Senate HELP Committee Releases Sweeping Legislative Package Targeting Health Care Costs

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On May 23, the Senate Health, Education, Labor and Pensions (HELP) Committee released a comprehensive health care package (the "Draft Bill") that would target rising health care costs and billing practices. Entitled the "Lower Health Care Costs Act," the Draft Bill—released on a bipartisan basis by Sens. Lamar Alexander (R-TN) and Patty Murray (D-WA), the Chairman and Ranking Member of the Senate HELP Committee, respectively—takes aim at so-called "surprise" balance medical bills, which have been the subject of various legislative proposals in recent years. The Draft Bill also proposes a number of measures addressing prescription drug costs, price transparency, and certain public health initiatives. The Senate HELP Committee accepted comments on the package until June 5, with the hopes of marking up the bill in late June, with potential Senate floor consideration some time over the summer. While passage of any large scale health care legislation in the current political environment seems unlikely, the current bipartisan support, along with the Administration's support for both surprise balance billing solutions and price transparency, means that the proposal is a serious one.

GROOM INSIGHT | Even if this legislation does not pass into law as currently drafted, these proposals and similar proposals will be in the mix for future health care reform debate. When compared with broader proposals to remake the American health care system, like Medicare for All, these bipartisan proposals are likely to have ongoing support in Congress.

Below we provide an overview of the legislative package.

Surprise Balance Billing

The Draft Bill contains a host of proposals targeting surprise balance billing. By way of background, surprise balance billing arises primarily in two settings, both of which involve the patient having limited ability to know whether the provider is in- or out-of-network. In the first scenario, a patient in need of emergency services may, by necessity, receive stabilizing care from an out-of-network hospital. In the second scenario, a patient may select an in-network facility for a procedure but receive services from an out-of-network professional working at the facility (such as an anesthesiologist, radiologist, or pathologist). In both cases, after the individual's insurer or group health plan pays the benefits under the terms of the plan, the provider submits a bill to the individual for the difference between the amount paid by the plan and the billed charges, which can often drastically exceed what the individual expected.

In seeking to protect patients against surprise balance bills, the Draft Bill would hold patients harmless, requiring them to pay only the in-network cost-sharing amount for out-of-network emergency care and for care provided by ancillary out-of-network providers. The bill would also mandate in-network cost-sharing for lab and diagnostic tests performed at in-network facilities. With respect to deductibles and out-of-pocket maximums in the emergency setting, the bill would also require that emergency health care charges to a patient—whether in-network or out-of-network—are counted toward the patient's in-network deductible and in-network out-of-pocket maximum.

The Draft Bill proposes three different legislative options for resolving disputes over balance bills between payers and providers. Under the first option, to address surprise balance bills that arise as a result of services provided by an out-of-network professional at an in-network facility, as a matter of contracting with the plan, an in-network facility would be required to guarantee that every provider at the facility is either in-network with the plan or issuer, or has agreed to accept the in-network rate negotiated by the in-network facility. The first option addresses emergency services in a different manner by imposing a default reimbursement rate of the median contracted rate, with no ability for dispute resolution.

Under the second option, for surprise bills greater than $750, either the plan or the provider could elect to initiate an independent dispute resolution process using an arbiter certified by the Department of Health and Human Services (HHS). The independent dispute resolution process will require the arbiter to select the most reasonable of the final best offers submitted by the parties. The arbiter can consider relevant factors including the median contracted rate. The losing party is responsible for the costs of the arbitration.

Finally, under the third option, the health plan would simply pay the provider or facility an amount that equals the median contracted rate for services in that geographic area.

GROOM INSIGHT | Of all the provisions included in the proposal, the efforts to address surprise balance billing have the most widespread support (in both the House and the Senate), and from Republicans and Democrats alike. As a result, even if the broader package does not pass, Congress could conceivably pass some form of surprise balance billing relief on a stand-alone basis.

Prescription Drug Costs

The Draft Bill also takes aim at rising prescription drug costs by proposing various reforms to the drug patent system. Specifically, the bill would make it easier for generic drugs to make it to market by speeding up the citizen petition process, which some believe has been used to delay unnecessarily the approval of generic drug applications. The Draft Bill would allow the Food and Drug Administration (FDA) to determine that a citizen petition was submitted for the primary purpose of delaying the approval of an application, at which point the FDA would then be permitted to deny the citizen petition. The Draft Bill would also require individuals to submit petitions within 60 days after the petitioner knew, or reasonably should have known, the information that forms the basis of the petition.

Relatedly, the Draft Bill would make it more difficult for brand-name drugs to maintain exclusive patents. Under the bill, eligibility for five-year new chemical entity (NCE) exclusivity would be available only for a drug containing no active moiety (*i.e.*, no component responsible for pharmacological action) that has been previously approved in the United States—a proposal designed to ensure that only the most innovative or novel drugs qualify for NCE exclusivity. Finally, the bill would prevent first-to-file generic drug applicants from blocking the entrance of subsequent generic drugs beyond a 180-day exclusivity period.

Health Care Cost Transparency

The Draft Bill contains a host of provisions aimed at improving health care cost transparency. For example, the bill would prohibit so-called "gag" clauses in contracts between providers and health plans that prevent participants and plan sponsors from accessing cost and quality data on providers. The bill would also ban other "anti-competitive" contractual terms between providers and health plans, such as those that restrict plans from incentivizing patients to use lower-cost, higher-quality providers. These proposals amend the federal Public Health Service Act ("PHSA") and directly regulate provider contracts, which would represent a significant departure from current law where regulation of these contractual relationships is largely governed by state law.

GROOM INSIGHT | The Draft Bill regulates contracts between health insurance issuers and third-party administrators and the medical providers included in the network. This is the first instance of such regulation in the PHSA and is notable as it will significantly expand the reach of the PHSA and alter a number of frequently

used contracting terms. These provisions could potentially be enforced by a combination of state, HHS and DOL regulators. Issuers and TPAs alike should be mindful of the change in contract terms required under the Draft Bill and follow closely to ensure that internal policies and procedures are modified to accord with any bills enacted into law.

The Draft Bill creates an all-payer claims database that is overseen by the DOL and a committee consisting of representatives of both government agencies and private party stakeholders. The all-payer claims database applies only to self-funded group health plans and notably excludes insured arrangements. Self-funded plans administered by large third party administrators or carriers would be required to submit significant and detailed claims-related information. Authorized users (*e.g.*, researchers, employers and patients) would be able to access this information at cost and would be able to request customized reports of that information. The proposed language includes limitations on public disclosure of proprietary information in some cases and preserves existing health information privacy regulations.

GROOM INSIGHT | In a 2016 decision, Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936 (2016), the Supreme Court ruled that state laws creating all-payer claims databases were preempted with respect to self-funded group health plans under ERISA's broad preemptive scheme. The decision left in place state databases for insured plans and policies, however. As drafted, the Draft Bill's database provision would create a comprehensive federal health information database, but for self-funded group health plans only. Employers remain interested in accessing this type of information to inform plan and benefit design questions, with the goal of improving outcomes and reducing cost.

In an effort to increase transparency regarding certain group health plan service providers, the Draft Bill amends section 408(b)(2) of ERISA to impose a reporting scheme on brokers and consultants to group health plans. Covered entities would be required to disclose both direct and indirect compensation (in excess of $1000) to group health plans. The inclusion of this language in section 408(b)(2) renders a contract with a broker or consultant where such disclosure is not made a prohibited transaction, and seeks to harmonize the treatment of group health plans with the section 408(b)(2) regulations applicable to retirement plan service providers.

GROOM INSIGHT | The Draft Bill's amendment to section 408(b)(2) borrows heavily from the DOL's regulatory text applicable to retirement plan service providers. This level of detail included in the statute could limit the ability of DOL to adapt any implementing regulations to reflect unforeseen issues with the disclosure requirements included in the statute.

GROOM INSIGHT | The Draft Bill, by its terms, applies the 408(b)(2) disclosure requirements only to brokers and consultants of group health plans. This is a relatively narrow scope of application, as compared to the broad application of the 408(b)(2) regulations to retirement plan service providers. It will be interesting to see whether, if the bill is passed into law, DOL expands the scope of this provision to include others that provide services to health plans.

Significantly, the bill would require greater transparency for pharmacy benefit managers (PBMs), who act as intermediaries between drug manufacturers and health plans. PBMs would be required under the bill to provide quarterly reports to plan sponsors on costs, fees, and drug manufacturer rebates. PBMs would also be prohibited from engaging in "spread pricing"—that is, charging a plan or patient more for a drug than the PBM paid to the pharmacy for the drug. Finally, PBMs would be required to pass along to plan sponsors 100% of the value of any rebates, discounts, or other remuneration received from drug manufacturers. This mirrors in some respects recent proposed changes to the treatment of manufacturer rebates under the Medicare Part D program, and would significantly alter existing contractual relationships between plans and PBMs.

GROOM INSIGHT | This is an unexpected and sweeping provision. Not only does the Draft Bill alter the use of manufacturer rebates, it also materially changes and restricts how employers compensate PBMs with respect to group health plans. If enacted, it could effectively mandate "pass through" pricing and increase per claim or per enrollee administrative costs.

The Draft Bill would also require health care facilities and providers to give patients a list of services received upon discharge, and would require all bills to be sent to the patient within 30 business days. If a patient received a bill more than 30 business days after receiving care, the patient would have no obligation to pay. Further, providers and health plans would be required to give patients good-faith estimates of their expected out-of-pocket costs within 48 hours of a request by the patient.

Public Health

The Draft Bill contains an array of public health funding initiatives, including:

- **Data System Modernization**. The bill would authorize grants to state and local public health departments for the expansion and modernization of public health data systems to improve data collection for health information and electronic medical records.
- **Vaccine Awareness**. The bill would authorize grants for the purpose of educating people about vaccines and reducing vaccine-preventable diseases, including the establishment of a national campaign to increase vaccine awareness.

- **Discrimination Training**. The bill would establish an HHS program aimed at training health care providers to reduce and prevent discrimination, including training related to implicit bias.
- **Maternal Health**. The bill would establish a grant program for improving maternal health outcomes, and would authorize HHS to award grants to states to establish evidence-based programs that deliver integrated health care services to pregnant and postpartum women. HHS would be required to submit a report to Congress describing the outcomes of these grant-based initiatives.

Exchange of Health Claims Information

Finally, the Draft Bill would require commercial health insurers to make certain information—including claims data, in-network provider lists, and expected out-of-pocket costs—available to patients through electronic applications. In doing so, the bill aims to enable patients to have full, electronic access to their own health information and information about out-of-pocket costs on their mobile devices.

The bill would also authorize HHS to consider the cybersecurity practices of health care entities and business associates when conducting audits related to the Health Insurance Portability and Accountability Act (HIPAA) Security Rule. Specifically, HHS would be permitted to mitigate fines or decrease the length of an audit if it finds that the entity had recognized security practices in place for at least a year.

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A hearing on the Draft Bill is set for June 18. The HELP Committee is currently reviewing comments on most of the Draft Bill's provisions, including: the three proposed options for ending surprise medical bills; prohibiting spread pricing by PBMs; requiring 100% of rebates to be passed through to plan sponsors; and the proposal to ban "gag clauses" and other anti-competitive clauses in contracts between providers and health plans. The HELP Committee has indicated that it intends to mark up the legislation in preparation for consideration in the full Senate over the course of the summer, so changes to the Draft Bill are likely in the near future.

We will continue to monitor legislative developments related to these issues and provide updates as the legislation moves through Congress.