January 29, 2020

Submitted electronically at www.regulations.gov

Department of Health and Human Services
Attention: CMS-9915-P
P.O. Box 8010
Baltimore, MD 21244-8010

Re: Transparency in Coverage Proposed Rule

Dear Sir or Madam,

We write on behalf of the American Benefits Council ("the Council") to provide comments in connection with the Transparency in Coverage Proposed Rule ("proposed regulations") published in the Federal Register on November 27, 2019, by the U.S. departments of Health and Human Services, Labor and the Treasury (collectively, "the Departments") (84 Fed. Reg. 65464). The Departments issued the proposed regulations to require group health plans and health insurance issuers to disclose to participants and beneficiaries, upon request, through an internet-based self-service tool, cost-sharing information for covered items or services, generally including negotiated rates for in-network providers and allowed amounts for out-of-network providers. The proposal also directs plans and issuers to disclose to the public, through two machine-readable files, negotiated rates for in-network providers and historical allowed amounts for out-of-network providers. Also included in the package are proposed regulations by the Department of Health and Human Services (HHS) regarding the calculation of an issuer's medical loss ratio for "shared savings" programs. Finally, the proposed regulations include two specific requests for information relating to transparency in health coverage.

The American Benefits Council is a Washington D.C.-based employee benefits public policy organization. The Council advocates for employers dedicated to the achievement of best-in-class solutions that protect and encourage the health and financial well-being of their workers, retirees and families. Council members include over 220 of the world's largest corporations and collectively either directly sponsor or support sponsors of health and retirement benefits for virtually all Americans covered by employer-sponsored plans.

The Council appreciates the opportunity to provide comments on the proposed regulations regarding price transparency in health coverage. A key piece of solving the health care cost and quality puzzle remains a lack of price and quality transparency and the Council has long supported increased price and quality transparency and access to data for employer plan sponsors. Employers play a critical role in the health care system, leveraging purchasing power, market efficiencies and plan design innovations to provide health coverage to over 178 million Americans. Most employers that have had success decreasing the rate of health care spending have started by analyzing their data. They do this to better understand how much they are spending for various services delivered in different settings and, ultimately, to steer their enrollees to higher-value providers operating in higher-value settings. Thus, greater price and quality transparency in health care is an area of critical importance for employer plan sponsors.

The Council's long-term strategic plan published in 2014, *A 2020 Vision: Flexibility and the Future of Employee Benefits*, included this recommendation:

> **Support greater quality and price transparency in the health care system**. Meaningful information on price and quality is often hard to capture and adjusting for the clinical complexity of individual cases is difficult. Despite these challenges, greater transparency of quality and price information is important and urgently needed. Employees should have quality and cost calculators and other tools that provide enrollees with specific data about the quality and total out-of-pocket costs of certain services. Public policy should not impede employers' access to information needed to design and operate their plans and to help employees use these tools.

As to the important goals of lowering the cost and improving the value of health care in this country, the Council views transparency as a means to an end rather than the goal itself. As such, the Council recognizes that price is just one piece of the puzzle and that, in terms of value, the price of the health care service does not always correlate with the quality of care and, thus, equate to better value.[1]

Further, the Council notes that health care price transparency alone may not alter consumer behavior. However, employer plan sponsors can use transparent price and quality information to develop innovative plan designs that steer patients towards higher-value health care providers. Employers hold the key to changing the behavior of the 178 million Americans with employer-sponsored health coverage. Price and quality transparency is a necessary tool that employers need to drive this change to lower-cost, higher-quality care. Accordingly, we urge the Departments to promote transparency in such a way that enables employer plan sponsors to effectuate broader change by encouraging consumers to make educated decisions about where and from whom they receive their health care. As such, we urge the Administration to view transparency in a

[1] Colorado Value Hospital Report, Summer 2019 available at https://www.quantros.com/colorado-hospital-value-report/.

holistic way that involves payors, plans and patients, as well as providers.

In addition to our support for the Administration's efforts to increase transparency as a way to lower health care costs, the Council applauds Congressional efforts to do the same. We are particularly supportive of S.1895, the "Lower Health Care Cost Act" approved by the Senate Health, Education, Labor and Pensions Committee, which represents an important step in combatting rising costs through improving price transparency across the health care delivery system, facilitating the use of value-based insurance designs and addressing surprise billing.[2]

SUMMARY OF COMMENTS

The Council applauds the Departments for taking steps intended to increase price transparency in order to reduce health care costs. Throughout the comment we note a number of provisions in the proposed regulations that we strongly support. At the same time, we are concerned about the increased burden and liability imposed by certain aspects of the proposed regulations on employer plans. As such, we provide a number of comments intended to address those concerns.

More generally, our comments reflect that the goal of reduced health care costs by way of increased transparency cannot be achieved by the proposed regulations alone. Employers have long supported price and quality transparency and will continue to do their part under the proposed regulations. However, the Council also strongly urges the Administration, and Congress if necessary, to take additional efforts to address the critical role that other entities play, including providers and third party administrators (TPAs).

Although this letter includes comments on all aspects of the proposed regulations, the following are our key comments, each of which is discussed in detail later in the letter:

- The Council has long supported employee access to accurate, cost-sharing estimates, in order to ensure consumers have the information they need to seek out lower-cost, higher-value health care. As such, the Council generally supports the cost-sharing estimate tool in the proposed regulations.

- Notwithstanding its benefits, the cost-sharing estimate tool, both in development and maintenance, will impose substantial burdens on plans. The Council strongly urges a number of changes to mitigate those burdens, most significantly urging that the final regulations require disclosure of the *most common* items and

[2] See https://www.americanbenefitscouncil.org/pub/?id=CA7841E0-1866-DAAC-99FB-4F3FA0A1A070.

services, rather than *all* items and services, including as part of a phased-in approach.

- The Departments, along with their counterparts throughout the Administration, should develop rules that would require increased pre-service disclosures by providers to participants of the services included in their treatment and the pricing for the services. This rulemaking, which would have a separate timeframe, would address the essential role of the provider in health care transparency and acknowledge that providers, rather than participants and beneficiaries, are best positioned to determine which items and services, among thousands of other items and services, to include in a cost-sharing estimate inquiry.

- Increased transparency is needed with respect to a plan's and employer's access to and use of the plan's own pricing data, including claims data and provider-specific negotiated rates. The proposed regulations assume that employers have access to this information, but historically some employers have faced challenges in obtaining their own plan data from TPAs and issuers. This needs to be rectified by the Administration or Congress.

- The Council is deeply concerned that even with good faith efforts, plans may be unable to obtain some of the information needed to complete the required disclosures. The Council strongly urges that final regulations include a safe harbor to address this issue. Further, the Council urges the Departments to decline to finalize the regulations if this issue cannot be addressed sufficiently.

- We strongly urge that the applicability date be no sooner than plan years beginning on or after the date that is two years after the effective date of any final regulations, as one year is not a realistic timeframe to implement the proposed requirements, even for the most sophisticated employers and issuers. This would nevertheless impose an aggressive implementation timeline, but we support efforts to increase transparency as quickly as possible.

- It is essential that DOL take steps, by way of a safe harbor, to guard against the potential for increased litigation under ERISA due to the disclosure of negotiated rates, akin to the class action litigation that has befallen 401(k) plans.

- Due to the potential for higher prices, at least in certain markets, resulting from the public disclosure of negotiated rates, the Council requests that the Departments structure final regulations to avoid such unintended consequences. As such we suggest that if the Departments require public disclosure of negotiated rates, the disclosure be limited to the median or lowest negotiated rate for each item and service covered by a plan, based on the plan's in-network providers. We also suggest that, rather than requiring broad public disclosure of negotiated rates, the final regulations require disclosure to plan sponsors. The

Council also urges that any public disclosure capture only the most common items and services, rather than all items and services.

- The Council strongly supports additional quality transparency rules and encourages the Departments to proceed with those efforts expeditiously. Greater transparency of quality information is essential for achieving true health care value.

BACKGROUND

The proposed regulations were issued in response to White House executive order No. 13877, entitled "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (the executive order). The executive order directs the Departments to issue an advance notice of proposed rulemaking (ANPRM), consistent with applicable law, soliciting comments on a proposal requiring health care providers, health insurance issuers and self-insured group health plans to provide, or facilitate access to, information about expected out-of-pocket costs for items or services to patients before they receive care. As noted in the preamble to the proposed regulations, the Departments opted to issue a notice of proposed rulemaking that includes a substantive set of proposed rules, rather than an ANPRM, so commenters would be able to respond in a more useful way to specific proposals. Further, the Departments express the view that increases in health care costs and out-of-pocket liability without transparent, meaningful information about health care pricing have left consumers with little ability to make cost-conscious decisions when purchasing health care items and services and that proposed rules would allow the Departments to address this issue more quickly than would an ANPRM.

The proposed regulations would implement Section 2715A of the Public Health Service Act (PHS Act) and Section 1311(e)(3) of the Patient Protection and Affordable Care Act (ACA), which has already been implemented for qualified health plans (QHPs) on the Exchange. In general, Section 2715A of the PHS Act requires group health plans and health insurance issuers to comply with Section 1311(e)(3) of the ACA.

ACA Section 1311(e)(3), which generally applies to QHPs offered on the Exchange, requires QHPs to make certain information available to, among others, the public, including information on cost sharing and payments with respect to out-of-network coverage and any "[o]ther information as determined appropriate by the Secretary." This provision also requires QHPs to permit individuals to learn the amount of cost sharing under the individual's coverage that the individual would be responsible for paying with respect to a specific item or service by an in-network provider upon request of the individual. It also requires that the information must be made available to the individual, at a minimum, through an internet website and other means for individuals without access to the internet.

In the proposed regulations, the Departments propose two separate requirements for group health plans and health insurance issuers offering group or individual coverage: (1) disclosure of cost-sharing information through a self-service, internet-based tool, including negotiated rates and allowed amounts for covered items and services; and (2) public posting on an internet website of two machine-readable files for negotiated rates and historical allowed amounts. The Departments are also seeking stakeholder input through two specific requests for information: (1) whether to require in future rulemaking that plans and issuers make available discrete data elements through a standards-based application programming interface (API); and (2) how public and private sector quality measures might be used to compliment cost-sharing information for plans and issuers in the private health insurance market.

SPECIFIC COMMENTS

I. Internet-Based, Self-Service Tool for Disclosure of Cost-Sharing Information

In general, the Departments are proposing to require group health plans and health insurance issuers to disclose the following cost-sharing information upon the request of a participant, beneficiary, or enrollee (or his or her authorized representative) through an internet-based, self-service tool (or in paper form, if requested):

- An estimate of cost-sharing liability for a requested covered item or service provided by a provider based on the data elements that follow;
- Accumulated amounts incurred to date;
- Negotiated rate (reflected as a dollar amount) for an in-network provider for the requested covered item or service;
- Out-of-network allowed amount for the requested covered item or service, if the request for cost-sharing information is for an out-of-network provider;
- If the item or service for which a request is being made is subject to a bundled payment arrangement, a list of the items or services for which cost-sharing information is being disclosed; and
- Any prerequisite for the covered item or service.

A. Cost-Sharing Estimate Tool: General Comments

As noted above, as part of a broader recommendation regarding price and quality transparency in the health care system, the Council's long-term strategic plan included

that "[e]mployees should have quality and cost calculators and other tools that provide enrollees with specific data about the quality and total out-of-pocket costs of certain services." The Council supports the goal of reducing health care costs by way of increased price transparency reflected in the proposed regulations and applauds the Departments for taking a meaningful step toward achieving this goal.

Health care consumerism aims to put economic purchasing power and decision-making in the hands of plan participants, thereby enabling patients to become wholly involved in their health care decisions. Health care cost transparency is a critical element in consumer-based plan designs, because consumers cannot make cost-conscious decisions without being able to shop intelligently for procedures and providers.

Although employers have increasingly offered tools to deliver price and quality information about specific health care providers or services to their employees, many of those tools have provided generalized estimates, rather than participant-specific cost-sharing estimates. As such, the cost-sharing disclosures required by the proposed regulations should provide employees with more accurate cost-sharing information, which will enhance employees' ability to seek out lower-cost, higher-value care.

Although the Council generally supports the enhanced cost-sharing disclosures in the proposed regulations, we also note the burden that employers face in complying with the new requirements and emphasize that time will be needed for employers to come into compliance. Accordingly, below we offer a number of comments and suggestions intended to mitigate that burden, without undermining the increased transparency that the tool provides for participants and beneficiaries, and to increase the utility of the tool.

More generally, we urge the Departments, along with their counterparts throughout the Administration, also to address the critical role and responsibility of health care providers as part of the efforts to increase transparency to empower consumers to seek out lower-cost, higher-value care and for plan sponsors to create value-driven plan designs.

Under the proposed regulations, in order to obtain a cost-sharing estimate, the burden is on participants and beneficiaries to enter a billing code or descriptive term for an item or service and the accuracy and completeness of the resulting estimate will be tied to whatever information the participant or beneficiary enters. Given the complexities of the items and services that are provided and the plethora of codes (*i.e.*, there are over 10,000 CPT codes), having the participant or beneficiary correctly identify the specific items and services will be difficult. As such, a typical patient will likely be in a position to guess between various options. This highlights a gap in the proposed regulatory regime and supports further efforts to provide participants and beneficiaries with additional information from providers on a pre-service basis.

Specifically, the Council supports rules that would require increased pre-service disclosure by providers to health plan participants of the services included in their treatment and the pricing for the services. Requiring providers to provide participants with pre-service notice, in good faith, of the expected services will give plan participants more knowledge and better information to determine whether certain providers (for example, all providers in the expected continuum of care) are in-network, as well as the participant's estimated financial obligation for the health care services to be received. This would avoid the situation in which participants and beneficiaries are guessing at which items and services will be part of their treatment.

Requiring pre-service disclosures by providers directly to plans would also be beneficial, as this would allow plan sponsors upfront knowledge of the proposed services so that the plan could provide additional information to assist the consumer in their selection of care locations and could help the participant, in coordination with his or her provider, to more pro-actively identify the most cost-effective, preferred treatment. An ancillary benefit to requiring providers to provide this pre-service information is that it would result in patients knowing their balance bill for out-of-network providers and non-covered items, which are issues not addressed by the proposed regulations. The Council makes a number of comments on this topic in the next section of this letter.

The Council greatly appreciates the efforts made by the Departments in the proposed regulations and recognizes the Departments may be of the view that PHS Act Section 2715A does not expressly apply to providers. However, due to the importance of these issues, we take this opportunity to urge the Departments to work with their counterparts in the Administration, and with Congress, as necessary, to continue to develop a comprehensive and effective framework to provide transparency to consumers and plans, including efforts to increase disclosures by providers to fill the gaps. These efforts could include expansions of the HIPAA right of access to cover pre-service information and HIPAA standard transaction modifications to allow plans and issuers to request information from a provider on a pre-service basis. The Council stands ready to assist the Administration in these efforts.

B. Cost-Sharing Estimate Tool: Allowed Amounts and Billed Charges

The proposed regulations require disclosure of the plan's "out-of-network allowed amount" when a participant or beneficiary requests cost-sharing information for a covered item or service furnished by an out-of-network provider, to the extent the out-of-network allowed amount is relevant to the estimated cost-sharing liability.

The information regarding allowed amounts and cost-sharing based on allowed amounts required to be provided under the proposed regulations should be helpful to consumers, but without information on billed charges, consumers are missing essential

information about potential liability related to balance billed amounts, which can be substantial. As noted earlier, the Council emphasizes the importance of consumers having good faith estimates of a provider's billed charges *in advance* of seeking care to prevent unexpected costs relating to balance billing. Even if the Departments are constrained by jurisdictional limitations regarding health care providers under Section 2715A of the PHS Act, we must highlight for the Departments that the lack of pre-service billed charge information is a substantial missing piece of the puzzle for consumers. The Council encourages the Administration to take this issue on more broadly and work to fully address participant access to accurate health care costs on a pre-service basis, including considering HIPAA right of access expansions to require pre-service, good faith estimates of billed charges and HIPAA standard transaction modifications to allow plans and issuers to request billed charges from a provider on a pre-service basis for disclosure of cost-sharing liability estimates through the tool.

As Congress and the Departments are obviously aware, balance billing is also an issue in the context of out-of-network providers at in-network facilities and in emergency situations. Employers are deeply concerned about the burden that surprise medical bills from out-of-network providers place on employees and their families. The tool with the enhancements noted in the preceding paragraph would be helpful in preventing unexpected medical bills from out-of-network providers. However, as contemplated, this tool would not be able to provide protection from surprise billing.

The Council seeks to protect patients from surprise medical bills without undermining access to high-quality, high-value networks or increasing health care costs for individuals and employer providers of health coverage. Indeed, we view the effort to protect patients from surprise bills within the broader context of the effort to lower health care costs. As such, the Council urges Congress to take action to address surprise billing and the Departments to work to ensure that any final regulations are consistent with the legislative efforts to address surprise billing.

Also, as a technical matter, we note that the requirement to provide real-time disclosures of allowed amounts could be challenging to the extent that plans and issuers determine the allowed amount for certain out-of-network items and services based on a percentile of billed charges, as billed charges are unknown by the plan or issuer prior to a claim for health care services. As a result, in order for plans and issuers to be able to provide the cost-sharing information contemplated by the tool, providers would need to provide billed charge information on a pre-service basis and in a sufficiently timely manner for a plan or issuer to be able to comply with the requirement to provide a real-time estimate. If providers are not required to communicate billed charges to plans and issuers on a pre-service basis, the Council requests the Departments consider other ways that plans and issuers which base allowed amounts on billed charges can meet this requirement, such as permitting the use of historical allowed amounts or a historical median allowed amount based on amounts paid to out-of-network providers for a particular item or service.

C. Cost-Sharing Estimate Tool: Disclosure of Most Common Items and Services and Disclosures Regarding Certain Episodes of Care

Under the proposed regulations, plans and issuers are required to provide cost-sharing estimates for all items and services covered under the plan. This is a universe of many 1,000s of items and services and, although we assume the Departments are generally attempting to maximize transparency, we are concerned that the lack of a reasonable limitation on the items and services to which the disclosure obligation applies will have negative impacts on consumers and employers.

More specifically, as noted earlier, for a participant or beneficiary, the accuracy and usefulness of the estimates provided by the tool are based on the participant or beneficiary having the information necessary to enter a billing code or descriptive term that accurately captures the treatment the individual seeks. We are concerned that a tool that is populated with all covered items and services will provide an overwhelming amount of information which will cause confusion and could ultimately result in the individual failing to seek care. In fact, in order to avoid this issue and provide employees with digestible amounts of information, current cost-sharing tools provide estimates for a subset of covered items and services, rather than all covered items and services.

Further, the requirement to build and maintain a tool that provides an estimate for all items and services imposes a substantial burden on employers. In fact, this is the aspect of the proposed regulations generally identified by employers as imposing the most significant burden due to the number of items and services covered by most plans and the technical and administrative work and time that would be needed to build and maintain a tool that captures such a broad set of information. Moreover, employers are not just concerned that this aspect of the tool imposes burden, but rather that the burden is not justified by the potential benefit. In current cost-sharing tools, employers generally find that of the limited set of common items and services included, employees look up only a subset of those items and services. Thus, we are concerned about the expense and effort it would take to build a tool with the ability to capture all items and services if that is not what employees will ultimately use.

While we generally support increased price transparency, we also urge the Departments to consider the significant burden the proposed requirements place on employers and to mitigate that burden where, as here, the requirements can be narrowed in a way that does not meaningfully undermine the utility of the tool. Accordingly, we urge the Departments to limit the scope of items and services that are subject to the cost-sharing estimate tool requirement. Cost-sharing estimates should be required to be provided for a set number of the most common items and services, some of which could be specified by the Departments with the remainder to be chosen by the plan or issuer, as applicable, similar to the framework in the recent HHS final rules

regarding disclosure of hospital charges for "shoppable services."[3] As to the items and services designated by the Departments, we support the formation of a group of stakeholders (including employers, issuers and consumers) that the Departments would consult. So as not to undermine the goals of the proposed regulations, the number of items and services to which the disclosure obligations apply should be meaningful and sufficiently broad, capturing those items and services for which disclosure would be most useful and valuable for consumers. We also request that plans and issuers be allowed to provide cost-sharing disclosures for items and services in addition to the required items and services, if they so choose.

To the extent the Departments pursue an approach under which initial disclosure requirements apply to a subset of all items and services, we support an approach under which the Departments commit to revisit and expand the list of items and services covered by the tool in the future. Such a phased-in approach provides the opportunity for the Departments, plans, issuers, consumers and other stakeholders to observe the usefulness, utilization and impact of the tool over time, which would allow the list to be expanded in the most effective manner. Although the Council supports such an approach, to the extent the Departments adopt a phased-in approach, we also request that stakeholders be given a chance to comment in advance of potential future expansions. Further, we expect that the Departments may need to revisit the list periodically to keep pace with medical advancements and so encourage the Departments to include flexibility under the regulations allowing updates, as necessary.

Narrowing the items and services subject to the disclosure requirement under the cost-sharing tool also has the benefit of enabling disclosures based on episodes of care (referred to in the proposed regulations as allowing individuals to seek cost-sharing information by inputting a description of a treatment or procedure, such as knee replacement). Under the proposed regulations, plans and issuers are not required to disclose cost-sharing information for an episode of care (*e.g.*, knee replacement) unless the provider bills and the plan or issuer makes payment for those items and services, in a bundle. However, the Departments note in the preamble that they are considering imposing such a requirement and request comments on whether it would be feasible for plans and issuers to allow individuals to request cost-sharing information for treatments or procedures that involve multiple items and services if the plan or issuer makes payments based on discrete billing codes for each item and service associated with a treatment or procedure.

The Council understands the value for consumers in receiving a cost-sharing estimate for all items and services typically provided in connection with an episode of care, rather than having to obtain separate cost-sharing estimates for each item or service included as part of the treatment or procedure. As such, the Council is generally supportive of incorporating estimates for certain common episodes of care into the

[3] 84 FR 65524 (Nov. 27, 2019).

cost-sharing tool, which would presumably show the component items and services and component costs in addition to the total cost. However, as it is the case that for some episodes of care the items and services included are not standardized and can vary patient to patient, the Council asks that the Departments enumerate a limited number of common episodes of care to which this requirement would apply and make clear which items and services are included in the episode of care, rather than providing an open-ended standard which may cause confusion. Further, we support the ability of plans and issuers to provide cost-sharing estimates for episodes of care, in addition to those specifically required, if the plan or issuer so chooses.

D. Cost-Sharing Estimate Tool: Negotiated Rates and Negotiated Drug Prices

The proposed regulations would require plans and issuers to disclose through the tool certain "negotiated rates," reflected as a dollar amount, where the negotiated rate is necessary for an individual to determine his or her cost-sharing liability for a covered in-network item or service.

The Council fully supports disclosure of negotiated rates for participants and beneficiaries to determine cost-sharing liability through the tool to provide as accurate of an estimate of cost-sharing as possible.

To this end, the Departments seek comment on whether there are any reasons disclosure of negotiated rates should be required even if the negotiated rate is not relevant to calculating the individual's estimated cost-sharing liability. The Council is of the view that there are a number of benefits that could come from disclosure of negotiated rates through the cost-sharing tool, even in cases in which that information is not relevant to the specific cost-sharing estimate inquiry. This is because even if the participant's or beneficiary's cost is not affected, the plan's cost could be significantly affected. Allowing participants' and beneficiaries' awareness and visibility of negotiated rates could provide consumers with a greater understanding of health care costs and enable participants and beneficiaries to seek out lower cost providers, based on their expectation that this could lead to lower premiums in the long term. Further, although participants and beneficiaries will use the tool to look up estimated cost-sharing for specific items and services, often times they will also expect to seek services from the same provider repeatedly (*e.g.*, for ongoing treatment and follow-up care). It may be the case that in the future (*e.g.*, the next plan year when the deductible resets) the negotiated rates of specific providers for certain items and services will be relevant to the participant or beneficiary. Therefore, participants and beneficiaries may wish to have access to negotiated rates through the tool to choose providers in anticipation of future visits.

With respect to negotiated drug prices, the Departments state that outside of a bundled payment arrangement, plans and issuers may base cost-sharing liability for

prescription drugs on the undiscounted list price. Providing the rate that has been negotiated between the issuer or plan and the pharmacy benefit manager (PBM) could therefore be misleading, as this rate generally would seem to need to reflect drug manufacturer rebates and retail pharmacy discounts, etc. and, thus, could be lower than what the individual would pay and lower than the amount on which cost-sharing is based. The Departments specifically request comments on disclosure of drug prices, including whether the negotiated rate or list price should be disclosed for providing cost-sharing liability estimates to participants and beneficiaries.

As the largest purchaser of prescription drugs in the United States, employers are deeply concerned about prescription drug costs. Further, the status quo is unsustainable. Comprehensive reforms are needed to change the incentives that lead to higher list prices, increase competition among all the players in the pharmaceutical drug space and bring greater transparency to drug pricing. This effort by the Departments to provide accurate information about cost-sharing liability estimates for prescription drugs is an important step and should be part of a broader, collaborative effort among all stakeholders to help lower drug costs, while ensuring continued access to clinically effective – and cost-effective – pharmaceutical drug therapies. The Council appreciates the Departments' concern regarding the potential for consumer confusion in disclosing price information that is not the basis of cost-sharing and supports requirements that provide accurate cost-sharing liability estimates to participants and beneficiaries.

E. Cost-Sharing Estimate Tool: Required Notice

Under the proposed regulations, plans and issuers would be required to provide a notice, in connection with a request for cost-sharing liability, in plain language, informing participants and beneficiaries of the following:

- Out-of-network providers may balance bill participants, beneficiaries, or enrollees and the estimated cost-sharing liability does not account for these potential additional amounts;

- Actual charges for the covered items or services may be different from the cost-sharing liability estimate, depending on the actual items and services received at the point of care;

- The estimated cost-sharing liability for a covered item or service is not a guarantee that coverage will be provided for those items and services; and

- Any additional information the plan or issuer would like to include, as long as the additional information does not conflict with the above required information.

The Departments also issued model language that plans and issuers could use; however, plans and issuers would not be required to use this language to satisfy the notice requirement.

The Council supports the notice requirement, as key to ensuring that participants and beneficiaries understand the limitations of the cost-sharing estimate. To that end, the Council supports the Departments allowing plans and issuers the flexibility to create their own notices, while only requiring certain specified information to be conveyed as part of the disclosure.

As to the specific notice content elements, the Council supports the inclusion of a general statement about balance billing. The Departments ask for comments as to whether plans and issuers should be required to include a disclosure about state balance billing laws. The Council does not object to the addition of a requirement to include such a statement for insured group health plans noting that state law may prohibit balance billing for insured plans. However, the Council requests that the Departments not require the notices to be state-specific, as that would be burdensome on plans and issuers, and requests that such a requirement not apply to notices provided by self-funded group health plans, as state balance billing prohibitions do not apply to self-funded plans. For self-funded plans, statements regarding state balance billing protections would not be relevant and could be misleading.

In addition, the Departments ask if a disclaimer should be required to be added to the notice, noting that the cost-sharing liability estimate might not include unprocessed claims. The Council supports the addition of such a statement to the notice as it would provide useful information to participants and beneficiaries and protect against potential consumer confusion relating to the cost-sharing liability estimate, thereby mitigating employer concerns regarding potential liability. Further, as the Council understands, the statement would be a uniform statement for all notices and therefore requiring inclusion of such a statement would not meaningfully increase burden.

As to the Departments' request for comments regarding whether plans and issuers should be required to add to the notice a date on which the estimate will expire, the Council does not support an additional inquiry-specific requirement. Such a requirement would substantially increase the burden of the notice, primarily because it adds individual-specific information to the disclaimers, rather than a uniform disclaimer. Further, this additional burden does not seem necessary as it is most likely that participants and beneficiaries will be looking up cost-sharing information in relatively close timing to any planned procedure or receipt of health services. However, the Council does recognize how this information could be useful in some circumstances. Therefore, the Council supports employers having the flexibility to add this to the notice, if they choose to do so. More generally, the Council also supports the Departments requiring inclusion of a general disclaimer that the estimate is based on current information, which will change over time, and so participants and beneficiaries should use the tool as close in time as possible to receipt of the item or service, rather

than using the tool for long-term planning. To address changes that may or will occur on a plan year basis, we also support a disclaimer noting that the estimate is based on current plan year data and accumulated amounts and cost-sharing obligations may change year to year and the plan sponsor may change the plan design from year to year.

Lastly, the Council thanks the Departments for providing a model notice. The Council supports the use of the model notice being optional for plans and issuers and appreciates the Departments giving plans and issuers the flexibility to customize the notice, while adhering to the required content elements.

F. Cost-Sharing Estimate Tool: Form of Disclosure of Cost-Sharing Liability Estimates

The proposed regulations would require that the cost-sharing information be made available through a free internet-based, self-service tool that allows participants and beneficiaries to search for cost-sharing information for a covered item or service. The tool would need to allow users to search for both (1) cost-sharing information for a covered item or service by a specific in-network provider or by all in-network providers and (2) the out-of-network allowed amount for a covered item or service furnished by out-of-network providers, in either case by the user inputting:

- A billing code or a descriptive term, at the option of the user; *and*
- Other relevant factors used by the plan or issuer to determine the applicable cost-sharing amount (such as geographic location of the service in which the covered item or service will be sought or provided, facility name, or quantity or dosage).

Users must be able to use the tool to refine and reorder search results based on geographic proximity of providers and the amount of estimated cost-sharing liability for the covered item or service.

As noted above, the proposed regulations require the tool to be searched based on geographic proximity to providers, but it does not specify the geographic proximity in relation to what. The Council requests that the Departments clarify the intent of this search function so that plans and issuers understand their responsibility in building the tool. We suggest that the Departments provide that, as one permissible method, the tool may provide for geographic proximity based on a zip code entered by the participant or beneficiary, to enable the consumer to choose whether to search based on the proximity to home or work or some other location.

The Departments also solicit comments on whether the tool should be required to have additional refining and reordering functionality, including whether it would be helpful or feasible to refine and reorder a search by provider subspecialty. The Council

understands how such information may be helpful, but requests that any additional functionality relating to refining and reordering search results be optional for plans and issuers at this time. The proposed regulations already provide helpful sorting features and any additional functionality should be left to the discretion of plans and issuers.

The proposed regulations would also require that the requested information be provided in paper form, upon request and without a fee and that the information be mailed no later than two business days after the request is received.

The requirement to provide the requested information in paper form could potentially necessitate plans providing large volumes of paper disclosures, depending on individual requests. A voluminous paper response would not only be burdensome for plans and issuers but also would be overwhelming for participants and beneficiaries. The Council suggests the Departments establish a reasonable limit for requiring information in paper form, such as requiring paper form for no more than 25 providers for any single request for a covered item or service. The Council also requests the Departments clarify how participants are to make inquiries to plans and issuers for a paper form disclosure. For example, do the Departments intend for plans and issuers to provide a phone number to which participants can call, or do the Departments intend for participants to be able to request information in paper form as part of the tool? While the Council generally appreciates the Departments providing flexibility for plans and issuers, for this specific requirement, the Council requests that the Departments provide additional guidance so plans and issuers have a clear understanding of how to operationalize the requirement to provide this information in paper form.

The Departments also request comment on whether additional methods of providing information should be required, rather than permitted. The Departments note that they are particularly interested in feedback on whether plans and issuers should be required to provide the information over the phone, or by email, at the request of a participant or beneficiary. The Council appreciates the Departments' request for comment on additional methods and recommends that plans and issuers should have the option to provide the required information in other formats, but that this should not be required. Generally, plans and issuers take into consideration the most effective ways to communicate with participants and beneficiaries and the Council expects that plans and issuers similarly will consider any additional ways to communicate this specific information to participants and beneficiaries. The Council asks the Departments to clarify that if the plan or issuer provides this information through another method, such as by email, at the request of the participant or beneficiary, that this same information would not also need to be provided via paper form, as well.

Finally, the Departments seek comment on whether the final regulations should permit the proposed disclosure requirements to be satisfied with a self-service tool that is made available through a website or comparable means of accessing the internet, such as a mobile application, or whether multiple means, such as websites and mobile

applications, should be required. The Council is of the view that it is important to provide plans and issuers the flexibility to make such required information available through multiple means, such as a mobile application, but that this should not be an additional requirement. Ultimately, many plans and issuers may choose to provide the required cost-sharing information through additional means, including through a mobile application, but employers should not be required to do so and should be allowed to choose the best method according to their workforce. Ideally, a flexible standard would be provided that will allow for improvements in technology over time. If the final regulations allow the cost-sharing estimate tool to be provided other than on an internet-based website, the Council requests that the Departments clarify that plans and issuers that use an alternative method need not also provide the tool on a website.

G. Cost-Sharing Estimate Tool: Additional Requests for Clarification

The Council appreciates the detail contained in the proposed regulations but requests clarification regarding a handful of items, in order to support successful implementation.

- The Council understands that "participants" and "beneficiaries" intended to use the tool are those enrolled in the plan, but the proposed regulations use the ERISA definitions which also include individuals who may become eligible for the plan. The Council requests that the Departments confirm that the intent of the proposed regulations is that only participants and beneficiaries enrolled in the plan would have access to the tool.

- The definition of "accumulated amounts" refers to "the amount of financial responsibility a participant or beneficiary has incurred at the time of the request for cost-sharing information … ."

    - The Council requests that the Departments clarify whether this means the amount the person has already paid toward the deductible and/or maximum out of pocket limitation or whether it means the amount the participant or beneficiary still has to pay. For example, a participant has a $2,000 deductible and the participant has already paid $1,500 towards the deductible. Should the tool show what has already been paid (*i.e.*, $1,500) or the amount that is left to be paid toward the deductible (*i.e.*, $500)? The Council understands the intent of this aspect of the disclosure requirement generally and supports it as a key element of the cost-sharing liability estimate. However, the Council requests that the Departments clarify the intent so that plans and issuers understand exactly what needs to be displayed.

    - The Council understands that the proposed regulations do not require

that accumulated amounts or the cost-sharing estimate more generally take into account amounts made available under account-based arrangements available to the participant or beneficiary, including in cases in which the participant or beneficiary could or must use the amounts made available towards cost-sharing. There are an array of these types of arrangements of varying types and structures and to incorporate them into the cost-sharing estimate could be administratively challenging and would impose a significant burden. To avoid confusion in implementation, the Council requests that the Departments address this issue expressly and confirm amounts made available in account-based arrangements that can or must be used toward cost-sharing expenses need not be reflected in the accumulated amounts or cost-sharing estimate under the tool. To ensure that participants and beneficiaries understand that these amounts may be available, however, the Council supports allowing plans and issuers to include a related disclaimer in the required notice or, if the Departments deem necessary, require a general related disclaimer, if the employer offers such an arrangement.

- The Council requests that the Departments confirm that the prerequisites listed in proposed regulations (*i.e.*, concurrent review, prior authorization, step-therapy and fail-first protocols), which are required to be disclosed, are an exclusive list. The Council supports a definition of "prerequisite" that provides an exclusive list, in order to provide employers with certainty. Further, the Council does not support adding any other medical management techniques to the list of prerequisites.

- The proposed regulations provide that participants and beneficiaries must be able to use the tool to search for an out-of-network allowed amount for an item or service covered by out-of-network providers (whereas the tool must allow participants and beneficiaries to search for cost-sharing estimates for in-network providers). The Council's understanding is that the tool also is to provide cost-sharing information for out-of-network providers and not just the allowed amounts. The Council requests that the Departments clarify the intent so that plans and issuers understand exactly what must be displayed.

II. Negotiated Rate and Allowed Amount Machine Readable Files

The proposed regulations require group health plans and health insurance issuers to make available on a public internet website two machine-readable files that include information regarding negotiated rates with in-network providers and historical allowed amounts for out-of-network providers for all covered items and services.

A. General Comments on Public Disclosure of Negotiated Rates

Transparency should enable increased value, resulting in reduced costs, less consumer confusion and more informed and efficient consumption of health care. Transparency is not, and should not be, an end goal in its own right.

The Council strongly believes increased transparency is needed with respect to a plan and employer's access to and use of the plan's own pricing data, including claims data and provider-specific negotiated rates. Increasing employer access to and use of pricing data will enable market forces to work more effectively and efficiently, ultimately leading to lower cost and higher quality outcomes. Notably, of those employers that have had success in decreasing the rate of health care spending, many have done so by analyzing their own plan data to better understand how much is being spent on specific health care services. This is particularly the case with health care services delivered in various clinical settings for which the plan can encourage enrollees to select higher-value providers operating in higher-value settings. Programs that are focused on value-based benefit design and value-based payment reform have the potential to transform our system by realigning incentives that keep enrollees healthier – while at the same time lowering costs. Increased price transparency and plan sponsor access to pricing data will help facilitate the development and expansion of value-based programs. Accordingly, the Council strongly supports policies that ensure a plan and/or its employer plan sponsor has, at a minimum, access to providers' negotiated rates specifically applicable to the plan.

Relatedly, the proposed regulations require group health plans and health insurance issuers to publicly disclose negotiated rates for in-network providers. In the preamble to the proposed regulations, the Departments set out a number of related potential benefits for sponsors of self-funded and insured plans, including empowering plans to make meaningful comparisons between offers from issuers and TPAs and evaluate the prices offered by providers who wish to be included in their pool of in-network providers. More generally, the Departments note that "[g]iven that, as of 2017, more than 55 percent of the nation's population received coverage from their employers, the ability of group health plans to effectively negotiate pricing for coverage and services would be a boon to competition in the health care market." The Council agrees that employers play a unique and significant role in addressing rising health care costs and that access to information about negotiated rates by employer plan sponsors has the potential to empower employers to make decisions and pursue plan designs that could lead to lower-cost, higher-value care.

More generally, the Departments express the view that the public disclosure of negotiated rates and allowed amounts will spur competition in health care markets and slow or potentially reverse the rising cost of health care items and services. The Departments state that, based on general economic theory, with the public disclosure of negotiated rates and allowed amounts, consumers will be able to shop for services and items based on price and providers and suppliers will compete to lower prices and

improve quality. The Departments note that one of the primary purposes of the public disclosure files is to make this information available to software application developers and other innovators to compile and consolidate the information in a manner that supports meaningful comparisons by consumers.

However, in addition, the Departments state that:

> [T]he Departments recognize that the precise impact of making pricing information public cannot be predicted. As discussed in section VII of the preamble to these proposed rules, the Departments are aware that price transparency could have negative unintended consequences in markets where pricing will become very transparent, including narrowing of prices and increases in average costs. The Departments also recognize that information disclosures allowing competitors to know the rates plans and issuers are charging may dampen incentives for competitors to offer lower prices, potentially resulting in higher prices. Some stakeholders also have expressed concern that without additional legislative or regulatory efforts public availability of negotiated rates may have the unintended consequence of increasing costs for services in highly concentrated markets or result in anticompetitive behaviors. Notwithstanding these concerns, the Departments remain confident that the release of the data will help reduce pricing disparities and potentially drive down health care costs, as discussed earlier in this preamble. The Departments seek comment on these potential concerns and what additional rules would help to mitigate risk of these potential consequences.

As noted above, the Council supports increased price transparency where it is expected to bring down costs, reduce consumer confusion and result in more value-driven, informed and efficient consumption of health care services. In certain markets, for some items and services, the public disclosure of negotiated rates could increase competition and potentially lead to lower health care costs or less variation in health care costs. It is also possible that, conversely, the public display of negotiated rates may have the unintended consequence of increasing health care costs in highly concentrated markets or as a result of anticompetitive behaviors.

Therefore, the potential for higher prices, at least in certain markets, calls for the Departments to gather more data about the impact of public disclosure of negotiated rates and take steps to guard against this risk. In light of the uncertainty and potential unintended adverse consequences, the Council requests that the Departments consider such impacts and structure any final regulations to avoid such unintended consequences. For example, the Departments could require plans to disclose the median or lowest negotiated rate for each covered item and service, based on the rates of all in-network providers for the plan (*i.e.*, one rate would be provided for each item and service rather than provider-specific information for each item or service). This would increase price transparency generally but mitigate the risk of anticompetitive behavior. However, to avoid adverse consequences, we encourage the Departments to consider implementing this in a way that guards against reverse engineering of specific negotiated rates in concentrated markets.

Other strategies to reduce the potential for anticompetitive effects would be related to the extent of the disclosure/publicity of negotiated rates. As such, the Council supports making negotiated rates available to plan sponsors specifically (*i.e.*, plan sponsors would have access to all other plans' and issuers' negotiated rates, to use in their capacity as plan sponsors), thereby giving employers the data they need to make meaningful comparisons (*e.g.*, as part of a request for proposal) and to help steer participants and beneficiaries to higher-value care. If the extent of the disclosure was narrowed in this way, the disclosures could even be required at the request of the plan sponsor, rather than by posting machine readable files.

The Council supports the goal of decreased health care costs by way of increased transparency, but urges the Departments to exercise due care to ensure that the increased transparency will, indeed, achieve the goals of lower cost and higher quality health care for America's working families.

B. General Comments on Public Disclosure of Allowed Amounts

The Departments specifically seek comment on whether the required disclosures of historical out-of-network allowed amounts will provide useful information that can assist consumers in locating services at an affordable cost, or whether there is additional information that is both useful to anticipated users and practical for plans and issuers to disclose for this purpose. For instance, the Departments considered requiring plans and issuers to disclose in the allowed amount file amounts out-of-network providers charged participants and beneficiaries for covered items and services. The Departments note that such charge amounts would be included in any claim for out-of-network benefits and could be helpful to consumers shopping for services based on price. Therefore, the Departments seek comment on this data element.

As noted earlier, while allowed amounts are one piece of relevant information, the Council is concerned that the disclosure of allowed amount information alone does not provide the full picture for consumers making decisions about seeking medical care. The failure to also require disclosure of billed charges, which could lead to surprise bills, undermines the usefulness of this disclosure. Similar to the Departments, the Council understands that because the public file relating to allowed amounts provides historical data, plans and issuers would have data on the billed charges for a specific provider and could provide this as part of the disclosure. The Council supports requiring the disclosure of billed charges in the historical allowed-amount files as this would provide a more complete picture of potential liability for consumers considering seeking care from out-of-network providers and may reduce situations in which consumers are faced with surprise bills that they cannot afford.

C. Disclosure of All Items and Services in the Public Disclosure Files

The proposed regulations require that the in-network rate and allowed amount public files include information for all covered items and services. We understand that the primary purpose of the public files is that third parties could use the data provided to create shopping tools for consumers. As noted earlier in this comment letter, we are concerned that consumers will be overwhelmed if provided information on all items and services and that, based on employer experience with current tools, tools that cover the most common items and services are more likely to be useful. Further, based on the number of items and services typically covered and the scope of other data required in the public files, we understand that a file covering all covered items and services as defined by the Departments would be massive and require a great amount of resources to create and maintain. For these reasons, to the extent the final regulations require disclosure to the public (rather than solely to plan sponsors), we urge the Departments to limit the items and services required to be captured in the in-network rate and allowed amount files to the most common items and services, as described in more detail in section III.C (pages 8-10) of this letter.

D. Technical Comments on Public Disclosure of Negotiated Rates and Allowed Amounts

The proposed regulations provide that they do not prohibit a plan or issuer from satisfying the requirement to disclose allowed amounts in a public file by disclosing allowed amounts made available by, or otherwise obtained from, an issuer, a service provider, or other party with which the plan or issuer has entered into a written agreement to provide the information. The proposed regulations provide that in this circumstance, the third party with which the plan or issuer has contracted may aggregate allowed amounts for more than one plan or policy. The Council requests that the Departments clarify a plan's obligation if a third-party aggregates the allowed amount data. Specifically, the Departments should clarify whether the plan or third party is required to post the file and how the file document is required to be labeled. Also, the Council requests clarification on whether the posting is required to disclose that the information is aggregated. The Council supports the Departments providing flexibility for aggregation, but requests clarity regarding the specific requirements so plans and issuers (and third parties) understand the regulations.

Further, the Council understands the proposed regulations to require that plans and issuers include prescription drugs in the items and services listed in the negotiated rates and allowed amount files. The Council requests clarification as to the meaning of the negotiated rate for prescription drugs. We assume the Departments mean the drug price negotiated for the plan by the PBM but clarity would be appreciated as there are many elements to drug prices.

In addition, the proposed regulations provide that the Departments will issue technical guidance regarding the required machine-readable files. The Council supports the use of subregulatory guidance to provide the flexibility needed to address issues and questions that will arise during implementation and over time. However, the Council requests that plans and issuers have an opportunity to comment on such guidance and that any guidance be issued far in advance of the applicability date of any final regulations.

Lastly, the proposed regulations require monthly updates to the public files and the Departments ask if more frequent updates should be required, such as every 10 days. The requirement to update the files on a monthly basis is extremely burdensome and, thus, the Council does not support requiring more frequent updates. Rather, to address concerns regarding burden, the Council requests that plans and issuers only be required to update the files every six months. The data in these files will not substantially change on a month-to-month basis and, therefore, the Council requests that updates be required less frequently, as a way to mitigate burden without substantially undermining the accuracy of the posted files.

V. Increased Risk of ERISA Litigation

Disclosure of pricing information through the machine-readable files and through the cost-sharing tool raises concerns for plan sponsors about the potential for increased litigation under ERISA based on the release of payer-specific negotiated rates. For example, the Council is concerned that there may be an increased risk of fiduciary-based litigation similar to the increase in litigation following the implementation of mandated fee disclosures for employer-sponsored 401(k) plans.

In 2012, DOL issued final regulations requiring plan administrators to provide participants with disclosures regarding certain investment and recordkeeping fees applicable to their retirement plans. While this fee disclosure has provided participants with improved transparency regarding plan fees, it coincided with a spate of 401(k) plan class action litigation that continues to this day. Plaintiff participants generally make a claim that the employer violated its fiduciary duty by causing the plan to pay investment and recordkeeping fees that are higher than the investment and recordkeeping fees paid by similarly-situated plans. While this litigation may be resolved in favor of the sponsoring employer/named fiduciary, the costs of this litigation on the system (*e.g.*, in the form of forgone employer plan contributions) cannot be ignored. Further, many employers have paid significant sums to settle cases in order to avoid continuing costly litigation.

It is essential that DOL take steps to guard against the expensive (and often meritless) class action litigation that has befallen 401(k) plans for employer-sponsored group health plans as a result of disclosure of negotiated rates. More generally, we note that employers pay a material percentage of claims dollars and that participant and plan sponsor interests are aligned to have the most cost-effective program and best contract rates. To allow litigation based on certain instances where one provider or type of service does not have the absolutely lowest price ignores the broader range of services and providers covered by the plan and the factors other than price that the plan sponsor takes into account. Accordingly, the Council strongly urges that DOL effectively and expressly address this issue so that any disclosure requirement is crafted in a way that does not increase fiduciary liability for employer plan sponsors.

For example, DOL should consider proposing a safe harbor to protect employers from downstream litigation risk relating to the public disclosure of negotiated rates and disclosure of negotiated rates through the cost-sharing tool. Such a safe harbor could provide that so long as an employer can demonstrate it "considered" negotiated rates as part of its decision-making process in selecting an administrative services organization (ASO) for its group health plan, that it would not be deemed to have acted imprudently as a fiduciary for purposes of ERISA with respect to the selection of the ASO by virtue of the negotiated rates. This would be the case regardless of whether the employer selected an ASO with relatively lowest or lower negotiated rates. The Council is pleased to provide any information or assistance that might be helpful to DOL as part of this effort.

VI. Good Faith Safe Harbors and Anti-Duplication Rules

The proposed regulations include three good faith safe harbors:

(1) A plan or issuer will not fail to comply with the disclosure requirements solely because the plan or issuer, acting in good faith and with reasonable diligence, makes an error or omission in the required disclosure, provided the plan or issuer corrects the information as soon as practicable (error or omission safe harbor).

(2) A plan or issuer will not fail to comply with the disclosure requirements solely because, despite acting in good faith and with reasonable diligence, its internet website is temporarily inaccessible, provided that the plan or issuer makes the information available as soon as practicable (website inaccessibility safe harbor).

(3) To the extent compliance with the disclosure requirements requires a plan or issuer to obtain information from any other entity, the plan or issuer won't fail to comply with the disclosure requirements because it relied in good faith

on information from the other entity, unless the plan or issuer knows, or reasonably should have known, that the information is incomplete or inaccurate.

The Departments ask if additional measures should be taken to ensure that plans and issuers that have taken reasonable steps to ensure the accuracy of the required disclosures are not exposed to liability. The Council submits there is an additional area in which a good faith safe harbor is absolutely vital to ensuring plans that make good faith efforts are not exposed to liability.

In order to complete the required disclosures, plans will need to obtain information from certain third parties, including TPAs. The Council is deeply concerned that even with good faith efforts, plans may be unable to obtain some of the information needed to complete the required disclosures in the timeframes required by the regulations, in some cases as a general matter and in some cases due to short-term administrative or technical delays. For example, historically some employers have faced challenges in obtaining their own plans' negotiated rates from issuers and TPAs because negotiated rates have been cited as proprietary information by many issuers and TPAs. (We note that the Council is supportive of legislative efforts, in particular those outlined in the Lower Health Care Cost Act, that would prohibit restrictions on employers' access to and use of this information.) Further, it may be the case that certain other information needed to complete the required disclosure, specifically with respect to the cost-sharing tool, such as up-to-date accumulated amount information, must be obtained by a third party. There could be short-term delays in providing that information to the plan due to administrative or technical issues which would prevent real-time disclosure.

Although we expect that in some cases third parties, such as TPAs, may create and operate the tool or create the machine-readable files on behalf of the plan, in other instances plans may wish to create and operate these disclosures themselves. In any case, it is inconsistent with sound policy to penalize plans for failure to comply with the disclosure requirements due to actions or inaction by third parties outside of a plan's control, if the plan is making good faith efforts to obtain the required information. Therefore, the Council strongly urges that the final regulations include a safe harbor to address this issue.

Specifically, we suggest that the final regulations include a safe harbor that provides that plans will not fail to comply with the disclosure requirements solely because the plan fails to provide the disclosure, or certain aspects of the disclosure, due to the inability to obtain required data from a third party service provider, provided the plan acts in good faith and with reasonable diligence to obtain the required data and provides the disclosure as soon as practicable if the plan is ultimately able to obtain the data. In order for this safe harbor to provide the intended assurance, we request that the Departments provide examples of actions that would constitute good faith and reasonable diligence in this context. For example, we suggest that the Departments provide, as an example, that if a plan solicits the information at least twice, and at least

one of the solicitations is in writing, the plan will be considered to have acted in good faith and with reasonable diligence. We also ask that the Departments provide guidance on the extent to which plans should provide the required disclosures if they are unable to obtain some of the required data elements but are able to obtain the other data elements.

This topic is of great concern for our members. If the Departments are not able to sufficiently address this issue, the Council urges the Departments to decline to finalize the proposed regulations, to avoid regulations under which employer plans are subject to liability they are unable to avoid despite their best efforts. Further, although we request this safe harbor to address current practicalities and to avoid unfair and unreasonable exposure to liability, we reiterate our statement above that the Council strongly believes increased transparency is needed with respect to a plan's and employer's access to and use of the plan's own pricing data, including claims data and provider-specific negotiated rates.

More generally, the Council thanks the Departments for providing the good faith safe harbors included in the proposed regulations. Due to the sheer volume of information required to be disclosed, the speed at which it must be disclosed and the fact that many plans will need to rely on information from other entities (*e.g.*, TPAs), these good faith safe harbors are essential.

The Council has concerns regarding the potential for increased risk, in the form of litigation and otherwise, resulting from these new disclosure requirements. The good faith safe harbors take a meaningful step to addressing some of those employer concerns. The Council supports the retention of the safe harbors in the final regulations, subject to the following comments, and requests that the Departments apply them consistently both in the near term and the long term. That is, the Council anticipates that the safe harbors will be needed in the near term, as a form of transition relief, but also on an ongoing basis once initial implementation is complete.

As the good faith safe harbors are vital, we seek clarification on a number of related items. With respect to the error or omission safe harbor, the plan or issuer is required to correct the information as soon as practicable. However, additional guidance on what it means to "correct" the information is needed. Specifically, we urge the Departments to provide that a plan or issuer meets the requirements of this safe harbor if it corrects the information, as soon as practicable, on a prospective basis. Plans and issuers should not be required to conduct retroactive corrections (*i.e.*, providing updated information to each participant or beneficiary who previously conducted a search on the tool or to each individual who previously accessed the public file). Such a requirement would be overwhelming and unreasonable and the benefit would not justify the burden.

In addition, the website inaccessibility safe harbor appears to cover circumstances in which the relevant internet website is inaccessible temporarily. We suggest that the safe harbor more broadly cover situations in which the tool or machine readable files are

temporarily inaccessible, including because the internet website is inaccessible. This clarification would cover other technical issues, for example that may affect only the tool, even though the remainder of the issuer's or plan's website is accessible. To account for the myriad technical issues that can occur in systems as complex as the tool and the machine readable files, we request that the Departments broaden the language of the safe harbor to more generally capture technical, temporary issues. This would be consistent with what we understand to be the spirit of this safe harbor but would avoid making the safe harbor overly specific and, therefore, insufficient.

Further, the proposed regulations would permit a plan or issuer to satisfy the proposed regulations requiring public disclosure of negotiated rates and allowed amounts in machine readable files by entering into a written agreement under which another party (such as a TPA or health care claims clearinghouse) will make public the required information in compliance with the regulations. However, the proposed regulations go on to say that if a plan or issuer chooses to enter into such an agreement and the party with which it contracts fails to provide the required disclosures, the plan or issuer would be liable for violating the requirements related to the machine readable files. The Council understands this contracting right to be the case, even without this specific provision in the proposed regulations, such that, in the normal course, for all manner of requirements, plans and issuers can contract with third parties to meet an obligation but the plan or issuer is ultimately liable for compliance. Therefore, the Council requests clarification of the meaning of this safe harbor and the extent to which it is a safe harbor. If the Departments' intent is to provide additional protection for plans and issuers, the Council requests that this safe harbor be extended to the cost-sharing estimate requirements of the proposed regulations as well and not just the portion of the proposed regulations requiring public files.

Lastly, the proposed regulations include a special rule to streamline the provision of the required disclosures and avoid unnecessary duplication of the disclosures with respect to insured group health coverage. Specifically, if a group health plan is insured, the plan would satisfy the requirements of the proposed regulations if the issuer offering the coverage is required to provide the information pursuant to a written agreement between the plan and the issuer. If the issuer fails to provide the required disclosures, then the issuer, and not the plan, would violate the disclosure requirements. The Council thanks the Departments for this anti-duplication rule and strongly recommends it be retained in final regulations. As is its intent, the anti-duplication rule will be very helpful to employers sponsoring insured group health plans and will reduce confusion for participants and beneficiaries, by avoiding duplicative tools and unnecessary burden.

VII. Applicability

The Departments propose to apply the proposed requirements for plan or policy

years beginning on or after one year after the effective date of the final regulations. The Departments seek feedback on the proposed applicability date and, in particular, request information and comments from plans, issuers and TPAs on the timing necessary to develop the cost-estimation tools and machine-readable files.

We understand that the Administration is committed to taking urgent action to increase transparency and decrease health care costs. However, one year is not a realistic timeframe to implement the proposed requirements, even for the most sophisticated employers and issuers.

The proposed regulations will require disclosure of large volumes of data, which will have to be coordinated among various parties and for which systems will need to be put into place to ensure timely, accurate disclosure. Further, the technical build required for both the cost-sharing tool and the machine readable files will be substantial. Although many employers currently offer cost-sharing tools, the proposed regulations require significant additional disclosures. Many current cost-sharing tools are based on historical information (rather than actual negotiated rates or allowed amounts), provide look-up abilities for only some items and services (rather than all items and services) and provide ranges of possible costs (rather than a specific cost estimate). As to the machine readable files, that requirement is entirely new and is expansive. Accordingly, the Council strongly urges that the applicability date be no sooner than plan years beginning on or after the date that is two years after the effective date of any final regulations. We note that the effective date that we request nevertheless imposes an aggressive implementation timeline on plans and issuers but we support efforts to increase transparency as quickly as possible. Further, we believe the suggested applicability date will be feasible, in particular, if the Departments take steps to mitigate the burden as suggested in this letter including limiting the disclosure obligations to the most common items and services.

More generally, while we understand that the Departments will proceed with these regulations separately from the efforts we suggest on quality reporting and requirements on providers to furnish pre-service billing information, we strongly encourage the Departments to proceed with those efforts expeditiously. As discussed elsewhere in this letter, those additional efforts will be key to fully achieving the goals of the proposed regulations. Our comments in this letter on implementation timing relate to the current proposed regulations; we will evaluate the time plans will need to implement any additional future regulations separately.

Also as to applicability, the proposed regulations would not apply to grandfathered health plans, health reimbursement arrangements or other account-based group health plans, excepted benefits and short-term, limited duration insurance. The Council is particularly appreciative of the exception provided for account-based group health plans for which the proposed requirements would add no value, although we understand and support that other group health plan coverage, offered by the employer in addition to the account-based group health plan, would be subject to the disclosure

requirements. We also thank the Departments for confirming the additional exceptions, which are the result of the statutory structure.

In addition, the Departments noted they considered applying the proposed regulations only to insured plans but were worried about cost-shifting to self-funded plans. Although the Council is cognizant of the burdens the proposed requirements place on self-funded plans, the Council supports the approach of the Departments in the proposed regulations, specifically applying the rule to both insured and self-funded plans, to avoid cost-shifting.

Lastly, the Council is concerned that due to the detailed nature of the required disclosure and the centrality of technology to these new disclosures, over time and as implementation gets underway, there will be areas where the rules need to be clarified and refined, in part due to advancements in technology. Therefore, the Council suggests that the Departments include in the final regulations the ability to provide additional subregulatory guidance as needed.

VIII. Request for Information: Disclosure of Pricing Information Through a Standards-Based API

The Departments are considering further expanding access to pricing information – both an individual's access to estimates about their own cost-sharing liability, and information about negotiated in-network rates and data for out-of-network allowed amounts, in future rulemaking. Specifically, the Departments are considering whether to require, through future rulemaking, that group health plans and health insurance issuers make available discrete data elements through a standards-based API, such as the elements that would be disclosed through the proposed internet-based self-service tool, in-network negotiated rates and out-of-network allowed amounts.

The Council supports changes that will facilitate the sharing of pricing and other information with health plan participants and understands the potential usefulness of APIs for achieving such goals. As noted throughout this letter, the Council supports transparency of price information that can be easily utilized to render this information useful for participants and beneficiaries.

However, the Council is also cognizant of potential privacy issues related to providing an API that would allow consumers to choose any third-party application to access personal health information held by a plan or issuer, including the potential security risks to personal health information created by an API connecting to third-party applications. The Council understands that entities are not responsible under the HIPAA Rules for the security of protected health information once it has been received by a third-party application chosen by an individual. Nevertheless, the Council believes the Departments should consider safeguards to protect individuals' health

information from being misused. In particular, the Council is concerned that third party entities could deploy direct-to-consumer applications specifically in order to profit from obtaining, using, or disclosing individuals' protected health information (and potentially other information) in ways the individual either did not authorize or to which the individual did not knowingly consent. Importantly, plans and issuers would have to take greater care in configuring and maintaining the security functionalities of the API and the electronic information systems to which it connects.

Given the privacy and security risks, and the additional burden that would be placed on plans and issuers, the Council feels strongly that any requirement for group health plans to provide an API must be in a separate proposed rule and plans would need to be given time to comment on any specific proposal. For the Council to evaluate the utility of an API, the Council would need a clear understanding of what is being required, how it interacts with other proposed requirements and how any proposed requirements relate to what plans are currently doing, as well as how any proposed requirements address the privacy and security concerns noted above. The Council further notes that any proposed requirement should provide enough flexibility so that transparency initiatives can keep pace with new technology developments.

IX. Request for Information: Provider Quality Measurement and Reporting in the Private Health Insurance Market

In the preamble to the proposed regulations, the Departments express an interest in how public and private sector quality measures might be used to compliment cost-sharing information for plans and issuers in the private health insurance market. In this regard, the Departments seek comment on a number of specific questions relating to disclosure of quality standards, including whether in addition to the price transparency requirements, the Departments should impose requirements for the disclosure of quality information and whether such disclosures should be standardized across plans and issuers or if plans and issuers should have flexibility to provide quality information that is based on metrics of their choosing or state-based metrics.

The Council has long supported greater transparency of quality information, as the other half of the equation for achieving health care transparency, as a means to reduce health care costs. As noted earlier, the Council recognizes that price is just one piece of the puzzle and that, in terms of value, the price of the health care service does not always correlate with the quality of care and, thus, equate to better value. As such the Council very much supports the adoption and integration of quality measurements as part of increased price transparency and encourages the Departments to proceed with those efforts expeditiously.

Some employers are already providing quality measure reporting, or others are working toward that goal. Accordingly, the Council appreciates that employers can continue to provide such disclosures in conjunction with the new proposed requirements. The Council welcomes working with the Departments on any new proposals relating to quality transparency and would be pleased to provide additional information regarding the types of efforts employers are currently making, as the Departments proceed to consider proposing quality reporting requirements for plans and issuers.

Meaningful and aligned quality measures are a foundation of value-based purchasing decisions. As more large employers implement innovative payment reforms, like direct contracting or accountable care organizations, quality measures should be aligned across public programs and private plans to help lay a strong foundation to achieving more meaningful payment reforms. To that end, we note that that the Council is a member of the Core Quality Measures Collaborative (CQMC), a broad-based coalition of health care leaders, including the Centers for Medicare and Medicaid Services (CMS), insurance providers, medical providers, consumers and purchasers, promoting alignment of quality measures across public programs and the private sector. The Council encourages the Departments to work with the CQMC as the Departments consider whether to propose quality transparency requirements for private health coverage. More generally, the Council supports quality standards that are consistent, easily understood by consumers and plan sponsors and that, among other things, reflect patient safety and patient satisfaction data.

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Employers are on the front lines of implementing innovative strategies to get more out of every health care dollar they spend. When commitment to their employees is coupled with their drive for innovation, employers are the key to lowering health care costs and increasing quality for working families and the health care system as whole. The Council looks forward to working with the Administration and the Departments to improve transparency to achieve these goals. Thank you for considering these comments. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,

Ilyse Schuman
Senior Vice President, Health Policy