exchange of health information.

We appreciate your leadership on these issues and believe that the discussion draft is a very positive step forward in addressing the challenges of lowering costs and improving patient outcomes in these policy areas. We are pleased to provide ACP's perspective and suggestions on certain provisions of the discussion draft where we have established policy and where it has an impact on the care our members provide as internists. We also believe that while the LHCC discussion draft will help address many of the greatest concerns expressed by patients and clinicians over cost, affordability, and accessibility of care, we encourage the Committee to explore additional improvements, including policies to support high-value primary care, expand access and coverage, support a well-trained physician workforce, reduce administrative burdens on clinicians and patients, reduce the cost of prescription drugs, and continue to improve the Quality Payment Program as outlined in ACP's March 1st, 2019, response to the Committee on lowering health-care costs.

The American College of Physicians is the largest medical specialty organization and the second largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

TITLE I: Ending Surprise Medical Bills

LHCC Discussion Draft: The LHCC discussion draft eliminates surprise out-of-network billing for patients who receive out-of-network emergency services as well as ancillary out-of-network services and for out-of-network diagnostic services at in-network facilities. In addition, patients are protected for non-emergency care at in-network facilities when they are treated by out-of-network "practitioners." Patients are only responsible for the in-network cost-sharing amount. Facilities and "practitioners" are barred from sending patients "balance" bills for more than the in-network cost-sharing amount. (While the terms "provider" and "practitioner" are used throughout the draft, as is customary for legislation, ACP for its own purposes uses the term *physician* when referring to physicians, or *clinician* when referring to physicians and other health care professionals; accordingly, we have put "providers" and "practitioners" in quotes in the following comments to clarify when we are referring to the language of the discussion draft).

ACP Comment: Surprise billing, or unexpected bills patients receive as the result of receiving care from an out-of-network physician or facility or unexpected in-network service charges, can be a financial burden on patients that contributes to medical/consumer debt. Medical debt is a growing concern, even for those who are insured. The Kaiser Family Foundation found that more than 25 percent of adults reported that they or someone in their household have challenges created by medical debt, including 20 percent of insured individuals under the age of 65.

Reports of high and unanticipated "surprise" medical bills, especially in emergency situations for patients who do have health insurance coverage and were treated at in-network facilities, have resulted in calls for the federal government to take both legislative and regulatory action. We appreciate that lawmakers in both chambers, as well as the administration, are now heeding this call and are working in a bipartisan fashion to develop legislation to address this growing problem.

ACP's guiding policy on surprise medical bills is outlined in its position paper entitled, "Improving Health Care Efficacy and Efficiency Through Increased Transparency." Specifically:

ACP supports efforts to provide greater protections for patients from unexpected out-of-network health care costs, particularly for costs incurred during an emergency situation or medical situation in which additional services are provided by out-of-network clinicians without the patient's prior knowledge. While the College reaffirms the right of physicians to establish their own fees and to choose whether or not to participate as an in-network clinician, ACP supports establishing processes to reduce the risk for "surprise" bills for out-of-network services for which a patient was unable to obtain estimates for services prior to receipt of care or was not given the option to select an in-network clinician. Health plans also have an affirmative obligation to pay fairly and appropriately for services provided in- and out-of-network, and regulators should ensure network adequacy in all fields, including emergency care.

Efforts to reduce the negative impact of surprise billing should be made at the state and federal levels. Legislation aiming to limit surprise billing should, at a minimum, include one or more of the following components:

- *Support for increased pricing and out-of-pocket cost transparency;*
- *Dispute resolution process;*
- *Assessment of economic impact on patients, clinicians and non-physician "provider's", and payers.*

Emergency/Nonemergency Situations: The LHCC discussion draft essentially holds patients harmless from surprise medical bills in emergency situations and nonemergency situations at in-network facilities, as so defined in the draft, and holds them responsible only for the in-network rate.

ACP Comment: ACP supports this approach. In emergency situations, there simply is not enough time for the patient to know which clinicians are in- or out-of-network. In nonemergency situations at in-network facilities, without any prior notice, patients would assume that all of their care would be considered in-network. It is critical that a patient be given the knowledge up front that a clinician he/she will see is out-of-network so that the patient can make an informed choice before the care is rendered.

Resolution—Three options: The LHCC discussion draft includes three approaches to resolving a disagreement between the health insurer or plan and the "provider" or "practitioner". The first approach, "Subtitle A—Option 1: In-Network Guarantee," would require that an in-network facility guarantee to patients and health plans that every "practitioner" at that facility will also be considered in-network. "Practitioners" and facilities have two options to be considered in-network: 1) "Practitioners" can choose to join the networks for health plans that have a network agreement with the facility; OR 2) "Practitioners" who choose not to go in-network can choose to bill the health plan through the facility, rather than sending separate bills to the patient or the health plan. For emergency care delivered out of network, "practitioners" and facilities have 30 days to privately determine reimbursement with the health plan. If no agreement can be reached after 30 days, the plan will pay the facility and "practitioner" based on the median contracted rate for services in that geographic area.

"Subtitle B—Option 2: Independent Dispute Resolution," would resolve surprise bills that are $750 or less by having the health plan will pay the "practitioner" or facility based on the median contracted rate for services in that geographic area. For surprise bills that are greater than $750, either the health plan or the facility or "practitioner" can choose to begin an independent dispute resolution process, using a third-party arbiter certified by the Department of Health and Human Services (HHS), in consultation with the Department of Labor (DOL). The plan and "provider" will submit a best final offer, and the arbiter will be supplied with information to review the offer, including the median in-network rate for services in that geographic area. The arbiter will make a final, binding decision on the best offer, and the loser will pay for the cost of arbitration.

"Subtitle C—Option 3: Benchmark for payment," would simply require that for surprise bills, the health plan will pay the "practitioner" or facility based on the median contracted rate for services in that geographic area.

ACP Comment: The HELP Committee has indicated that it would like feedback about the three options it has proposed. ACP policy reaffirms the right of physicians to establish their own fees and to choose whether or not to participate as an in-network physician. ACP prefers that caps on payment for physicians treating out-of-network patients be avoided, preferably by establishing an arbitration process that would allow an independent arbitrator to establish an appropriate and fair payment level between the insurers' in-network rate and the clinician's charge. Should the HELP Committee choose in subsequent drafts of the LHCC Act to establish guidelines or limits on what out-of-network clinicians are paid, such limits or guidelines should reflect the actual charge data for the same service in the same geographic area from a statistically significant and wholly independent database. They should not be based on a percentage of Medicare rates, which have become increasingly inadequate in covering overhead costs, particularly for primary care physicians, nor should they be based on in-network rates, which would eliminate the need for insurers to negotiate contracts in good faith. *Accordingly, ACP would prefer Subtitle B-Option 2: Independent Dispute Resolution, of the three options offered by the LHCC discussion draft.* ACP policy calls for a dispute resolution process to be included in any legislation that that addresses surprise billing. While providing necessary relief for patients is necessary, ensuring that physicians and clinicians receive appropriate and fair payment for services also must be considered.

Informed Consent after patient is stabilized: The LHCC discussion draft requires that when a patient is stabilized after entering a facility through the emergency room, the patient must be given advance notice of any out-of-network care, an estimate of the patient's costs for out-of-network care, and referrals for alternative options for in-network care. The LHCC discussion draft requires that the patient would be protected from surprise bills or out-of-network cost sharing if adequate notice is not given.

ACP Comment: ACP supports establishing ways to hold patients harmless for "surprise" bills for out-of-network services for which a patient was unable to obtain estimates for services prior to the receipt of care or was not given the option to select an in-network clinician or "provider." ACP believes health plans and health care facilities should clearly communicate to a patient whether a clinician or is in-network or out-of-network and the estimated out-of-pocket payment responsibilities of the consumer.

Report: The LHCC discussion draft requires HHS in consultation with the Federal Trade Commission and the Department of Justice to conduct a study on the effects of the surprise billing provisions on the vertical and horizontal integration of the health-care system, overall health-care costs, and recommendations for enforcement.

ACP Comment: While the potential benefit and effects of eliminating surprise and balance billing for patients are seemingly apparent, there still needs to be adequate additional review and analysis to avoid unintended consequences and impacts on the health-care system.

Accordingly, legislation should take into consideration the overall economic impact on patients, physicians, payers, and the state and/or federal government. ACP supports the provision that requires a report to study the possible effects of the surprise billing provisions.

Network Adequacy: The LHCC discussion draft is silent on the issue of network adequacy as a possible contributing factor in surprise medical billing.

ACP Comment: How network adequacy and the fair payment of services for physicians may contribute to the increase in patients receiving out-of-network care should also be examined to ensure an appropriate number of available in-network physicians, especially in the emergency setting. Health plans also have an affirmative obligation to pay fairly and appropriately for services provided in- and out-of-network, and regulators should ensure network adequacy in all fields, including emergency care. Evidence exists that narrow networks contribute to out-of-network costs. Adequate access to all types of care in the health plan's network could help reduce surprise billing and the need for out-of-network services. Many patients may have no choice but to utilize out-of-network facilities and services, such as in emergency situations. The Department of Health and Human Services Notice of Benefit and Payment Parameters for 2017 included a provision related to network adequacy and cost sharing. The rule requires issuers to "count the cost sharing charged to the enrollee for certain out-of-network services at an in-network facility by an ancillary "provider" toward the enrollee's annual limitation on cost sharing," effective starting in 2018. ACP has long encouraged stringent quantitative network adequacy criteria; ongoing monitoring and oversight of "provider" networks; transparent "provider" network development criteria; accurate, easily accessible and up-to-date "provider" directories; and requirements that Qualified Health Plans should be prohibited from excluding health care clinicians whose practices contain substantial numbers of patients with expensive medical conditions. Further consideration of proposals to ensure levels of network adequacy is needed.

TITLE II: Reducing the Prices of Prescription Drugs

Ensuring timely access to generics and Preventing blocking of generic drugs: The LHCC discussion draft maintains the use of citizen petitions to allow interested stakeholders, including drug companies, to notify the Food and Drug Administration (FDA) of concerns with pending generic and other follow-on drug applications and tries to address the abuse of the citizen petition process, which can be used to unnecessarily delay the approval of a drug application. The LHCC discussion draft permits the FDA to deny a citizen petition that is submitted with the primary purpose of delaying the approval of an application and clarifies criteria that FDA may use to make this determination and requires a petition to be submitted within 60 days after the petitioner knew, or reasonably should have known, the information that forms the basis of the petition. Lastly, the LHCC discussion draft requires HHS to establish procedures for referring a petitioner to the Federal Trade Commission if determined that a petition was submitted with the primary purpose of delaying the approval of another application.

In addition, the LHCC discussion draft prevents first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period granted by FDA, the entrance of subsequent generic drugs to the market. The discussion draft also triggers the start of the first-to-file generic drug applicant's 180-day exclusivity when a subsequent applicant has been tentatively approved and the first-to-file applicant has not received final approval within 30 months of submission of its application.

ACP Comment: ACP supports policies or programs that increase competition for brand-name and generic sole-source drugs, including bringing generic drugs to market faster. When brand-name drug manufacturers use techniques to block the approval of other drugs to compete with their products in the marketplace, such as abusing the citizen petition process, competition is restricted and costs to patients remain high. Therefore, ACP supports giving the FDA more discretion to deny citizen petitions in instances where brand-name drug manufacturers are clearly using the process to delay applications and the introduction of competitors' products to the marketplace.

Protecting access to biological products and Streamlining the transition of biological products. The LHCC discussion draft clarifies that biological products, including insulin products that will transition from the drugs pathway to the biologics pathway in March 2020, cannot receive new, extended market exclusivities. It preserves certain unexpired exclusivities for biological products as FDA transitions the regulation of such products from the drugs pathway to the biologics pathway.

In March 2020, a small subset of biological products, including insulin, will transition from the drugs pathway to the biologics pathway, opening the biological products up to biosimilar competition. The LHCC discussion draft ensures that marketing applications submitted six months prior to the transition that are still under FDA review at the time of the transition date will not have to be resubmitted, avoiding delays in product availability.

ACP Comment: ACP supports these provisions because it will prevent brand-name drug manufacturers from extending exclusivity timeframes and will help increase competition, something sorely needed with regard to the availability of insulin. ACP policy opposes extending market or data exclusivity periods beyond the current exclusivities granted to small-molecule, generic, orphan, and biologic drugs and therefore supports not extending exclusive timeframes because of the FDA transition from the drugs pathway to the biologics pathway.

In addition, ACP agrees that as the transition to the biologics pathway takes place, that already-submitted applications (within six months) still under review should not have to be resubmitted.

In the case of insulin, which has been on the market for decades, there have been dramatic price increases that result in patients not be able to afford the medication. A recent study found that between 2002 and 2013, the price of insulin increased dramatically, with the typical cost for patients increasing from approximately $40 a vial to $130. As a result, according to a published report on the new study, "a surprisingly large number of people with diabetes are

using less insulin than prescribed because of the rising cost of the drug, putting themselves in danger of serious complications."

Education on biological products: The LHCC discussion draft requires the FDA to establish an internet website to provide educational materials for health care "providers," patients, and caregivers on biological products, including biosimilar and interchangeable biological products. The discussion draft also permits HHS to possibly develop and improve continuing medical education for health care "providers" regarding biosimilar biological products.

ACP Comment: ACP believes that biosimilar drug policy should aim to limit patient confusion between originator and biosimilar products and ensure safe use of the biosimilar product in order to promote the integration of biosimilar use into clinical practice. The relatively new nature of biosimilar introduction into the U.S. market represents an opportunity for physicians to understand the relative safety and efficacy of biosimilars and establish reasoned prescribing practices for biosimilars. One of main issues has to do with the substitution of biosimilars for originator biologic products. Not all biosimilars will be considered interchangeable, and the indications for a biosimilar may differ from those of an originator product. The issues of substitution and naming pose challenges to establishing a strong base for biosimilar use. When substituting a generic drug for a brand-name drug, the pharmacist and physician can be confident in the chemical composition of the drug; to gain FDA approval, the generic substitute must be chemically identical to the brand-name product. However, the sensitivity of biosimilars to minor differences in their composition, manufacturing, and handling can result in variability compared with the originator product, and patients cannot assume that they will have the same reaction to the biosimilar as to the originator product. Thus, it is imperative that policies are in place to ensure physicians are consulted and notified of any biosimilar substitution.

ACP Further Comment on Prescription-Drug Costs: The College greatly appreciates the provisions of the LHCC discussion draft to increase transparency for biological products, limit exclusivities for drugs approved by the FDA, ensure timely access to generic drugs, and protect access to biological products. We also encourage the HELP Committee to use its oversight and legislative authority to develop policies to promote more competition for brand-name and generic drugs and biologics. ACP also provides the following recommendations—including support for bipartisan legislation—to prevent a number of techniques that brand name drug companies use to block the approval of other drugs to compete with their products in the marketplace.

Congress should enact policies that improve competition for single-source drugs. The focus on brand-name drugs and new biologics results in a greater desire for companies to protect the investments in these drugs and keeping them as profitable for as long as possible. Congress also needs to provide the tools for oversight of companies that engage in product-hopping or ever greening. In these practices, companies prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grant the company longer patent protection, or they remove the drug from market, forcing patients to switch to a reformulated version of the same drug. Restrictions against pay-for-delay, also known as "reverse payment settlement," is a patent settlement strategy in which a patent

holder pays a generic manufacturer to keep a potential generic drug off the market for a certain period. The Congressional Budget Office estimated that enacting legislation restricting pay-for-delay settlements would cut the federal deficit by $4.8 billion over 10 years. Accordingly, ACP requests that the HELP Committee consider including these proposals in the LHCC Act:

- The *Preserve Access to Affordable Generics and Biosimilars Act, S. 64*, would prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market. ACP calls for robust oversight and enforcement of pay-for delay agreement in order to limit anti-competitive behaviors that keep lower cost alternative off the market and we believe legislation is needed to address these harmful tactics.

- The *Reforming Evergreening and Manipulation that Extends Drug Years (REMEDY) Act, S. 1209*, would expedite generic drug applications by the FDA by removing certain incentives for name-drug manufacturers to file excessive patents to keep generic drugs off of the market and lift legal barriers that delay generics' entry into the market, improving patient access to those medications.

Limited competition—even in the generic market—can also drive up the cost of a medication. The generic manufacturing market is becoming more consolidated, and progressively some generics are being manufactured by a single company or are disappearing from the market. Lack of competition limits the cost-containing power of competition. When there is no competition, patients have little choice. Even the generic market is not immune to this happening. Single-source generics are more expensive than other generics; some health plans place these drugs in the preferred drug tier in absence of a competitor, resulting in higher costs to the patient. There have also been anti-competitive practices by a few manufacturers of brand name drugs to prevent or delay other companies from developing alternative lower-cost products. Accordingly, ACP requests that the HELP Committee consider including this proposal in the LHCC Act:

- The *Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, S. 340,* attempts to prevent brand name companies from misusing the REMS process and ETASU requirements by determining when the denial of adequate samples and impending participation in joint-safety protocol have occurred and creates a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief.

For decades, pharmaceutical manufacturers have claimed that drug pricing is based on research and development costs and that innovation and is well regulated by market forces. We appreciate the LHCC discussion draft's provisions to increase transparency in the marketplace. This effort to increase transparency in the prescription drug marketplace is necessary for Congress and the Administration to have the data that they need to enact legislative and regulatory policies to lower the cost of prescription drugs. However, more transparency is necessary, such as actual on research and development costs contributing to a drug's cost and on real material and production costs. Since pricing methodologies for biomedical products are

notoriously covert, and it is difficult to pinpoint to what extent a price reflects research, development, marketing, or administration costs. Accordingly, ACP requests that the HELP Committee consider including these proposals in the LHCC Act:

- The *Prescription Drug STAR Act, H.R. 2113,* to promote drug pricing transparency by requiring manufacturers to justify and explain price spikes on their drugs as well as reveal the price and quantity of the drug free samples that they give to clinicians.

- The *Fair Accountability and Innovative Research (FAIR) Drug Pricing Act, H.R. 2296/S. 1391*, which would require drug companies to disclose and provide more information about imminent drug-price increases, including data about research and development costs.

The College hopes that the HELP Committee would consider including such legislation to require greater transparency in pricing, including the FAIR and STAR bills, in subsequent versions of the LHCC Act.

TITLE III: Improving Transparency in Health Care

Increasing transparency by removing gag clauses on price and quality information. The LHCC discussion draft bans gag clauses in contracts between "providers" and health plans that prevent enrollees, plan sponsors, or referring "providers" from seeing cost and quality data on "providers." The discussion draft also bans gag clauses in contracts between "providers" and health insurance plans that prevent plan sponsors from accessing de-identified claims data that could be shared, under HIPAA business associate agreements, with third parties for plan administration and quality improvement purposes.

ACP Comment: ACP supports legislation to prohibit "gag clauses" and similar contractual arrangements that interfere in the transparency of relevant health care data**.** Contractual clauses that impose confidentiality, also known as "gag clauses" and "nondisclosure agreements," block the full transparency and public disclosure of health care prices. Without the disclosure of negotiated prices between hospitals, physicians and health insurers or plans, consumers are at a disadvantage when choosing a plan and choosing clinicians within a plan. This information could also be helpful to employers to ensure that the plan they choose for their employees has negotiated effectively with the local "provider" clinicians and other "providers" of services, as well as to inform strategies by employers to encourage employees to avoid high-priced physician practices and hospitals. The importance of this information is elevated by the increase in health care coverage through high-deductible plans. These gag clauses also limit the availability of important information to various state-wide All payer claims Data Bases (APCDs), used to assist both consumers in making health care decisions and policymakers in ensuring the accessibility of effective health care throughout their region.

Designation of a nongovernmental, nonprofit transparency organization to lower Americans' health care costs. The LHCC discussion draft designates a nongovernmental, nonprofit entity to improve the transparency of healthcare costs. The nonprofit entity, in compliance with current

privacy and security protections, will use de-identified health care claims data from self-insured plans, Medicare, and participating states to help patients, "providers," academic researchers, and plan sponsors better understand the cost and quality of care, and facilitate state-led initiatives to lower the cost of care, while prohibiting the disclosure of identifying health data or proprietary financial information. The discussion draft creates an advisory committee composed of public and private sector representatives to advise the entity on the format, scope, and uses of this data, and establishes the entity's research and reporting objectives. The discussion draft creates custom reports for employers and employee organizations seeking to utilize the database to lower health care costs. The discussion draft authorizes grants to states to maintain or create similar transparency initiatives.

ACP comment: While ACP policy does not directly address a national or federal level APCD-like nongovernmental, nonprofit entity, we do support the intent of helping patients, clinicians, researchers, and payers get a better understanding of cost and quality. APCDs, whether at a state or national level, consider additional relevant sources of information, beyond charges and payments by insurers, such as sources of vital statistics, data contained in regional health information exchanges, or data compiled in quality clinical data repositories (QCDRs). ACP also recommends that payers, plans, and other health care organizations develop patient-targeted health care value decision-making tools that are written for patients at all levels of health literacy that make price, estimated out-of-pocket cost, and quality data available to consumers. This information should be communicated in an easy-to-understand way. Tools should aggregate price, cost, and quality information on health care services and treatments, including prescription drugs. Health care comparison tools should include the following components:

- Total estimated price of the medical service or treatment both in-network and out-of-network;
- A personalized estimate of the patient's potential out-of-pocket cost for the medical service both in-network and out-of-network;
- All services provided within the estimate;
- Availability to search or compare by CPT code;
- Assistance to consumers in identifying potentially unnecessary or avoidable procedures or medical services;
- Quality or outcomes data for the medical service or treatment alongside price information;
- Data updated in a timely manner.

Protecting patients and improving the accuracy of "provider" directory Information: The LHCC discussion draft requires health plans to have up-to-date directories of their in-network "providers", which shall be available to patients online, or within 24 hours of an inquiry. As an incentive to keep the directory up-to-date, if a patient provides documentation that they received incorrect information from an insurer about a "provider's" network status prior to a visit, the patient will only be responsible for the in-network cost-sharing amount.

ACP Comment: Health plans and health care facilities should clearly communicate to a consumer whether a "provider" or clinician is in-network or out-of-network.

State All-Payer Claims Databases: The LHCC discussion draft helps to address transparency by encouraging states to develop or maintain an all-payer claims database (APCD) by authorizing $100 million in grants to states over 10 years.

ACP Comment: ACP supports efforts to help states establish all-payer claims databases and to require private and public health plans to submit data in a standardized manner to such databases. The APCD approach aggregates claims data from all relevant sources within the state, and this larger degree of transparency in health care information can be used for such purposes as creating tools for consumers and purchasers to compare prices and quality across payers as they make health care decisions or to provide statewide information on costs, quality, utilization patterns, and both access and barriers to care to inform health care policy decisions. APCDs directly address the current problem of silos of health care information—information is available from some, but not all, relevant public and private sources and is not reported in a standard manner that would facilitate use by multiple stakeholders. In order to expand the use, function, and benefit of APCDs, policymakers and systems architects should structure APCDs to ensure the ability to link the system to additional sources of information like vital statistics databases and health information exchanges.

Ensuring enrollee access to cost-sharing information: Requires "providers" and health plans to give patients good faith estimates of their expected out-of-pocket costs for specific healthcare services, and any other services that could reasonably be provided, within 48 hours of a request.

ACP Comment: Health plans and health care facilities should clearly communicate the estimated out-of-pocket payment responsibilities of the consumer. Pricing transparency should start at the point-of-enrollment in health plans and continue through all stages of care. Disclosure of the best available estimated out-of-pocket cost sets the foundation for a greater level of informed decision-making. Patients should have access to information on estimated negotiated price, estimated total price for care, and the consumer's share of costs.

However, providing supplemental information about the cost of a patient's care should not put additional burden on the physician; it should be the primary responsibility of health plans to provide this information, including whether patients might encounter additional out-of-pocket costs outside a cost estimate. In addition to the time burden of just 48 hours for the "provider," there are challenges of accurately informing patients in advance of services, "the expected cost-sharing" for each service rather the estimated cost of care. Determining the actual price for a service and its cost sharing is more difficult because it is not always known what the cost of care will be until the patients is undergoing treatment. This includes the difficulty of factoring in billing for services from multiple clinicians.

ACP therefore recommends that payers, plans, and other health care organizations develop patient-targeted health care value decision-making tools that are written for patients at all levels of health literacy that make total estimated price of the medical service or treatment both in-network and out-of-network and a personalized estimate of the patient's potential out-

of-pocket cost for the medical service both in-network and out-of-network available to consumers.

TITLE IV: Improving Public Health

Improving awareness of disease prevention and Grants to address vaccine-preventable diseases: Authorizes a national campaign to increase awareness of vaccines for the prevention and control of diseases, combat misinformation, and disseminate scientific and evidence-based vaccine-related information. Authorizes grants for the purpose of 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.

ACP Comment: ACP strongly supports legislation to improve the rate of vaccinations in this country through increased awareness of the public health benefits of immunizations. ACP supports public health programs to inform the public of the benefit of vaccinations for children, adolescents and adults, to counter misinformation about the risks of vaccinations, and to encourage increased vaccination rates, particularly for vulnerable populations, are especially important for the health of the population. Evidence-based educational strategies should be used to influence behavior and increase vaccination rates.

ACP supports the immunization of all children, adolescents, and adults, according to the recommendations and standards established by the U.S. Advisory Committee on Immunization Practices (ACIP), National Vaccine Advisory Committee (NVAC), and the Centers for Disease Control and Prevention (CDC). The College supports state, local, and national initiatives designed to promote all recommended immunizations. The College calls on states to pass legislation to eliminate any existing exemptions, except for medical reasons, from their immunization laws. ACP firmly believes that allowing exemptions based on non-medical reasons poses a risk to public health and our patients.

Guide on evidence-based strategies for State health department obesity prevention programs: The LHCC requires 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.

ACP Comment: Public policy should support steps to increase the health and wellness of the population, promote changes in unhealthy behaviors, and reduce the burden of chronic disease, such as obesity. Obesity prevention, as well as healthy nutrition and physical education should be promoted in our schools and communities. Policies should promote community planning that supports walking, bicycling, and other physical activities for healthy lifestyles. It is particularly important that federal, state, tribal, and local agencies prioritize and appropriately allocate funding to programs that have the greatest need for funding and the greatest potential benefit to the public's health. ACP recommends that funding priority should go to programs that a review of the evidence shows have been effective in promoting critical public health

objectives such as encouraging healthful diets and exercise to reduce obesity, particularly child obesity.

Expanding capacity for health outcomes: The LHCC discussion draft authorizes grants to evaluate, develop, and expand the use of technology-enabled collaborative learning and capacity building models to increase access to specialty health care services in medically underserved areas and for medically underserved populations.

ACP Comment: ACP supports the expanded role of telemedicine as a method of health care delivery that may enhance patient–physician collaborations, improve health outcomes, increase access to care and members of a patient's health care team, and reduce medical costs when used as a component of a patient's longitudinal care. ACP believes that telemedicine can be most efficient and beneficial between a patient and physician with an established, ongoing relationship. ACP also supports increased interprofessional communication and collaborative models that encourage a team-based approach to treating patients. Collaboration is needed to improve access to specialty services for disadvantaged patients in a way that promotes continuation of care and reduces confusion for the patient. Providing specialty care services to underserved populations can also result in savings.

Innovation for maternal health: The LHCC discussion draft directs HHS to establish a grant program for the purpose of improving maternal health care quality and eliminating preventable maternal mortality and severe maternal morbidity by identifying, developing, and disseminating best practices to improve maternal health outcomes. The entities awarded grants would collaborate with State maternal mortality review committees to identify issues for the development and implementation of evidence-based practices to improve maternal health outcomes and reduce preventable maternal mortality and severe maternal morbidity and providing technical assistance and support the implementation of best practices to entities providing health care services to pregnant and postpartum women

ACP Comment: ACP supports the establishment of maternal mortality review committees (MMRCs) and other state or local programs to collect pertinent data, identify causes of maternal death, and develop and implement strategies with the goals of preventing pregnancy-related or pregnancy-associated death and improving maternal outcomes in the United States. ACP believes MMRCs should have access to necessary data across jurisdictions and that MMRCs should implement best practice standards for data collection and analysis with an emphasis on improving the consistency and comparability of data.

Training for health care "providers" and Study on training to reduce and prevent discrimination: The LHCC discussion draft establishes an HHS grant program for the training of health care professionals to reduce and prevent discrimination, including training related to implicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

The discussion draft also requires HHS, through a contract with an independent research organization, to study and make recommendations for best practices associated with training

for health care professionals to reduce and prevent discrimination, including training related to implicit biases, in the provision of health care services related to prenatal care, labor care, birthing, and postpartum care.

ACP Comment: ACP believes internists are well-suited to provide high quality women's health care and that clinicians in all specialties and fields, including internal medicine, who care for women should receive appropriate training in health issues of particular relevance to the population of women seen in their practice setting. Training should emphasize both primary and comprehensive care of women such as office gynecology as well as the internist's role in team-based care for complex issues.

ACP believes that it is essential for women to have access to affordable, comprehensive, nondiscriminatory public or private health care coverage that includes evidence-based care over the course of their lifespans. Health insurers should not be allowed to charge women higher premiums or impose higher cost sharing on women because of their sex or gender.

TITLE V: Improving the Exchange of Health Information

Requirement to provide health claims, network, and cost information: The LHCC discussion draft requires commercial health insurers to make information available to patients through application programming interfaces (APIs) including health insurance claims data, in-network practitioners, and expected out-of-pocket costs. The discussion draft's intent is to help patients pick the best insurance plane and have access to their own health information and the cost of out-of-pocket care. Note that all existing privacy and security protections for patient health data under the Health Insurance Portability and Accountability Act (HIPAA) and state laws apply.

ACP Comment: ACP is supportive of efforts to place pertinent health information directly in the hands of patients and make it more easily accessible. Doing so can enhance patient-physician collaboration and empower patients to participate in healthcare decision-making and the self-management of their well-being, resulting in the provision of safer, more efficient, and more effective care.

Privacy Concerns: The College agrees that standards-based APIs are an important component in advancing patients' access to their health data and have long advocated for their use to help promote electronic health information (EHI) exchange. However, we have concerns around the use of API's related to patient privacy and security. The College is concerned that a number of patient privacy issues will arise when allowing third-party app developers to access, through the use of APIs, EHI on behalf of the patient when the patient is unaware of who they are actually allowing to access their data. There have been multiple reports of app developers selling patient data to third parties, not sharing their privacy policies with patients, or failing to adhere to their published privacy policies. Personal health information is some of the most sensitive and private information for an individual. Patients have a right to access their personal health information; however, without the necessary privacy and security controls, it is critical to

acknowledge the very real risk present that may ultimately impact the patient's inclination to share information with their physician. Additionally, as the ever expanding ecosystem of personal health and wellness apps that track, store, and share patient health information advances, it will become all the more crucial that patients be adequately informed and counselled around what they are agreeing to when signing up for and using an app, including any personal EHI risks.

Data Quality Concerns: As payer claims-based data are made available to patients via APIs, the College has concerns with data quality issues within the claims data that may contradict the clinical information maintained by the patient's physician and other health care professionals. Moreover, the claims data itself may be difficult for patients to interpret and understand. The College is concerned that the responsibility to examine and correct such data—potentially out of context, which is problematic in and of itself—could fall to a patient's primary care physician, adding to existing administrative burden that is increasingly interfering with the patient-physician relationship

Price Transparency: The College supports transparency of reliable and valid price information, expected out-of-pocket costs, and quality data that allows consumers, physicians, payers, and other stakeholders to compare and assess medical services and products in a meaningful way. However, before this information is included within the scope of an already extremely broad definition of EHI, there are a number of concerns and caveats that need to be addressed when promoting price transparency. The complexity of medical billing can make it difficult or misleading to come up with a standard or average price for a particular service. Prices can vary widely based on information unique to the individual patient and visit, including comorbidities, necessary follow-up care or tests, and site of service, among a range of other factors. Pricing for self-pay patients and those privately insured are determined through two distinct processes that would require separate approaches to price transparency. Moreover, the Medicare reference price is not going to be applicable to most, and might serve to add more confusion than be useful. ACP recommends that price estimates be available prior to scheduling (i.e., at the point of sale) and that all costs are reflected (including coinsurance, deductible, etc.) to provide as much relevant and context-rich information as possible. A critical element in promoting price information transparency is cooperation and agreement amongst the health IT vendor, health system or physician organization, and the payer.

Beyond that, individual hospital-payer contracts can bundle services, treatments, and drugs completely differently, making direct, national, or even regional price comparisons difficult. What matters most to the patient is not the total cost of a service; it is their own out-of-pocket responsibility. Health plans are in the best position to communicate important coverage information that impacts their customers' total out of pocket cost. The College urges Congress to encourage health plans to share information with clinicians and patients regarding important coverage, cost, and quality information, such as whether a clinician is in-network or out-of-network. Integrating cost, quality, and coverage data into EHRs, quality clinical data repositories, regional health information exchanges, or all payer claims databases, would help physicians be more effective partners in helping patients to navigate this information and make

informed, cost-effective decisions about their care. The growing prevalence of narrow network plans exacerbates this problem and should be separately studied and addressed.

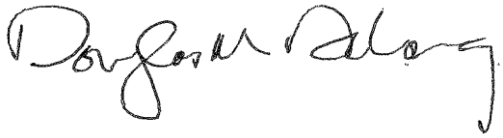
As Congress looks to legislate in the complex and sensitive pricing environment with the potential for wide-reaching implications on payers, clinicians, and patients alike, the College recommends a graduated, targeted approach to any new price transparency initiatives and frequent consultation with stakeholders throughout the process. Gradual implementation will help to minimize the potential for major disruptions to physician payments and patient care.

GAO study on the privacy and security risks of electronic transmission of individually identifiable health information to and from entities not covered by the Health Insurance Portability and Accountability Act: The LHCC discussion draft requests a Government Accountability Office study to better understand existing gaps in privacy and security protections for health information as patients move their information to third parties, such as mobile applications, that are not covered by the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules. The study would identify potential opportunities for improving the privacy and security protections for that health information.

ACP Comment: ACP is supportive of GAO studying the privacy and security risks of electronic transmission of individually identifiable health information – as outlined in the discussion above about patient privacy concerns.

In closing, thank you for your shared commitment in wanting to address the growing problem of health care costs. As you continue to garner feedback from stakeholders for these important issues and further refine this discussion draft for introduction, we look forward to providing additional input as needed. If you have any questions, please contact Jared Frost at jfrost@acponline.org or 202-261-4526.

Sincerely,



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