Centers for Medicare & Medicaid Services

Open Door Forum: Physicians, Nurses, Allied Health Professionals

September 29, 2021

2:00 pm ET

Coordinator: ...standing by. All participants will be in a listen-only mode until the question-and-answer session. I'd like to inform all parties that today's call will be recorded. If you have any objections, you may disconnect at this time. I'd now like to turn the call over to your host, Ms. Jill Darling. You may begin whenever you're ready.

Jill Darling: Great, thanks, (Becca). Good morning and good afternoon everyone. I'm Jill Darling in the CMS Office of Communications. And welcome to today's Physicians, Nurses & Allied Health Professionals Open Door Forum.

Before we get into the agenda, I have one brief announcement. This Open Door Forum is open to everyone. But if you are a member of the press, you may listen in. But please refrain from asking questions during the Q&A portion of the call. If you do have any inquiries, please contact us at CMS at Press@cms.hhs.gov. And I will hand the call off to Dr. Gene Freund.

Dr. Eugene Freund: Hi and welcome to this Physicians, Nurses & Allied Health Professionals Open Door Forum.

Right now, I just want to say that this is an interesting call and I want to do a little bit of stage setting for the first item. Rebecca Lund from our Center for Consumer Information and Insurance Oversight, will be talking

essentially about the provider enforcement component of the No Surprises Act rulemaking.

So, I know most of the people in this group do not react enthusiastically to the idea of enforcing rules on providers but it's part of a whole big picture and it's real important to listen. And there's also a comment period under way, and it's really important for people to comment about how we can make this happen in the best way possible.

I want to see if my co-chair, Mr. Gift Tee, has any comments before turning it over to Ms. Lund.

Gift Tee: No, thank you, Dr. Freund. Good afternoon everyone.

Dr. Eugene Freund: Okay. So, talking about the proposed policies for HHS enforcement of the new provider requirements regarding surprise billing and transparency, Rebecca Lund, go ahead.

Rebecca Lund: Thanks for the intro, Gene, appreciate it. And first, hi everyone. As Gene said, my name is Rebecca Lund and I'm going to give a brief overview of some of the provisions in a recently issued proposed rule that are related to provider enforcement.

And so, by way of background, this will include proposals to implement certain Public Health Service Act provisions that were added by the Consolidated Appropriations Act, 2021. These provisions establish new protections for consumers related to surprise billing and transparency in

healthcare, and they impose new requirements on health insurance issuers, providers, facilities and providers of air ambulance services.

And under the statute, states actually have primary enforcement authority over these new requirements. And HHS is only able to enforce a provision when a state fails to substantially enforce.

And we are required to step in and take over enforcement when we do determine that the state is failing to substantially enforce. The statute also provides HHS authority to impose civil money penalties against providers, facilities and providers of air ambulance services that violate the applicable requirements in those states where HHS is responsible for direct enforcement.

So, in the proposed rule, we propose to extend CMS's existing processes for determining whether a state is not substantially enforcing the Public Health Service Act requirements applicable to issuers to also include these new Public Health Service Act requirements that are related to providers, facilities and providers of air ambulance services. We did not propose any substantive changes to this process. We simply proposed amendments to include those new provisions that are applicable to providers.

We also propose to create a process for initiating investigations and determining that a provider or facility or provider of air ambulance services is in violation of a PHS Act requirement. And we also propose that CMS would have authority to initiate an investigation when we receive a complaint or other indication of a potential violation. We include examples, such as reports from plans or issuers, state insurance departments, state health departments,

medical boards, the National Association of Insurance Commissioners, and any other federal or state agencies.

And we propose that CMS may conduct random or targeted investigations to ensure that providers and facilities in the states where we're responsible for direct enforcement are in compliance with the applicable Public Health Service Act requirements.

So, if we do determine that an investigation is warranted, we would send a written notice to the provider or facility that describes the reason that we're initiating the investigation, requests any relevant documentation and provides the deadline for sending such documentation to CMS. It would also state that CMS may require the provider or facility to take corrective actions or pay a civil money penalty if the provider or facility is found to be in violation.

And we would allow providers and facilities to request an extension for providing their responsive documentation. However, failure to do so within the initial deadline or any extensions granted by CMS may result in the imposition of a civil money penalty based on the initial complaint or other indication of a potential violation.

If at the conclusion of the investigation we do determine that the provider facility has violated the PHS Act requirements, then we would have the authority to impose a civil money penalty in an amount not to exceed $10,000 per violation, adjusted annually under federal rules.

And in determining the actual penalty amounts, CMS would consider several factors, including the nature of the violation and circumstances under which they were presented, the degree of culpability of the provider or facility, the provider or facility's history of prior violations, the frequency of the violation, the level of financial and other impacts on affected individuals and any other matters as justice may require. And we also propose mitigating and aggravating circumstances that CMS may consider in determining the penalty amount.

Additionally, CMS would be required to waive any penalty if the provider or facility does not knowingly violate, and exercising due diligence should not have reasonably known that they violated the rules prohibiting balance billing, and the provider or facility withdraws the bill and reimburses the plan, the issuer or affected individual, the overage plus interest within 30 days of the violation.

We also propose that if we do identify a violation and determine that a civil money penalty is warranted, we would send the provider or facility a notice of proposed penalty that provides the proposed penalty amount, also includes the factors CMS considered in determining that amount, and the instructions for responding.

This notice would also clearly indicate that the provider or facility has a right to appeal the proposed penalty by requesting a hearing with an administrative law judge within 30 days. If no such hearing is requested, the penalty becomes final, and CMS would send a subsequent notice with instructions for paying the penalty amount.

If the provider or facility does request a hearing, the administrative law judge would, at the conclusion of the hearing, issue an initial agency decision that is based only on the record and applicable law. And once the administrative law judge's decision is entered, then the CMS administrator may review that decision in whole or in part.

If the administrator elects to do so, he or she would be required to notify the provider or facility that the administrative law judge decision is under review. And the administrative law judge's decision is final and appealable after 30 days unless it is modified or vacated by the CMS Administrator.

Once an administrative law judge or CMS's Administrator's decision becomes final, then the provider or facility may appeal the decision in the US Court of Appeals for the circuit where the person resides or where the violation occurred by filing a written petition requesting the decision be modified or set aside. And the decision would have to be submitted within 60 days of the ALJ or CMS Administrator's decision becoming final.

And lastly, we propose that CMS would notify certain organizations if a penalty does become final. This would include the state's or local medical or professional association, the State's Department of Health, the appropriate state or local licensing agency organization, and the appropriate utilization and quality control peer review organization.

We also propose to have authority to share the information with the State Department of Insurance or similar agencies, State Attorney General,

Secretary of Labor, Secretary of Treasury or Director of the US Office of Personnel Management.

And as Dr. Gene noted, we are seeking comments on this proposed rulemaking, and those comments are due by October 18th. And so, we welcome and encourage you to submit comments.

And with that, I will pass it back to you, Jill. Thanks.

Jill Darling: Great, thanks, Rebecca. And next, we have Sarah Harding who will talk about the PAMA reporting in the Clinical Laboratory Fee Schedule.

Sarah Harding: Yes, thank you. Good afternoon, thank you for having me. As was mentioned, my name is Sarah Harding. I work on the Clinical Laboratory Fee Schedule here at CMS. I just wanted to take a few minutes to tell this group about our upcoming data reporting period for certain laboratories.

This data reporting, again as was mentioned, is mandated by the Protecting Access to Medicare Act, or PAMA as it's more commonly known. Under this legislation, certain laboratories are required to periodically report data to CMS about the lab tests on the CLFS that they perform. Specifically, data include laboratory test HCPCS code, associated private payor rate and the associated volume data. So, the good news is that it's not a lot of information. But CMS does use these data to update the rates on the CLFS.

So, the next data reporting period is coming up. It is beginning January 1st in 2022 and will end March 31, 2022. The updated rates on the CLFS will go into effect January 1, 2023.

The applicability criteria largely has to do with whether the laboratory meets a majority of Medicare revenue thresholds.

So that is in a data collection period if it receives more than 50% of its Medicare revenues from one or a combination of the CLFS or PFS during the data collection period. It also must meet a low expenditure threshold, which in this case is at least $12,500 of its Medicare revenues from the CLFS during the data collection period. In this case, the data collection period would have been the first six months of 20199.

The reason for the gap between the time at which a laboratory would be looking at its own data and then ultimately reporting it to CMS is there have been two consecutive delays in the data reporting period. So again, the next period is coming up this January.

So, we wanted to highlight this requirement and highlight the resources available on the CMS Web site. If you visit CMS.gov and search for PAMA, the PAMA Regulations Web page will come up. I'll say it this way just because the Web address is quite long and I'm sure I would misspell it to this group. So, the simplest thing to do is to use the search function on CMS.gov and search for PAMA, P-A-M-A.

This page outlines the guidance for laboratories to determine whether they are an applicable laboratory as well as what needs to be reported and how to report. There's an extensive list of frequently asked questions that can also help if you've never reported.

If you determine your laboratory is indeed considered applicable under the PAMA definition, we have an online data collection system for you to submit your data. This will start - the system won't be open until January 1st but registration for this system is ongoing. And you could do that today if you wanted. You're welcome to get this part of the process started.

Again, information on that system, on PAMA definitions and everything else you could probably wonder about is available on that PAMA Resources Web page at CMS.gov.

If you have additional questions about PAMA or the updating - upcoming data reporting period, we do have an e-mail address dedicated to this reporting period. It is clfs_inquiries@cms.hhs.gov. Again it's clfs_inquiries@cms.hhs.gov.

Thank you. And that's all I had. Thanks.

Jill Darling: Great, thank you, Sarah and Rebecca. (Becca), will you please open the lines for Q&A, please?

Coordinator: At this time, if you'd like to ask a question, please press star 1. And clearly record your first and your last name for your question to be introduced. Again, that is star 1, if you have a question at this time. And there are no questions...

((Crosstalk))

Coordinator: ...currently in queue. Again, that is star 1, if you have a question. Thank you.

Jill Darling: All right, everyone. (Becca), please interrupt me if a question does come in. But if there are no questions, well, we appreciate your time for calling in and joining us. But I'll pass it back to Gene for some closing remarks.

((Crosstalk))

Coordinator: And we actually do have a couple of...

Dr. Eugene Freund: Oh, go ahead.

Coordinator: ...questions.

Dr. Eugene Freund: Go ahead, (Becca).

Coordinator: We do have a couple of questions for the participants here. One moment, please. The first question comes from (Sandy Higgins). Your line is now open.

(Sandy Higgins): Yes, can you tell me on the surprise billing act if that just pertains to providers in the hospital setting or does it also pertain to providers in the outpatient setting?

Rebecca Lund: Yes, (Sandy), thanks for that question. So, the answer to that actually comes from another rule that was issued earlier this year. We issued an interim final regulation to implement the requirements applicable to providers.

And in that rule, we define the term "facility" to mean with respect to a group health plan in the context of non-emergency services as a hospital, a hospital outpatient department, a critical access hospital and an ambulatory surgical center.

We also include a definition for independent freestanding emergency department, which is a healthcare facility, but not limited to those described in the definition of healthcare facility with respect to non-emergency services, that is geographically separate and distinct and licensed separately from the hospital under applicable state law and provides emergency services. We also include a definition of a non-participating emergency facility and a non-participating provider.

And so, it may be helpful to take a look at that rulemaking for clarity as far as what requirements are applicable to what types of providers and facilities.

(Sandy Higgins): Can you tell me if it includes just a regular physician's office not affiliated with the hospital or just to regular PCP?

Rebecca Lund: Yes, for certain requirements. Yes.

(Sandy Higgins): So, it does include for PCPs for certain requirements?

Rebecca Lund: Yes.

(Sandy Higgins): Okay. Thank you.

Rebecca Lund: (Unintelligible).

Coordinator: So, we do have another question. Our next question comes from (Shay Vaughn). Your line is now open.

(Shay Vaughn): Hi. So, this rule is set to be applicable or effective on January 1, 2022. Is that correct? And is there a possibility of it being delayed a little bit since comments aren't going to be summarized until after mid-October?

Rebecca Lund: (Thanks for) the question. So, comments are due October 18th, and then we will, of course, carefully review those comments and based on them, issue a final rule. The statutory requirements are effective starting January 1, 2022.

But the rule would not be effective until for - I believe it is 60 days after the final rule is issued. So, if we issue the final rule on December 21st -- I'm just throwing out a random date -- then the provisions in the rule would not be effective for 60 days after that. And it's just the statutory requirements that are effective on the first of the year.

(Shay Vaughn): Okay, thank you.

Rebecca Lund: You're welcome. Thanks for the question.

Coordinator: There are no further questions at this time.

Dr. Eugene Freund: Okay. Well, this is Gene Freund. Thank you very much for your attention and the good questions.

It is complicated. You know, we released one interim final rule that does not have a comment period and will be in effect on the 1st of the year. That's the statutory requirements that Rebecca mentioned. Her - the rule she talked about is a proposed rule. And so, keep an eye on those. There's a little more rulemaking also coming. So, keep an eye on that and please get your comments in. This is a little bit different thing to build into our processes, and the comments will doubtless be helpful. So, thank you very much for that.

And that ends the call, I think. Jill, do you have anything else to add?

Jill Darling: No, you ended it. Thanks, Gene. Just we thank everyone for joining our call. And have a wonderful day.

Coordinator: That concludes today's call. Thank you for your participation. You may disconnect at this time.

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