November 30, 2022 – Administrative Simplification Listening Session on Modifications to the NCPDP Retail Pharmacy Standards and Adoption of a New Pharmacy Subrogation Standard (CMS-0056 P) Transcript

Introduction

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Transcript

Moderator: Hello and thank you for joining today's Pharmacy Standards Updates Proposed Rule HIPAA National Listening Session. Our presenter is Geanelle Herring, Technical Advisor at CMS. Geanelle will begin the presentation with an introduction and background on retail pharmacy standards for electronic transactions adopted under the Administrative Simplification subtitle of HIPAA. She'll then provide a detailed overview of the provisions in the proposed rule, otherwise known as docket number CMS-0056-P in the Federal Register. Finally, CMS will go over resources and the public comment period. We encourage you to submit comments on the proposed rule by January 9th, 2023. The slides from today's listening session are posted on the Administrative Simplification website, and the transcript will be posted in the coming weeks. Now I would like to introduce Geanelle Herring. Geanelle, you may begin.

Geanelle Herring: Thank you, Enzo. Hello, everyone, and welcome to the Centers for Medicare and Medicaid Services listening session on the modifications to the National Council for Prescription Drug Programs, retail pharmacy standards, and the adoption of a new pharmacy subrogation standard proposed rule that was published on November 9th of 2022. As stated earlier, my name is Geanelle Griffith Herring, and I will serve as your presenter for today's call.

Today's listening session is an opportunity for CMS to present the proposals in the modification to the National Council of Prescription Drug Programs, retail pharmacy standards, and adoption of a new pharmacy subrogation standard proposed rule.

The goal of today's listening session is to provide the industry with a better understanding of each proposal and to discuss how the public can submit comments. We invite the public to submit comments aimed at developing or improving this proposed rule, or by recommending against it. If you are joining us, the link to the slide presentation for today's discussion was just dropped in the chat. Should you like to follow along with me, please take the time now to download the slides.

Due to the federal regulation – excuse me, due to the federal rulemaking process, comments on this proposed rule must be submitted based on the instructions that will be outlined in this presentation, as well as in the NPRM. Again, the comment period for this proposed rule closes on January 9th, 2023. You can now advance the slides.

As you see before you, there's the agenda, which is the introduction which we just completed. I will start with the background on the rule, give an overview of the provisions, and then provide information on resources that we have available for your use. Next slide, please. Before I begin, I just wanted to point out that we'll be using some acronyms within this presentation, and so they are before you on slides four and five. Next slide, please. Next slide, please.

So yes, HIPAA addresses the adoption of standards to enable health information to be exchanged more efficiently and to achieve greater uniformity in transmission of health information. This slide gives you that information, and I won't read it all. But again, HIPAA transactions involve electronic transmission of information between two parties to carry out health care related financial and administrative activities, such as claims and prior authorization requests. These transactions represent a uniform requirement for data interchange or EDI transactions. Next slide, please.

This proposed rule proposes to adopt the updated versions of the retail pharmacy standard for electronic transactions adopted under the Administrative Simplification subtitle of the HIPAA of 1996. These updated versions will be modifications to the currently adopted standards for the following pharmacy transactions: health care claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization, and coordination of benefit related transactions. This proposed rule also seeks to broaden the applicability of the Medicaid pharmacy subrogation standard to one that will apply to all covered entities, subrogating pharmacy claims rather than just to Medicare claims – excuse me, Medicaid claims. To that end, this rule proposes to rename and revise the definition of the current subrogation transaction for Medicaid and establish an initial standard for all covered entities. Next slide, please.

So, this background slide gives you an overview of the statutes that govern HIPAA and Administrative Simplification provisions. These statutes are discussed in greater detail in the proposed rule, but for the purposes of the presentation, I'll just go into them very briefly. The law requires that at Section 1172(c) of the Social Security Act, then any standard adopted under HIPAA must be developed and adopted or modified by a standard setting organization, or SSO. For the purposes of this proposed rule, the SSO applicable is the National Council for Prescription Drug Programs, or NCPDP. NCPDP develops standards for pharmacy transactions and data. Section 1171 of the Act also recommends and provides that an SSO must be accredited by the American National Standards Institute, or ANSI for short. Next slide, please.

Section 1174(b)(1) of the Act also requires that the Secretary review and adopt standards, as well as adopt modification to standards, including any additions to the standards as appropriate, but not frequently than once every 12 months, unless the Secretary determines that the modification or initial standard is necessary in order to permit compliance. Section 1175(b)(1) of the Act also provides a compliance date to be no later than 24 months after the date on which an initial standard or implementation specification is adopted for all covered entities except small health plans, which must comply no later than 36 months after such adoption. Next slide, please.

Section 1175(b)(2) states that if the Secretary adopts a modification to a HIPAA standard or implementation specification, the compliance date for the modification may not be earlier than 180 days following the date of the adopted modification. The section also states that the Secretary must consider the time needed to comply with the nature and extent of the modification when determining compliance dates and may extend the time for compliance for small health plans if the Secretary deems it is appropriate. Next slide, please.

So, in January 2009, HHS published a final rule that adopted the current version of the pharmacy standards that are in use today. Those standards are NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0, known as Version D.0, and its equivalent, NCPDP Batch Standard Implementation Guide Version 1, Release 2, or Version 1.2. However, we refer to both of them as Version D.0. The same rule also adopted NCPDP Batch Standard for Medicaid Subrogation Implementation Guide, Version 3, Release 0, or Version 3.0, for state Medicaid agencies seeking reimbursement from a responsible health plan for a pharmacy claim that a state Medicaid agency paid on behalf of a Medicaid recipient. Next slide, please.

So now, having gone over the background and introduction of the proposed rule, I will now take the time to go through the proposed provisions of this proposed rule. As you know, business requirements for covered entities have changed since the current pharmacy standards were adopted in 2009. Therefore, these proposals to update the pharmacy standards seeks to address these changes based on those new business requirements. These updated versions of the standards would be modifications to the currently adopted standards for the following transactions, which I've said earlier. Healthcare claims or equivalent encounter information, eligibility for a health plan, referral certification and authorization, and coordination of benefit related transactions. Next slide, please.

Therefore, we are proposing to replace Version D.0 with the NCPDP Telecommunication Standard Implementation Guide, Version F6, or Version F6 and the equivalent Batch Standard Implementation Guide, Version 15. And that will replace the NCPDP equivalent Batch Standard, Version 1.2. So, for the purposes of this regulation, we are referring to both of those combined as Version F6. F6, we believe, would bring the much-needed upgrades over Version D.0, such as improvements to the information attached to controlled substances, which would distinguish refills from multiple dispensing events for a single fill.

Version F6 will also provide more specific fields to differentiate various types of fees, including taxes, regulatory fees, and medication administration fees. This modification would also enable covered entities to better support their business processes, because it would enable increased process automation and require less manual processing, which will increase efficiency, reduce costs, and reduce provider burden. Version F6 also increases the dollar amount field length and would simplify coverage under prescription benefits of new and innovative drug therapies that are priced at or in excess of one million dollars. The current adopted standard, D.0, does not support this business need. Next slide, please.

The current Medicaid Subrogation Implementation Guide, Version 3.0, was adopted to support federal and state requirements for state Medicaid agencies to seek reimbursement from the correct responsible health plan. Industry stakeholders reported that there is a need to expand the use of the subrogation transaction beyond Medicaid agencies. In addition, it was noted that a broader use of the subrogation standard would be a positive step for the industry. Therefore, Version 10 of the pharmacy subrogation transaction seeks to broaden the scope of the subrogation transaction to apply to all health plans and not just state Medicaid agencies. Next slide, please.

So, for the proposed compliance dates for both Version F6 and Version 10, we are proposing that it would be 24 months after the final rule's effective dates for all covered entities to be in compliance with the use of the standards. Since Version F10 will be an initial standard for all covered entities outside of Medicaid state agencies, we are proposing that small health plans affected by this initial standard would have 36 months after the final rule's effective date to comply with Version 10. So again, since Version F6

and Version 10 for HIPAA covered entities would be considered a modification, we are proposing 24 months after the effective date of the final rule. However, since its initial standard, Version 10 will be an initial standard for health plans and HIPAA covered entities outside of being a state Medicaid agency, we are proposing that small health plans would have 36 months after the effective date of the final rule to comply. Next slide, please.

So, where and when to submit comments. HHS is allowing the public 60 days to comment on this proposed rule. Comments must be received by January 9th, 2023. In commenting on this proposed rule, please use and refer to file code CMS-0056-P. Again, when commenting, please refer to file code CMS-0056-P. To have your comments considered on this proposed rule, you must officially submit them, including any mass comment submissions. They must be submitted in the following three ways.

You can choose only one of the three ways that is listed in the NPRM or based on what is being shared today in this presentation. You could submit them electronically through Regulations.gov. You could submit them by regular mail, or you can submit them using express or overnight mail. And the addresses for regular mail or express or overnight mail is outlined in the proposed rule. Next slide, please.

On this slide are the resources that we mentioned earlier that is available and essential for you and your practice. The first resource is the CMS website where you can find additional information on all Administrative Simplification requirements, as well as any regulations that we have related to our work. The other bullet depicts or provides information on how you can sign up to receive email updates. Those email updates will provide to you information on upcoming calls and recently released guidance on Administrative Simplification, as well as link you to frequently asked questions. Lastly, we've created a special mailbox to receive questions and comments and feedback on guidance letters, bulletins and FAQs and any related matters regarding Administrative Simplification. The address for this mailbox is depicted on the slide and will also be dropped into the chat for your use.

At this time, I will now turn the presentation back over to Enzo. And thank you very much for joining us today in discussion on this upcoming – excuse me, on this proposed rule. Thank you.

Moderator: We've reached the end of the listening session. I want to thank everyone for joining us today. As a reminder, you can find that the slides posted on the Events and Latest News page, and the transcript will be available in the coming weeks. Thanks again and have a great afternoon.