# The Lower Health Care Costs Act: A Bipartisan Federal Effort to Improve Competition in Healthcare Markets

The Lower Health Care Costs Act, released in May 2019 by Senators Lamar Alexander and Patty Murray, addresses many inefficiencies in healthcare markets and has the potential to both increase competition and lower costs for healthcare services. The 195-page draft federal bill, also known as the Alexander-Murray Bill (S 1895), contains more than three dozen provisions designed to address health care costs. The bill is divided into five titles: 1) Ending Surprise Medical Bills, 2) Reducing the Prices of Prescription Drugs, 3) Improving Transparency in Health Care, 4) Improving Public Health, and 5) Improving the Exchange of Health Information. On June 18, 2109 the Senate Committee on Health, Education, Labor, and Pensions (HELP) heard testimony about the bill and Committee Chair Alexander expressed hope that bipartisan support for the bill would speed its passage through Congress.

This post summarizes the provisions of the first three titles in this extensive bill – those related to price and competition – and discusses whether they are likely to significantly improve the function of the U.S. healthcare market. While this long list of provisions can seem like a laundry list of incremental improvements, the beauty of this bill is its attempt to address multiple market inefficiencies simultaneously. The synergistic effects of this bill have the potential to meaningfully increase competition in healthcare markets.

## Title 1: Ending Surprise Medical Bills

Surprise billing occurs when a patient receives care from an out-of-network provider without knowing the provider was out-of-network or without the ability to choose an

in-network provider. (See The Source's <u>coverage of surprise billing</u> for more details). Laws to protect patients from surprise billing, including the Lower Health Care Costs Act, typically limit the cost-sharing for patients to the amount they would have paid if they had been cared for by an in-network provider. This cost-sharing is also typically applied to their deducible and out-of-pocket payment limits that also apply to in-network care. The more difficult considerations include how to ensure that the out-of-network provider gets appropriate compensation from the insurer for the care delivered to the patient when there is no contract between that provider and the insurer.

The draft of the Lower Health Care Costs Act includes three options to address the problem of surprise billing. The first option requires that hospitals guarantee in their contracts with a health plan that each health care practitioner who provides services in the facility will be under contract as a participating provider and that all diagnostic and laboratory services provided in the facility will be included in the contract. Under this option, providers can choose whether to be reimbursed directly from the health plan or through the hospital. The second option in the bill establishes an independent dispute resolution (IDR) process whereby each party, the hospital or provider and the insurer, each submit their final offer of what they think is a reasonable reimbursement rate to an IDR entity. Under this baseball style arbitration, the IDR entity will choose "the more reasonable amount" of the two offers and the party whose final offer was not chosen will pay the IDR fees. The third and final option in the draft of the Lower Health Care Costs Act sets a benchmark rate at the median contracted rate for "a similar service that is provided by a provider in the same of similar specialty and in the geographic region in which the service is furnished."[1]

These three options would meaningfully protect patients from massive unexpected out-of-network charges, but each of the options addresses the market failures that resulted in surprise billing differently. Much of the testimony provided at the HELP Committee hearing on June 18<sup>th</sup> compared these three proposals. The first option, supported by the American Enterprise Institute and the Brookings Institute,[2] requires market actors (the insurer, hospital, and physicians) to negotiate a contract and appropriate rate because all healthcare practitioners in the hospital must be in-

network for every plan in which the hospital is in network. This option is the only one that would eliminate surprise bills (there would be no out-of-network providers in an in-network facility) and would eliminate the need for an arbitration panel. Tom Nickels, the executive vice president of the American Hospital Association, however, expressed concern that this proposal could severely limit an out-of-network practitioner's ability to negotiate with insurers because these physicians, especially anesthesiologists and radiologists, will no longer have the ability to walk away from the contract if they want to see patients at that facility.

The other two options require either an explicit benchmark or an arbitration process with a decision about what an appropriate payment would be. Many senators and witnesses, however, expressed the difficulty in setting these rates appropriately. Elizabeth Mitchell, President and CEO of the Pacific Business Group on Health, suggested setting benchmarks at 125% of Medicare rates, but Sean Cavanaugh, Chief Administrative Officer of Aledade, discussed the issues and growing pains associated with trying to set a benchmark, "it's rate setting of a sort and someone needs to figure out how to set them." Additionally, Senator Murkowski is concerned about cases where there is a single, dominant provider or no in-network provider and how these rates would affect rural hospitals. Nonetheless, all witnesses and Senators at the hearing agreed on the seriousness of surprise billing and commended the bill for serious attempts to resolve the issue.

Finally, this section of the bill contains provisions to simplify the billing practices of air ambulances. The Airline Deregulation Act of 1978 prohibits states from regulating the price of air ambulances.[3] Most air ambulance companies are not affiliated with a hospital[4] and charge staggering amounts[5] to patients in critical condition who have little choice to refuse services. The Lower Health Care Costs Act requires air ambulances to itemize bills for transportation and medical services separately. While the proposal takes the first step toward federal regulation of billing practices of air ambulances, it does little to ensure patients are protected from huge medical bills they cannot avoid.

# Title 2: Reducing the Prices of Prescription Drugs

The second title of the Lower Health Care Costs Act includes nine proposals to increase competition among prescription drugs and biosimilars. These include provisions to help inform generic and biosimilar manufacturers of patents that protect approved medications, reduce gaming of the citizen petition and "deeming" of licenses at the Food and Drug Administration (FDA) to artificially extend market exclusivity, reduce the ability of branded manufacturers to pay generic manufactures to delay their entry to the market, and encourage the uptake of biosimilars in the U.S. market.

<u>Section 201</u> and <u>202</u> create drug patent databases to assist biosimilar and generic manufacturers to identify patents that could be the basis for an infringement suit and modernizes the Orange and Purple Books, which list the patents protecting the FDA-approved small molecule and biologic drugs, respectively.

Section 203 allows the Secretary of Health and Human Services (HHS) to refer citizen petitions filed with the FDA to the Federal Trade Commission (FTC) if he or she determines that the petition "was submitted with the primary purpose of delaying approval of an application" for a generic equivalent. [6] The FDA created citizen petitions as a way for individuals to contact the FDA if they had concerns about the safety of a drug.[7] In practice, however, most citizen petitions are filed by pharmaceutical companies in an attempt to delay approval of generic equivalents.[8] Generally, citizen petitions filings are clustered in the last year and half of the exclusivity period of the drug they challenge and the FDA denies 80% of the petitions.[9] The Lower Health Care Costs Act attempts to minimize the abusive use of this program by allowing the FDA to refer petitions to the FTC for antitrust enforcement. Unfortunately, however, the FTC lost the only case it brought against a drug company for anticompetitive practices related to the citizens petition program in FTC v. Shire ViroPharma. The FTC alleged Shire ViroPharma engaged in an unfair method of competition when it filed 43 citizen petitions to maintain its monopoly for its drug Vancocin, but the Third Circuit Court held that the FTC was unable to establish that Shire "is violating or is about to violate the law" as required under 15 U.S.C. § 53(b).[10] As a result, while Section 203 represents an important first step toward addressing abuse of the citizen petition pathway, it is unlikely to completely address the problem.

Section 204 and 205 of this title minimize the ability of biologic and generic manufacturers to artificially extend exclusivity periods of their drugs. In particular, Section 204 prevents an additional 12 years of exclusivity for biological products based on a difference in whether the product applied for a license after the Biologic Price and Competition and Innovation Act of 2009 (BPCIA)[11] or had an approved application "deemed to be a license". This section closes a loophole used to extend the exclusivity of biologics approved prior to the process created by the BPCIA. Section 205 limits the period of exclusivity for the first generic equivalent of a small molecule drug to 180 days after the earlier of either the first commercial marketing of the first generic applicant or 30 months after the submission of the application for marketing. This section limits the exclusivity period for the first generic competitor and should also reduce the ability of branded manufacturers to pay the generic manufacturer to delay market entry.

<u>Section 206</u> encourages the FDA to provide education to healthcare providers and patients about the approval process for biosimilars to assure them of its high standards, thereby increasing the uptake of biosimilars.

The final three sections in this title, <u>Sections 207-209</u>, update and clarify language in the Federal Food and Cosmetic Act to ensure continuity in approval process if the other provisions in the Lower Health Care Costs Act are enacted and to clarify the meaning of "new chemical entity" to more accurately reflect the chemistry of newly developed drugs.

### Title 3: Improving Transparency in Health Care

Title 3 contains many important provisions to improve transparency in health care. The Source has covered many <u>state efforts</u> to improve transparency,[12] but a federal Act would ensure that all residents are afforded a uniform level of protection. Furthermore, the Lower Health Care Costs Act states that it seeks to work in conjunction with state laws rather than preempt them. As such, the provisions in this section, if passed, would represent significant progress toward a more transparent healthcare market and give both patients and policymakers across the nation more information when making decisions about healthcare services.

In particular, <u>Section 301</u> removes gag-clauses on price and quality information. While <u>Congress</u> and <u>many states</u> passed laws banning contracts that prohibit pharmacists from disclosing information about the cost of prescriptions and lower cost alternatives, the provisions in this bill prohibit any agreements between insurers and providers of healthcare services that limit the ability of insurers to give patients provider-specific cost and quality information. The Source <u>discussed</u> how this lack of transparency hampers right-to-shop programs. Allowing patients access to cost and quality information is the first step in any program that seeks to give patients an incentive to choose higher-value care and banning gag-clauses is an important step on that path.

Section 302 goes beyond gag-clauses and bans other anticompetitive terms in contracts between facilities and insurers. In particular, the bill prohibits insurers or third-party administrators from entering into contracts with providers that contain three types of clauses: 1) anti-steering clauses that prevent insurers from encouraging or steering enrollees to use high-value providers, 2) all-or-nothing clauses that require the health plan to contract with or set payment rates for affiliates of the provider or hospital that are not party to the contract, and 3) mostfavored nation clauses that restrict the insurer from paying a lower rate to another provider. In addition, third-party administrators working with self-insured plans may not enter into any contracts that the health plan is not allowed to review. In 2018, the Wall Street Journal interviewed dozens of insurance company executives, hospital officials and researchers and found that "[d]ominant hospital systems use an array of secret contract terms to protect their turf and block efforts to curb health-care costs."[13] Similar contract terms were the basis of recent antitrust lawsuits filed by the Department of Justice (DOJ) against Atrium Health (formerly Carolinas HealthCare System) and by California's Attorney General against Sutter Health. While the case against Sutter Health has not yet been heard, the North Carolina federal court held in the case against Atrium that the DOJ plausibly alleged that the steering restrictions limited consumer choices and drove up insurance prices. These lawsuits, however, can be expensive and time consuming to prosecute. The draft of the Lower Health Care Costs Act would ban all contracts with these terms, thereby ensuring additional transparency to those purchasing healthcare. In addition, when coupled with the gag-clause ban in section 301, insurers should be

able to design coverage options that help patients choose higher value providers, thereby reducing overall health expenditures and insurance premiums.

<u>Section 303</u> would establish a federal All-payer Claims Database (APCD). The Source previously <u>discussed</u> how, after the Supreme Court decision in <u>Gobeille v. Liberty Mutual Insurance Co. Inc.</u>, state APCDs cannot demand claims data from self-insured employers, or about a third of the non-elderly population of the country. The provisions in Section 303, therefore, are particularly important because they would create a federal repository for claims data that includes data from self-insured group health plans, Medicare, and state APCDs. This section also describes a process by which the Secretary of Labor may award "grants to States for the purpose of establishing and maintaining State all-payer claims databases that improve transparency of data".[14] The Source described how APCDs promote transparency to help patients shop for care, but more importantly, allow <u>policy makers and regulators to assess</u> the functioning of healthcare markets and design policy interventions. Having an APCD with data from all payers, therefore, is particularly important to inform policy decisions at both the state and federal levels.

<u>Section 304</u> requires insurers to keep updated provider directories to limit surprise bills by allowing patients to determine in-network versus out-of-network providers. This section provides requirements for health plans to update provider directories at least every 90 days. Similar to the surprise billing protections in Title 1, these provisions protect patients from paying more cost-sharing than they would be required to pay for in-network services if they relied on incorrect or outdated information in an insurer's provider directory. For example, if a patient identified an in-network provider on her insurer's website, but couldn't get an appointment for a few months, and in that time the provider moved out-of-network, the patient would be protected by the provisions in Section 304, if she can show that the provider directory listed the physician as "in-network" when she tried to find a provider.

<u>Section 305</u> offers additional protection to patients by requiring timely billing from facilities and providers (within 30 business days) and gives patients 30 days after receipt of the bill to pay for such services.

Section 306 regulates pharmacy benefit managers (PBMs). Specifically, it requires

insurers and third-party administrators (TPAs) to provide group plan sponsors with an annual report of their spending on prescription drugs that includes cost and price information (both per day supply and total net spending), utilization, and rebates from drug manufacturers. In addition, for any drug that the plan issuer spent more than \$1000 during the reporting period, the report must include a list of all other drugs, including brand name, generic, biologic, and biosimilar products, that are in the same therapeutic class. The report must give the list price for those potential substitute drugs and list the formulary tier and utilization mechanism for each drug. This section provides that contracts between the PBM and manufacturers, distributors, and wholesalers must allow the PBM to provide all of the information required in these reports to insurers and TPAs. Section 306 also eliminates spread pricing, by prohibiting PBMs from charging more than the price paid to the pharmacy for the drug. The Source described how multiple state Medicaid programs saved millions of dollars by ending contracts with PBMs that used spread pricing as part of their compensation. This section prohibits spread pricing in any PBM contract and further requires a PBM or TPA to pass 100% of the rebates and discounts from any pharmaceutical manufacturer or distributor to the health plan. These provisions have the potential to pop the gross-to-net bubble that obscures the price of drugs and allow patients and providers to make value-based decisions about pharmaceuticals.

The final three sections in this title address somewhat smaller, but nonetheless important considerations to improve competition in healthcare.

<u>Section 307</u> calls for the Comptroller General of the United States to study and report on the effects of profit and revenue sharing arrangements among healthcare providers, including physicians, laboratory services, surgical services, and rehabilitation services.

<u>Section 308</u> requires disclosure of direct and indirect compensation for consultants to employer-sponsored health plans and enrollees in individual plans. This verbose section may appear to be a long list of mundane reporting requirements, but it contains important provisions. As Marilyn Bartlett, Special Projects Coordinator for The Commissioner of Securities and Insurance Office of the Montana State Auditor, testified, these brokers and consultants work on behalf of the buyers of health care

(i.e. plans and plan sponsors), but are often paid by sellers in undisclosed arrangements. Ms. Bartlett described her experience as the Plan Administrator of the Montana State Employee Group Health Plan, where she and her colleagues "found up to 17 undisclosed revenue streams in one employer health plan, adding hidden costs to health care."[15] She urged the committee to consider expanding these disclosure requirements to all third parties that provide a product or service to a plan.

Finally, <u>Section 309</u> requires providers and insurers to disclose good faith estimates of cost-sharing information (including deductibles, copayments and coinsurance) within 48 hours.

### Conclusion

The Lower Health Care Costs Act contains an impressive number of thoughtful provisions with the potential to meaningfully increase transparency and competition for healthcare services. As discussed above, nearly all of the sections represent targeted interventions to address market inefficiencies and would begin to move the needle on healthcare spending. The most significant feature of this Act, however, is that the individual provisions will likely have a cumulative effect. For example, increased transparency of healthcare claims data from a federal APCD, coupled with the prohibition of anticompetitive contract terms and aligned financial incentives for consultants, has the potential to allow employers and insurers to redesign benefit packages to improve the value of healthcare services. As a result, insurance premiums should decrease for both individuals and employers. Furthermore, the bans on surprise billing should help ensure that number of bankruptcies due to healthcare costs (currently at 66% of all bankruptcies) would decline.

The most encouraging moment in the HELP committee meeting occurred when Senator Murray described this bill as a first, momentum gaining moment. This bill would bring much needed transparency and accountability to healthcare markets and allow policymakers to assess the quality of other policies to decrease healthcare costs and improve quality. The Source will continue to follow developments in this bill and other efforts to bring needed reforms that begin to address the drivers of

increasing healthcare costs.

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[1] Lower Health Care Costs Act Title 1 § 103.

[2] Benedic Ippolito Testimony on the Lower Health Care Costs Act. Statement before the Senate Committee on Health, Education, Labor, and Pensions on the Lower Health Care Cost Act. Available from: https://www.aei.org/wp-content/uploads/2019/06/HELP-Written-Testimony-June-16-2019.pdf

[3] See *Med-Trans Corp. v. Benton*, 581 F. Supp. 2d 721 (E.D.N.C. 2008) and *Valley Med Flight, Inc. v. Dwelle*, 171 F. Supp. 3d 930 (D.N.D. 2016) for cases where courts held state air ambulance regulations preempted.

[4] The Affordable Care Act prevents hospital-affiliated air ambulances from balance billing by considering them an extension of the emergency room.

[5] Jen Christensen, Sky-high prices for air ambulances hurt those they are helping, CNN (2018),

https://www.cnn.com/2018/11/26/health/air-ambulance-high-price/index.html.

[6] Lower Health Care Costs Act Title 2 § 203 p. 49.

[7] 21 C.F.R. § 10.30.

[8] Robin Feldman & Connie Wang, A Citizen's Pathway Gone Astray — Delaying Competition from Generic Drugs, 376 New England Journal of Medicine 1499-1501 (2017).

[9] Id.

[10] Fed. Trade Comm'n v. Shire ViroPharma, Inc., 917 F.3d 147 (3d Cir. 2019).

[11] 42 U.S.C.A. § 262 (West),

- [12] The Source also created and maintains <u>The Database of State Laws Impacting</u> <u>Healthcare Cost and Quality</u> (SLIHCQ), which catalogues state legislative efforts to increase transparency of prices in healthcare.
- [13] Anna Wilde Mathews, Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition The Wall Street Journal (Sept 18, 2018), https://www.wsj.com/articles/behind-your-rising-health-care-bills-secret-hospital-deal s-that-squelch-competition-1537281963?mod=article\_inline (last visited Jun 19, 2019).
- [14] Lower Health Care Costs Act Title 3 § 303 p. 90.
- [15] Marilyn Bartlett Written Testimony of Marilyn Bartlett, June 18, 2019 before the Senate Committee on Health, Education, Labor, and Pensions on the Lower Health Care Cost Act. Available from: <a href="https://www.help.senate.gov/imo/media/doc/Bartlett2.pdf">https://www.help.senate.gov/imo/media/doc/Bartlett2.pdf</a>.