Centers for Medicare & Medicaid Services

Open Door Forum: Physicians, Nurses and Allied Health Professionals

Moderator: Jill Darling

Wednesday, January 18, 2023

2:00 pm ET

Coordinator: Welcome, and thank you all for standing by. At this time, all participant lines are in a listen-only mode. During the Q&A session, if you would like to ask a question, you may do so over the phone by pressing Star 1 at that time. Today's call is being recorded. If you have any objections, you may disconnect at this time.

It is my pleasure to turn the call over to your host for today, Miss Jill Darling. Thank you, ma'am. You may begin.

Jill Darling: Great. Thank you, (Holly). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communications, and welcome to today's first of 2023 Physicians, Nurses and Allied Health Professionals Open Door Forum. We greatly appreciate your patience in waiting for the call to begin, waiting for more participants and speakers to arrive. So, greatly appreciate it. Thank you.

I have one brief announcement, and then we'll get into - or I'll hand it off to our co-chair, Gene Freund. 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 CMS at press@CMS.hhs.gov. And I'll hand it off to Dr. Gene Freund.

Dr. Eugene Freund: Hi, and on behalf of my co-chair, Gift Tee, who was not available to come, I want to welcome you to today's session, the first of the year. And I just want to tell you that I'm really excited about the agenda we have. We have a lot of good work by CMS staff that we're going to be talking about.

And I think it's stuff that should be of interest, and hopefully, many of you find encouraging that we're making progress. And I want to encourage you for the rules, especially the Office of Burden Reduction and Health Informatics rules on interoperability, to get on the - get online and submit your comments before the comment period expires. We really rely on people submitting public comments, and want to really encourage that.

Without further ado. I'm going to move it back to Jill who will orchestrate the rest of the call. Go ahead, Ms. Darling.

Jill Darling: Thanks, Eugene. Thank you. First up, we have Adele Pietrantoni, who will speak on the Inflation Reduction Act, the Medicare Vaccine and Insulin Provision.

Adele Pietrantoni: Thank you so much. So, good morning, and good afternoon. I'm Adele Pietrantoni. I'm a Division Director in the CMS Office of Program Oversight and Local Engagement. This afternoon, I'll be providing information regarding Medicare coverage of insulin and vaccines, which were included in the Inflation Reduction Act of 2022, also known as the IRA.

The IRA makes changes to Medicare so that millions of people with Medicare, will spend less on their prescriptions starting this year. Someone with Medicare who takes insulin that is covered by their prescription drug plan, or through a traditional pump covered under traditional Medicare, will have access to each one month's supply of insulin for no more than $35.

That person also won't pay a deductible for their covered insulin products. The new rules began on January 1st, 2023, for insulin covered under Medicare prescription drug plans. Starting July 1st, 2023, insulin used through a traditional pump covered under traditional Medicare's durable medical equipment benefit, will cost no more than $35 for a month's supply, with no deductible when the service is provided by traditional Medicare or a Medicare Advantage plan.

The IRA insulin provision sets a cap on insulin cost-sharing that will benefit at least 1.4 million people with Medicare. The Inflation Reduction Act also improves coverage and lowers out-of-pocket costs for recommended vaccines in Medicare, Medicaid, and the Children's Health Insurance Program.

As of January 1st, 2023, people with Medicare drug coverage will pay nothing out of pocket for adult vaccines recommended by the Advisory Committee on Immunization Practices, or ACIP, including the shingles and tetanus, diphtheria, whooping cough vaccines.

Most adults enrolled in Medicaid or the Children's Health Insurance Program, will be guaranteed coverage of ACIP-recommended vaccines with no cost to them beginning October 1st, 2023. We have received questions from providers, and I select - and we have answers, and I've selected a few of them for review with you this afternoon.

So, the first one. If someone takes insulin through a traditional pump and is using that pump on January 1st, 2023, will they be required to pay the Medicare Part B deductible when they get insulin for the pump? Will they have any additional out-of-pocket costs for insulin? And if so, will a Medigap supplemental plan cover the cost?

So, the answer, from January 1st, 2023, through June 30th, 2023, the Part B deductible will apply for insulin use through a traditional pump covered under the durable medical equipment benefit. However, starting July 1st, 2023, the Medicare Part D deductible does not apply for insulin used through a traditional pump that is covered under the durable medical equipment benefit.

In addition, beginning July 1st, 2023, co-insurance that someone with Medicare Part B pays for a month's supply of insulin, cannot exceed $35. If someone has a Medigap supplemental plan that covers Medicare Part B co-insurance or co-payments, that plan should cover the $35 maximum co-payment beginning July 1st, 2023.

The second question, does the IRA's $35 insulin cap apply to disposable patch pumps? The answer, people with Medicare, with Part D coverage who use an insulin patch pump, which is a small wireless tubeless pump worn directly on the body, for example, Insulet, Omnipod, will continue to obtain their insulin through their Part D prescription drug and benefit.

For these people, the $35 cost cost-sharing cap for a month's supply of each covered insulin product that goes into their pump, applies starting January 1st, 2023. The disposable pump itself can be covered under Part D as an insulin supply, but because it is a supply and not a covered insulin product, the cost-sharing for the disposable pump is not subject to the $35 cost-sharing cap, and the plan deductible may apply.

The final question, are other types of prescription drugs that a Medicare beneficiary takes to manage diabetes such as Trulicity, Byetta, and Ozempic, included in the monthly $35 cost-sharing cap? The answer, prescription drugs, including injectable drugs that aren't insulin products, or combination

products that combine an insulin product with another drug for diabetes management, aren't covered by the IRA's cost-sharing cap of $35 for a month's supply of a covered insulin product. And that concludes my presentation. And I'll turn it back over to you, Jill.

Jill Darling: Great. Thank you, Adele. Next, we have Scott Weinberg, who has an update from the Office of Burden Reduction and Health Informatics on Interoperability.

Scott Weinberg: Great. Thank you, and hope everyone can hear me okay. I want to provide a very quick overview of our proposed rule that is currently out for comments. On December 13th, 2022, we posted the advancing interoperability and improving prior authorization processes proposed rule.

If finalized, the effective date for most of the provisions, which I'll briefly go over would be January 1st, 2026. The provisions cover policies related to application programming interfaces, or APIs that certain payers would have to implement. So, there's four of those.

Also, some proposals related to improving the prior authorization processes for the impacted payers, as well as new measures for eligible hospitals and providers in the promoting interoperability programs for, you know, the respective programs that apply to those providers.

So, the impact to payers that our proposed rule would apply to are Medicare Advantage, State Medicaid and CHIP agencies, Medicaid and CHIP managed care plans, and then the qualified health plans on the federally facilitated exchanges.

As I mentioned, the impacted - the providers that are directly impacted by this

rule would be those that are - will be those eligible hospitals and critical access hospitals under the Medicare promoting interoperability program, as well as eligible clinicians who are reporting the promoting interoperability performance category of the merit-based incentive payment system. Sorry about that.

And then finally, we're proposing five requests for information. So, the first policy related to application program interfaces or APIs, would be an expansion of our already established patient access API that was finalized in May 2020. It would require payers to include information about prior authorization requests and decisions via a standards-based API.

We're also proposing that these payers report metrics about patient use of the API to CMS on an annual basis. A new API that we're also proposing in this proposed rule, would be provider access API. This would enable data exchange between the impacted payers and a provider who would be able to request data, the same data that a patient can request via the patient access API, on their established patients with whom they have a relationship.

The third API that we're proposing is a payer-to-payer API. So, this is one that would exchange - that would enable the exchange of data between payers, specifically when a patient changes payers, or when a patient has concurrent coverage between two or more payers.

These - I'll note that these three APIs that I just talked about, would be required to - all of them are exchanging these same data. And then we have a number of policies related to improving the prior authorization process.

So, the first would be another API that we're terming the prior authorization requirements documentation and decision API, or the PARDD, P-A-R-D-D

API, the PARDD API. And this would be a standard-based API that would be populated with a payers list of covered items and services, excluding drugs.

I will note here that none of our prior authorization proposals would apply to drugs, just items and services, but this API would be populated with the payers' list of covered items and services for which a prior authorization is required, and the documentation requirements. It would also be used to communicate prior authorization decisions.

Now, some non-API proposals related to prior authorization, we are proposing that the impacted payers would be required to include a specific denial reason when denying a prior authorization request, regardless of how they're sending the prior authorization decision.

We're also proposing to shorten decision timeframes for prior authorizations. So, for certain impacted payers, we're proposing that they be required to send standard prior authorization decisions within seven days and expedited decisions within 72 hours.

And then finally, the impacted payers will be required to - should our rule be finalized as proposed, would be required to publicly report aggregate data about their prior authorization process on a publicly accessible website.

And then we're also proposing a new measure for the Medicare promoting interoperability program for eligible hospitals and critical access hospitals, as well as an identical measure for the - for MIPS-eligible clinicians promoting - in the promoting interoperability category in MIPS.

This measure will be called electronic prior authorization. And it would - and those who would report the measure, would report the number of unique prior

authorizations that are requested from a PARDD API that I mentioned before, the prior authorization API, using data from their certified health IT.

This - we're proposing that reporting would start in calendar year 2026. It would be - we're proposing that it would be required starting then, but it would not be scored. And then finally, we have five requests for information.

The first, we're requesting information on barriers related to adopting standards and opportunities to accelerate the adoption of standards related to social risk data. Our second RFI, we're seeking comment on how we might be able to leverage APIs to facilitate electronic data exchange between and with behavioral health providers and community-based organizations. The third RFI is on improving the electronic exchange of information in Medicare fee-for-service.

So, how Medicare fee-for-service could support improved documentation exchange between and among providers, suppliers, and patients. We're also seeking comment on how health IT standards could be used to promote interoperability to improve maternal health outcomes.

And then finally, we're seeking comment on how to encourage providers and payers to enable exchange under the Trusted Exchange Framework and Common Agreement, or TEFCA, in order to make patient information available to providers and support transmission of coverage and prior authorization requests from providers.

So, as I mentioned, this proposed rule is currently out for comments. The comment deadline is March 13th of 2023. So, we look forward to your comments. Thank you.

Jill Darling: Great. Thank you, Scott. And last, we have Camille Kirsch, who has some updates about the No Surprises Act.

Camille Kirsch: Hi, everybody. I'm Camille. I am a No Surprises Act Coordinator at the Center for Consumer Information and Insurance Oversight, and I'm here to provide information on two recent developments related to the No Surprises Act.

Firstly, CMS recently issued two pieces of guidance related to good faith estimates for uninsured and self-pay individuals. These are good faith estimate FAQs three and four, and they can both be found on the CCIIO regulations and guidance page, as well as on the No Surprises Act website.

FAQ three extends enforcement discretion pending future rulemaking for situations where good faith estimates for uninsured or self-pay individuals do not include expected charges from co-providers or co-facilities.

This extended enforcement discretion will allow time to establish standards for the creation of comprehensive GFEs, and will give providers and facilities sufficient time to implement such standards.

Any rulemaking to fully implement the convening provider and convening facility requirements will include a prospective applicability date that gives providers and facilities a reasonable amount of time to comply.

The second FAQ, FAQ four, is for providers and facilities that offer sliding fee discounts based on an individual's income and family size, as well as for providers and facilities that do not expect to bill uninsured or self-pay individuals for any items or services.

For sliding fee discount providers, CMS is providing additional flexibilities to, in certain circumstances, provide a good faith estimate to a new uninsured or self-pay patient that lists the undiscounted rate for items and services.

Additionally, in cases where a provider or facility does not expect to charge a patient for any items or services, CMS recognizes that a full good faith estimate may not be appropriate. Therefore, as specified in the guidance, providers who know in advance that they will not bill a patient for items or services may provide an abbreviated version of the good faith estimate, and a sample abbreviated good faith estimate is available in the guidance for such providers to use.

Second thing, on December 23rd, the Departments of Health and Human Services, Labor, and the Treasury, released an initial partial report on the federal independent dispute resolution process under the No Surprises Act. The report covers the second and third quarters of 2022, and is available online at cms.gov/nosurprises.

The Departments have previously published data on IDR throughput, both on August 19th, 2022 in a status update, and in December 2022, as part of the guidance establishing fees for the federal IDR process for 2023.

While those publications included data on the high volume of disputes in the system and delays in achieving payment determinations, this new report provides information for the first time on the parties engaged in dispute, the types of services under dispute, and the states in which disputed items and services were provided.

Moreover, the Departments are providing additional detail and context to help

stakeholders understand the data being provided in this initial report. Notably, the departments chose to publish a partial report now, rather than prioritizing manual data processing needed for a full report, in order to allow certified IDR entities to focus on issuing eligibility and payment determinations, and to give the Departments time to continue automating the Federal IDR portal to improve dispute processing.

The Departments intend to later supplement this initial partial report with a full report for each of the two calendar quarters covered. The Departments are committed to transparency in implementing the No Surprises Act and believe this report will help stakeholders and the public better understand the status of the federal IDR process, as well as some of the factors that have contributed to the issues experience by disputing parties thus far.

The information available in the report includes: the top states that disputes are being initiated in, which include Texas, Florida, Georgia, Tennessee, and North Carolina; the organizations who appear most often as initiating or non-initiating parties in disputes; and the CPT codes that are being disputed most often. Notably, two-thirds of disputes involved an emergency department services CPT code. So, again, that report is available at cms.gov/nosurprises.

Finally, I have some additional announcements. We wanted to make you aware of some additional IDR resources that were recently posted. The IDR YouTube playlist was updated to include new demos of additional parts of the IDR portal. A new job aid for the IDR entity selection response form was added to the NSA website and fact sheets page.

And we have updated the charts showing federal versus State IDR applicability, and those have been posted to the webpage and the NSA

website. We will send out links to the guidance documents and newly posted resources after this meeting. Thank you.

Jill Darling: Great. Thank you, Camille, and Scott, and to Adele. And (Holly), we will go into our Q&A, please.

Coordinator: Thank you. If you would like to ask a question, please unmute your phone, press Star 1, and record your first and last name clearly when prompted so I may introduce you. To withdraw your request, please press Star 2. Again, to ask a question, press Star 1. And it may take a few moments for questions to come in. Please stand by. Our first question is from William Rogers. You may go ahead.

Dr. William Rogers: Thanks. The RPM codes and RTM codes are pretty new, and there's still some uncertainty around the implementation. And what I was wondering, and I'm sure you don't have the answer at your fingertips, but hopefully can get it, is whether the surgeon who was treating a patient while still under the global period, would be able to bill RPM codes and RTM codes, or would those RPM codes and RTM codes not be covered because the patient was in the global period for the surgical procedure. Thanks.

Dr. Eugene Freund: Thanks so much, Dr. Rogers. I'm pretty confident that we don't have any of the experts on that on this call now, but we can take that back and work our process on it. Thank you for giving us that question.

Dr. William Rogers: Thanks, Gene.

Coordinator: And our next question is from Ed Gaines. You may go ahead.

Ed Gaines: Thank you, CMS. A question about the January 13 CMS IDR toolkit issuance. You issued a number of tools, I believe 11 tools for the IDR fees. And I believe it was in tool number four, you listed the administrative fee, the non-refundable administrative fee assessed to both sides at $50.

And previously, in December, I believe it was December 23rd, you issued a memo that the non-refundable IDR fee for each side was going to be increased from 50 to $350 effective January 1. And I was confused if you had countermanded your previous issuance, or was that a typo, or could you comment?

Camille Kirsch: Hi. Thank you for that question. Yes, you're correct. That was a typo. We're aware of the error, and it will be corrected shortly.

Ed Gaines: Thank you.

Coordinator: And I have no additional questions at this time, but again, if you would like to ask the question, please press Star 1. And we have no more questions at this time.

Jill Darling: Okay, great. Well, thank you to all of our speakers. I'll see if Gene has any closing remarks.

Dr. Eugene Freund: I just want to thank everybody for calling in. Want to thank our speakers, want to encourage everybody to submit formal comments to these rules. Also, there's a part C, D rule that deals with prior authorization in the Federal Register hopper, and those close on February 13th. So, please read and comment on those rules because I think they're important to everyday practice life. And that's all I have to say.

Jill Darling: Great. Thank you, Gene. And thank you again for everyone joining us, and have a wonderful day

Coordinator: And this concludes today's conference. Thank you for participating. You may disconnect at this time. Speakers, please stand by.

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