

FAQS ABOUT AFFORDABLE CARE ACT AND CONSOLIDATED APPROPRIATIONS ACT, 2021 IMPLEMENTATION PART 49

August 20, 2021

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act (ACA) and certain provisions of title I (the No Surprises Act) and title II (Transparency) of Division BB of the Consolidated Appropriations Act, 2021 (the CAA). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs> and <http://www.cms.gov/ccio/resources/fact-sheets-and-faqs/index.html>), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

Transparency in Coverage Machine-Readable Files

The Transparency in Coverage Final Rules (the TiC Final Rules) require non-grandfathered group health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets to disclose on a public website information regarding in-network provider rates for covered items and services, out-of-network allowed amounts and billed charges for covered items and services, and negotiated rates and historical net prices for covered prescription drugs in three separate machine-readable files.¹ The machine-readable file requirements of the TiC Final Rules are applicable for plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q1: Will the Departments enforce the machine-readable file provisions in the TiC Final Rules?

Yes, subject to two exceptions, plans and issuers must make public machine-readable files disclosing in-network rates and out-of-network allowed amounts and billed charges. Under the first exception, as an exercise of enforcement discretion, the Departments will defer enforcement of the TiC Final Rules' requirement that plans and issuers publish machine-readable files relating to prescription drug pricing pending further rulemaking, as described below.² Under the second exception, as an exercise of enforcement discretion, the Department will defer enforcement of the TiC Final Rules' requirement to publish the remaining machine-readable files until July 1, 2022, as described in Q2.

After the Departments finalized the TiC Final Rules, Congress enacted the CAA, which imposes important new transparency requirements on plans and issuers, including prescription drug reporting requirements under section 204 of division BB of the CAA. These requirements

¹ 85 FR 72158 (Nov. 12, 2020).

² 26 CFR 54.9815-2715A3(b)(1)(iii), 29 CFR 2590.715-2715A3(b)(1)(iii), and 45 CFR 147.211(b)(1)(iii).

significantly changed the regulatory landscape since the TiC Final Rules were adopted. Moreover, stakeholders have expressed concern about potentially duplicative and overlapping reporting requirements for prescription drugs. For example, under the TiC Final Rule, plans and issuers must publicly post pricing information for all covered prescription drugs by January 1, 2022. Under section 204 of the No Surprises Act, however, plans and issuers must also report some of the same prescription drug pricing information to the Departments by December 27, 2021.

In response to the later statutory enactment and stakeholder concerns, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement in the TiC Final Rules that plans and issuers must publish machine-readable file related to prescription drugs while it considers, through notice-and-comment rulemaking, whether the prescription drug machine-readable file requirement remains appropriate. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

Q2: Are plans and issuers required to make public the machine-readable files for in-network rates and out-of-network allowed amounts and billed charges for plan years (in the individual market, policy years) beginning on or after January 1, 2022?

The Departments recognize the number of CAA provisions plans and issuers are required to implement by January 1, 2022 and the considerable time and effort required to make the machine-readable files available in the form and manner required in the TiC Final Rules at the same time.³ Therefore, with respect to plan or policy years beginning on or after January 1, 2022, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement to make public the machine-readable files for in-network rates and out-of-network allowed amounts and billed charges, until July 1, 2022.

On July 1, 2022, the Departments intend to begin enforcing the requirement that plans and issuers publicly disclose information related to in-network rates and out-of-network allowed amounts and billed charges for plan years (in the individual market, policy years) beginning on or after January 1, 2022. For 2022 plan years and policy years beginning subsequent to July 1, 2022, plans and issuers should thus post the machine-readable files in the month in which the plan year (in the individual market, policy year) begins, consistent with the applicability provision of the TiC Final Rules. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

Price Comparison Tools

The TiC Final Rules require plans and issuers to make price comparison information available to participants, beneficiaries, and enrollees through an internet-based self-service tool and in paper

³ 26 CFR 54.9815-2715A3, 29 CFR 2590.715-2715A3, and 45 CFR 147.212.

form, upon request.⁴ This information must be available for plan years (in the individual market, policy years) beginning on or after January 1, 2023, with respect to the 500 items and services identified by the Departments in Table 1 in the preamble to the TiC Final Rules,⁵ and with respect to all covered items and services, for plan or policy years beginning on or after January 1, 2024.⁶

Internal Revenue Code (Code) section 9819, Employee Retirement Income Security Act (ERISA) section 719, and Public Health Service (PHS) Act section 2799A-4, as added by section 114 of division BB of the CAA, require plans and issuers to offer price comparison guidance by telephone and make available on the plan's or issuer's website a "price comparison tool" that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider. This requirement is applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q3: How do the different regulatory and statutory requirements for the self-service price comparison tools under the TiC Final Rules and the CAA interact?

The TiC Final Rules created a comprehensive set of requirements for plan and issuer disclosure of estimated cost-sharing information through an online tool, and in paper form, upon request. These requirements for the disclosure of cost-sharing information would allow a participant, beneficiary, or enrollee to request cost-sharing information for a discrete covered item or service by billing code or descriptive term, according to the participant's, beneficiary's, or enrollee's request. Further, the TiC Final Rules require a plan or issuer to provide cost-sharing information for a covered item or service in connection with an in-network provider or providers, or an out-of-network allowed amount for a covered item or service provided by an out-of-network provider, according to the participant's, beneficiary's, or enrollee's request, permitting the individual to specify the information necessary for the plan or issuer to provide meaningful cost-sharing liability information.

Because the price comparison methods required by the CAA are largely duplicative of the internet-based self-service tool component of the TiC Final Rules, the Departments intend to propose rulemaking and seek public comment regarding, among other issues, whether compliance with the internet-based self-service tool requirements of the TiC Final Rules satisfies the analogous requirements set forth in Code section 9819, ERISA section 719, and PHS Act section 2799A-4. These provisions, however, add a requirement that was not imposed under the TiC Final Rules: that price information also must be provided over the telephone upon request. Therefore, the Departments intend to propose rulemaking requiring that the same pricing information that is available through the online tool or in paper form, as described in the TiC Final Rules, must also be provided over the telephone upon request.

⁴ 26 CFR 54.9815-2715A2(b), 29 CFR 2590.715-2715A2(b), and 45 CFR 147.211(b).

⁵ 85 FR 72158, 72182 (Nov. 12, 2020).

⁶ 26 CFR 54.9815-2715A2(c)(1), 29 CFR 2590.715-2715A2(c)(1), and 45 CFR 147.211(c)(1).

Additionally, because plans and issuers have already been expecting to implement the first phase (500 items and services) of the internet-based self-service tool of the TiC Final Rules for plan years (in the individual market, policy years) beginning on or after January 1, 2023 and have been working towards that applicability date, as an exercise of enforcement discretion, the Departments will defer enforcement of the requirement that a plan or issuer make available a price comparison tool (by internet website, in paper form, or telephone) before plan years (in the individual market, policy years) beginning on or after January 1, 2023, aligning the enforcement date of Code section 9819, ERISA section 719, and PHS Act section 2799A-4 with the TiC Final Rules requirements. . Until that time, the Departments will focus on compliance assistance. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach. However, the Departments encourage plans and issuers with existing tools or programs to continue to make those tools or programs accessible. Plans and issuers are encouraged to work toward updating the standards of these tools and programs to meet the minimum requirements in the TiC Final Rules by the regulatory applicability date.

Transparency in Plan or Insurance Identification Cards

Code section 9816(e), ERISA section 716(e), and PHS Act section 2799A-1(e), as added by section 107 of division BB of the CAA, require plans and issuers to include in clear writing, on any physical or electronic plan or insurance identification (ID) card issued to participants, beneficiaries, or enrollees, any applicable deductibles, any applicable out-of-pocket maximum limitations, and a telephone number and website address for individuals to seek consumer assistance. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q4: Will the Departments be issuing regulations addressing the ID card requirements prior to the effective date?

No. However, the Departments do intend to engage in future rulemaking addressing implementation of the ID card requirements, including how plans and issuers offering complex plan and coverage designs should represent information on an ID card. Pending future rulemaking, plans and issuers are expected to implement the ID card requirements using a good faith, reasonable interpretation of the law.

Plans and issuers may design various, but reasonable, methods to comply with the law. When analyzing a plan's or issuer's efforts to comply with the ID card requirements, the Departments will consider whether the plan's or issuer's provision of information on ID cards is reasonably designed and implemented to provide the required information to all participants, beneficiaries, and enrollees entitled to access it on their ID cards. More specifically, the Departments will consider each of the specific data elements included on relevant ID cards; whether any data element required, but not included on the face of an ID card, is made available through information that is provided on the ID card, as well as the mode by which any information absent from the card is made available; the date by which a plan or issuer makes required information available on relevant ID cards; and, for QHP issuers that offer plans through an Exchange,

whether the ID card complies with applicable accessibility standards for people with disabilities and people with limited English proficiency under 45 CFR Part 92 and 45 CFR 155.205(c).

As an example, pending any implementing rulemaking, the Departments would not deem a plan or issuer to be out of compliance with ID card requirements where a plan or issuer includes on any physical or electronic ID card issued to participants, beneficiaries, or enrollees the following: the applicable major medical deductible and applicable out-of-pocket maximum, as well as a telephone number and website address for individuals to seek consumer assistance and access additional applicable deductibles and maximum out-of-pocket limits. Additional deductibles and out-of-pocket maximum limits could also be provided on a website that is accessed through a Quick Response code (commonly referred to as a QR code) on the participant's, beneficiary's, or enrollee's ID card or through a hyperlink in the case of a digital ID card.

Good Faith Estimate

PHS Act section 2799B–6, as added by section 112 of division BB of the CAA, requires providers and facilities, upon an individual's scheduling of items or services, or upon request, to inquire if the individual is enrolled in a health plan or health insurance coverage, and to provide a notification of the good faith estimate of the expected charges for furnishing the scheduled item or service and any items or services reasonably expected to be provided in conjunction with those items and services, including those provided by another provider or facility, with the expected billing and diagnostic codes for these items and services. If the individual is enrolled in a health plan or coverage (and is seeking to have a claim for the item or service submitted to the plan or coverage), the provider must provide this notification to the individual's plan or coverage. In the case that the individual is not enrolled in a health plan or coverage or does not seek to have a claim for the item or service submitted to the plan or coverage, the provider must provide this notification to the individual. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q5: Will HHS be issuing regulations addressing the Good Faith Estimate requirement prior to the statutory effective date?

HHS intends to issue regulations implementing good faith estimate requirements for individuals not enrolled in a health plan or coverage or who are not seeking to have a claim for the scheduled items or services submitted to the plan or coverage prior to the statutory effective date.

However, given the complexities of developing the technical infrastructure for transmission of the necessary data from providers and facilities to plans and issuers, HHS recognizes that compliance with this section related to individuals who are enrolled in a health plan or coverage and are seeking to have a claim for the scheduled items or services submitted to the plan or coverage is likely not possible by January 1, 2022. Accordingly, until rulemaking to fully implement this requirement to provide such a good faith estimate to an individual's plan or coverage under is adopted and applicable, HHS will defer enforcement of the requirement that providers and facilities provide good faith estimate information for individuals enrolled in a health plan or coverage and seeking to submit a claim for scheduled items or services to their plan or coverage. HHS is of the view that insured consumers have existing recourse to challenge

out-of-pocket costs through the internal claims and appeals and external review process described under existing law and regulations,⁷ described under and are therefore not in the same position as uninsured consumers or consumers not seeking to submit a claim to their plan or coverage would be without enforcement by the CAA's statutory deadline. However, HHS will investigate whether additional interim solutions for insured consumers are feasible. HHS encourages states that are primary enforcers of this requirement with regard to providers and facilities to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach. HHS notes that any rulemaking to fully implement the requirements of PHS Act section 2799B-6 will include a prospective applicability date that gives providers and facilities a reasonable amount of time to comply with any new requirements.

Advanced Explanation of Benefits

Code section 9816(f), ERISA section 716(f), and PHS Act section 2799A-1(f), as added by section 111 of division BB of the CAA, require plans and issuers, upon receiving a "good faith estimate" regarding an item or service as described in PHS Act section 2799B-6, to send a participant, beneficiary, or enrollee (through mail or electronic means, as requested by the participant, beneficiary, or enrollee) an Advanced Explanation of Benefits notification in clear and understandable language. The notification must include: (1) the network status of the provider or facility; (2) the contracted rate for the item or service, or if the provider or facility is not a participating provider or facility, a description of how the individual can obtain information on providers and facilities that are participating; (3) the good faith estimate received from the provider; (4) a good faith estimate of the amount the plan or coverage is responsible for paying, and the amount of any cost-sharing for which the individual would be responsible for paying with respect to the good faith estimate received from the provider; and (5) disclaimers indicating whether coverage is subject to any medical management techniques. The notice also must indicate that the information provided is only an estimate based on the items and services reasonably expected to be provided at the time of scheduling (or requesting) the item or service and is subject to change and any other information or disclaimer the plan or coverage determines appropriate that is consistent with information and disclaimers required under this section of the statute. These provisions apply with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q6: Will the Departments be issuing regulations addressing the Advanced Explanation of Benefits prior to the effective date of January 1, 2022?

No. The Departments have received feedback from the public about the challenges of developing the technical infrastructure necessary for providers and facilities to transmit to plans and issuers, starting January 1, 2022, the good faith estimates required under PHS Act section 2799B-6, which plans and issuers must then include in the Advanced Explanation of Benefits. Stakeholders have requested that the Departments delay the applicability date of this provision until the Departments have established standards for the data transfer between providers and facilities and plans and issuers and have given enough time for plans and issuers and providers and facilities to build the infrastructure necessary to support the transfers. The Departments agree

⁷ See PHS Act section 2719; 26 CFR 54.9815-2719; 29 CFR 2590.715-2719; 45 CFR 147.136; 29 CFR 2560.503-1.

that compliance with this section is likely not possible by January 1, 2022, and therefore intend to undertake notice and comment rulemaking in the future to implement this provision, including establishing appropriate data transfer standards. Until that time, the Departments will defer enforcement of the requirement that plans and issuers must provide an Advanced Explanation of Benefits. However, HHS will investigate whether interim solutions are feasible for insured consumers. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.

Prohibition on Gag Clauses on Price and Quality Data

Code section 9824, ERISA section 724, and PHS Act section 2799A-9, as added by section 201 of division BB of the CAA, prohibit plans and issuers from entering into an agreement with a provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers that would directly or indirectly restrict the plan or issuer from: (1) providing provider-specific cost or quality of care information or data to referring providers, the plan sponsor, participants, beneficiaries, or enrollees, or individuals eligible to become participants, beneficiaries, or enrollees of the plan or coverage; (2) electronically accessing de-identified claims and encounter data for each participant, beneficiary, or enrollee; and (3) sharing such information, consistent with applicable privacy regulations. In addition, plans and issuers must annually submit to the Departments an attestation of compliance with these requirements. These provisions are effective December 27, 2020 (the date of enactment of the CAA).

Q7: Will the Departments be issuing regulations addressing the prohibition on gag clauses?

No. The statutory language of section 201 of division BB of the CAA is self-implementing, and the Departments do not expect to issue regulations on gag clauses at this time. Until any further guidance is issued, plans and issuers are expected to implement the requirements prohibiting gag clauses using a good faith, reasonable interpretation of the statute. However, the Departments intend to issue implementation guidance to explain how plans and issuers should submit their attestations of compliance and anticipate beginning to collect attestations starting in 2022.

Protecting Patients and Improving the Accuracy of Provider Directory Information

Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A-5(a) and (b), as added by section 116 of division BB of the CAA, establish standards related to provider directories that are intended to protect participants, beneficiaries, and enrollees with benefits under a plan or coverage from surprise billing. These provisions generally require plans and issuers to establish a process to update and verify the accuracy of provider directory information and to establish a protocol for responding to requests by telephone and electronic communication from a participant, beneficiary, or enrollee about a provider's network participation status. If a participant, beneficiary, or enrollee is furnished an item or service by a nonparticipating provider or nonparticipating facility, and the individual was provided inaccurate information by the plan or issuer under the required provider directory or response protocol that stated that the provider or facility was a participating provider or participating facility, the plan

or issuer cannot impose a cost-sharing amount that is greater than the cost-sharing amount that would be imposed for items and services furnished by a participating provider or participating facility and must count cost-sharing amounts toward any in-network deductible or in-network out-of-pocket maximum. These provisions are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Code section 9820(c), ERISA section 720(c), and PHS Act section 2799A-5(c), as added by section 116 of division BB of the CAA, require plans and issuers to make certain disclosures regarding balance billing protections to participants, beneficiaries, and enrollees that are similar to disclosure requirements applicable to providers and facilities under PHS Act section 2799B-3, as implemented in 45 CFR 149.430. In general, plans and issuers must make publicly available, post on a public website of the plan or issuer, and include on each Explanation of Benefits for an item or service with respect to which the requirements under Code section 9816, ERISA section 716, and PHS Act section 2799A-1 apply, information on: (1) the requirements under those sections, as applicable; (2) the requirements and prohibitions applied under PHS Act sections 2799B-1 and 2799B-2; (3) other applicable state laws on out-of-network balance billing; and (4) contacting appropriate state and federal agencies if an individual believes the provider or facility has violated the prohibition against balance billing. These disclosure requirements are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q8: Will the Departments be issuing regulations addressing the provider directory requirements prior to January 1, 2022?

No. The Departments intend to undertake notice and comment rulemaking to implement the provider directory requirements, but rulemaking will not be issued until after January 1, 2022. Until further rulemaking is issued, plans and issuers are expected to implement these provisions using a good faith, reasonable interpretation of the statute. Pending any implementing rulemaking, the Departments will not deem a plan or issuer to be out of compliance with provider directory requirements as long as the plan or issuer imposes only a cost-sharing amount that is not greater than the cost-sharing amount that would be imposed for items and services furnished by a participating provider, and counts those cost-sharing amounts toward any deductible or out-of-pocket maximum, in a case when a participant, beneficiary, or enrollee receives items and services from a nonparticipating provider and the individual was provided inaccurate information by the plan or issuer under a provider directory or response protocol that stated that the provider or facility was a participating provider or participating facility.

Q9: Will the Departments be issuing regulations addressing the balance billing disclosure requirements applicable to plans and issuers prior to the effective date of the requirements?

No. As stated in the preamble to the Requirements Related to Surprise Billing; Part 1 (July 2021 Interim Final Rules), the Departments may address the balance billing requirements in more detail in future guidance or notice and comment rulemaking. Until further guidance or rulemaking is issued, plans and issuers are expected to implement these requirements using a good faith, reasonable interpretation of the statute. The Departments will take into account the

statutory applicability date and the timeframe for implementation when determining good faith compliance with the law.⁸

To reduce burdens and facilitate compliance with these disclosure requirements, the Departments issued a model disclosure notice that may be used to satisfy the disclosure requirements regarding the balance billing protections.⁹ As the Departments stated in the July 2021 Interim Final Rules, the Departments will consider use of the model notice in accordance with the accompanying instructions to be good faith compliance with the disclosure requirements of Code section 9820(c), ERISA section 720(c), and PHS Act section 2799A-5(c), if all other applicable requirements are met.¹⁰

Continuity of Care

Code section 9818, ERISA section 718, and PHS Act sections 2799A-3 and 2799B-8, as added by section 113 of division BB of the CAA, establish continuity of care protections that apply in the case of an individual with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer. These protections ensure continuity of care in instances when terminations of certain contractual relationships result in changes in provider or facility network status. These provisions are applicable with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2022.

Q10: Will the Departments be issuing regulations addressing the continuity of care requirements prior to January 1, 2022?

No. The Departments intend to undertake notice and comment rulemaking to implement the continuity of care requirements, but do not expect to do so until after January 1, 2022. The Departments note that any rulemaking to implement these provisions will include a prospective applicability date that provides plans, issuers, providers, and facilities with a reasonable amount of time to comply with any new requirements. Until rulemaking to fully implement these provisions is adopted and applicable, plans, issuers, providers, and facilities are expected to implement the requirements using a good faith, reasonable interpretation of the statute.

Grandfathered Health Plans

Section 1251 of the Affordable Care Act provides that grandfathered health plans are not subject to certain provisions of the Code, ERISA, and the PHS Act, as added by the Affordable Care Act, for as long as they maintain their status as grandfathered health plans.¹¹ For example, grandfathered health plans are subject neither to the requirement to cover certain preventive services without cost sharing under section 2713 of the PHS Act, nor to the annual limitation on

⁸ 86 FR 36872, 36877 (July 13, 2021).

⁹ The model disclosure notice is available at <https://www.cms.gov/httpswwwcmgovregulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10780>.

¹⁰ 86 FR at 36877.

¹¹ For a list of the market reform provisions applicable to grandfathered health plans under title XXVII of the PHS Act that the Affordable Care Act added or amended and that were incorporated into the Code and ERISA, visit <https://www.dol.gov/sites/default/files/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/grandfathered-health-plans-provisions-summary-chart.pdf>.

cost sharing set forth under section 2707(b) of the PHS Act. If a plan or coverage were to lose its grandfathered status, it would be required to comply with both provisions, in addition to several other requirements.

Q11: Are grandfathered health plans generally subject to the requirements under the CAA?

Yes. The CAA does not include an exception for grandfathered health plans that is comparable to section 1251 of the Affordable Care Act. Furthermore, section 102(d)(2) of division BB of the CAA amended section 1251(a) of the Affordable Care Act to clarify that the new and recodified patient protection provisions of division BB of the CAA, including those related to choice of health care professional, apply to grandfathered health plans.

Reporting on Pharmacy Benefits and Drug Costs

Code section 9825, ERISA section 725, and PHS Act section 2799A-10, as added by section 204 of division BB of the CAA, include certain reporting requirements for plans and issuers. These reporting requirements primarily relate to prescription drug expenditures, requiring that plans and issuers submit relevant information to the Departments. This information includes general information regarding the plan or coverage, such as the beginning and end dates of the plan year, the number of participants, beneficiaries, or enrollees, as applicable, and each state in which the plan or coverage is offered. Plans and issuers must also report the 50 most frequently dispensed brand prescription drugs, and the total number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each such drug; and the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year.

Additionally, plans and issuers must report, among other things, total spending by the plan or coverage broken down by the type of costs, including hospital costs and provider and clinical service costs, for primary care and specialty care separately; spending on prescription drugs by the plan or coverage as well as by participants, beneficiaries, and enrollees, as applicable; and the average monthly premiums paid by participants, beneficiaries, and enrollees and paid by employers on behalf of participants, beneficiaries, and enrollees, as applicable. Plans and issuers must report the impact on premiums of rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers with respect to prescription drugs prescribed to participants, beneficiaries, or enrollees in the plan or coverage, including the amount paid with respect to each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year. Finally, plans and issuers must report any reduction in premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration.

Finally, these provisions require the Departments to issue biannual public reports on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the impact of prescription costs on premium rates,

aggregated in such a way that no drug or plan specific information will be made public. In addition, these reports must not include any confidential or trade secret information submitted to the Departments.

Q12: How do the Departments intend to implement the reporting requirements for plans and issuers to submit information to the Departments related to pharmacy benefits and drug costs?

The Departments intend to issue regulations that will address the pharmacy benefit and drug cost reporting requirements. However, the Departments recognize the significant operational challenges that plans and issuers may encounter in complying with these reporting requirements by the statutory deadlines set forth in the statute. The Departments anticipate that plans and issuers may also need additional time to modify contractual agreements to enable disclosure and transfer of the required data between various entities; to develop internal processes and procedures; and to identify, compile, prepare, and validate the required data. Accordingly, the Departments will defer enforcement of the requirement to report the specified information by the first deadline for reporting on December 27, 2021 or the second deadline for reporting on June 1, 2022, pending the issuance of regulations or further guidance. Until regulations or further guidance is issued, the Departments strongly encourage plans and issuers to start working to ensure that they are in a position to be able to begin reporting the required information with respect to 2020 and 2021 data by December 27, 2022. HHS encourages states that are primary enforcers of this requirement with regard to issuers to take a similar enforcement approach, and will not determine that a state is failing to substantially enforce this requirement if it takes such an approach.