

Centers for Medicare & Medicaid Services
Changes to Level II Healthcare Common Procedure
Coding System (HCPCS) Coding and
Application Submission Procedures for 2019
Special Open Door Forum
Moderator: Jill Darling
December 18, 2018
1:30 p.m. ET

Operator: Good afternoon. My name is (Lisa) and I'll be your conference facilitator today. At this time, I would like to welcome everyone to the Centers for Medicare and Medicaid Services Special Open Door Forum Changes to Level II Healthcare Common Procedures Coding System, Coding and Application Submission Procedures for 2019 Special Open Door Forum.

All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone key pad. If you would like to withdraw your questions, press the pound key. Thank you.

Jill Darling, you may begin your conference.

Jill Darling: Great. Thank you, (Lisa). Good morning and good afternoon everyone. Thank you for your patience. We were trying to get more folks in for today's call. I'm Jill Darling in the CMS Office of Communications.

So, before we get into today's call, I have one brief announcement. This special open door forum is not intended for the press. And the remarks are not considered on the record. 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 have any inquiries, please contact CMS at press@cms.hhs.gov.

And now, I will hand the call over to Laurence Wilson.

Laurence Wilson: Good afternoon. My name is Laurence Wilson and I'm the director of CMS's chronic care policy group. Welcome to CMS's open door forum on HCPCS coding. I'm joined by Cindy Hake, who leads CMS's group responsible for HCPCS coding and by Joel Kaiser, the director of the division of DME post policy here at CMS.

Healthcare common procedure codes are an essential element of claims processing used across the healthcare system. Essentially, they're the language that conveys important technologies like drugs, devices important for the care needs of patients, the codes facilitate transactions among payers and providers and thus are extremely important to how healthcare is provided and making the system as a whole work properly.

CMS has heard a lot of input over the past year from stakeholders including from the requests for information or RFI that was included in a number of rule makings in 2017 where we received comments from many stakeholders around HCPCS and also from letters and visits from various stakeholders over the course of the past year or more.

CMS is very interested in making changes in the process to ease the burden but also importantly to facilitate the introduction of new technologies for the healthcare system broadly but also for Medicare beneficiaries that rely on new technologies to address their care needs.

CMS made a number of changes for the calendar year 2019 cycle, which we posted on our website over the last several weeks. We're interested in hearing more about what other changes might be important for this process moving forward.

Cindy is – Cindy Hake who is as I said is the leader of our HCPCS group here at CMS is going to walk through the 2019 cycle changes as well as provide some other information.

So, Cindy, I will pass the microphone to you.

Cindy Hake: OK. Good afternoon everybody and good morning depending on what time zone you're in. Thank you for joining our call and for your interest in our coding program and specifically the changes we are making to it this year and on an ongoing basis.

Before I begin to talk about these changes, I just wanted to talk a little bit more about the code sets and the codes that are used across all electronic transactions for medical claims across the country and just a couple a little bit.

Under the Health Insurance Portability and Accountability Act, everyone who submits or processes an electronic medical claim is required by law to utilize standard national medical code sets adopted under the HIPAA Law.

And there are six such standard medical code sets including like the current procedural terminology code set that identifies medical procedures, procedures performed by healthcare practitioners and that code set is maintained by the American Medical Association. That is level one of the HCPCS.

There's a national drug code set. There are – there's the current diseases and diagnoses code set. There is a code set parallel to the AMAs current procedural terminology which is current – called current dental terminology maintained by the American Dental Association.

And finally, there is the level two of the HCPCS code set which identifies items and sometimes services that are not captured in the level one HCPCS code set.

So, level two code set is maintained by CMS. It's designated by the Secretary of the Department of Health and Human Services. So, it identifies typically items sometimes services that would be use in a physician's office or in a patient's home. Just some background for those of you who aren't familiar with our HCPCS coding process.

The procedure itself is a transparent government process includes application taking on an annual cycle. And we begin taking applications in early January

of every year from anyone who wishes to submit a request to modify the existing standard national level to HCPCS code set.

And CMS reviews all those applications and summarizes the applications. And we put on our website a summary of each application that's submitted to us so the general public has an idea of what we're looking at.

And in addition following an initial review of all the applications, CMS also publishes its preliminary HCPCS coding recommendation and Medicare payment recommendation. And those recommendations and the application summaries are typically published in April and May of every year.

And following publication, about a month following publication, we have public meetings. At which time, we gather input from anyone in the general public applicants, medical specialty societies, beneficiaries, individuals or organizations, sometimes product competitors, anyone in the general public who would like to come to CMS and comment not just on the application itself but also on preliminary coding and Medicare payment recommendations published by CMS.

And CMS does not formulate its final coding decisions until after we have had an opportunity to hear and assimilate all information provided with regards to the individual application submitted to us.

And final decisions then are published on our website around November 1st of each year. And in addition, we submit – we sent individualized decision letters to all of our applicants. And those decision letters are also published on CMS's website.

So, we have – there's a very public component to the level two HCPCS coding process. And following the final decisions and obviously CMS is working at pulling together the annual update and publishing that and sending that to contractors and publishing on our website.

And the new codes that are created as a result of the annual coding process are typically effective in January of the following year although CMS does have

the flexibility to code sooner when there's a national program operating need to do so.

And as such, many of you have seen on our website quarterly changes or even interim changes on our website to address urgent issues such as new cancer treatments or new blockbuster drugs where we expect a rapid intake very quickly in high volume and et cetera.

So, our process is mainly annual. We do also introduce quarterly updates to the HCPCS code set.

And so, I wanted to walk through with you some of the changes that CMS has made for the 2019-2020 coding cycle. And also say of course that as many of you know CMS has always been interested in making changes to the code set.

Iteratively, those of you who have been with us as applicants over the years know that it's not unusual at all for us to introduce improvements and changes as often as we can and that we've been very responsive to feedback and interested in improving our processes because that only makes it better for everybody.

The changes that we're going to be talking about for 2019-2020 are the beginning of additional changes that we hope to make – if continuing into the future so that we have a coding system that is responsive to the needs of varying stakeholders as it can be.

OK. So, for the changes that we've introduced for this year, you may have seen on our website or within the invitation and the announcement of this open door forum a series of six changes that we're announcing for this year.

And that includes clarifying our website guidance with regard to the application process. And we have actually updated the application form and format relative to other changes made like with regarding decision criteria for example.

Just skipping to number three on our list, we – CMS has eliminated the 3 percent volume criteria for – it's a decision criteria for non-drug items. Previously, marketing criteria has not been required for drug items.

We're eliminating the volume component of the application requirements for non-drug items like the DMEPOS items. But we will continue to collect marketing data but have dropped that volume requirement. And we expect that that might be a popular change as it's been one that's been requested by various stakeholder organizations.

So, that is reflected on the application of course as they're – the directions now are to not answer that volume question. And as we go through another iteration of the application with the PRA, we can – we will likely just sort of eliminate that question all together.

And so, we have an analogous change on our HCPCS decision tree. Those of you who have noticed the newly revised decision tree on our website, the volume criteria is no longer included in the decision tree or in the instructions on page two of the decision tree.

So, we basically revised all the documentation and the forms and instructions surrounding the changes and the decision criteria of course.

With regard to the application itself, we are also this year advancing an electronic application taking process and doing a pilot testing of an electronic application process for CMS with this coding cycle. That's been a long time coming. And we're very pleased to be able to announce that.

This will mean that in the future, hopefully, we will be taking electronic applications either exclusively or voluntarily as we work towards a roll out of all electronic transmissions in the coming year or so.

And so, that will eliminate the requirement to make copies – 35 copies – of the applications and to ship all that weight and boxes to CMS. So, we also expect that that will be a popular change. That's been something that's been

requested by outside stakeholders for some time. And it's also been something that CMS has been interested in implementing for a long time.

One of the hold backs on implementing that, not indolent implementing that sooner is – has to do with the security of the information coming in. There's lots of proprietary information as many of you know within the HCPCS code application. We're concerned about submitting that kind of information electronically without the appropriate protections.

And finally, last year in 2017 I believe or early 2018, CMS on boarded a system called screen door which enables us to have a secured electronic application developed that into an application that mimics our HCPCS code application and utilize that format as a means to submit electronically to CMS.

So, we finally have the technology that we needed for a long time. And we have developed that into a pilot program for now.

So, this year, we have a number of volunteer. Some of you may be on the phone with us; I'm not sure. I don't want to just take the liberty of announcing who they are. But we have stakeholders who have been kind enough to volunteer to participate in our automated application taking pilot and will submit this year both on paper and electronically.

And the electronic submission will be used just to evaluate that, the electronic component and the submission of data CMS's ability to collect it. The viability of the form, user friendliness of the format, and the intake process and also how well the automated procedures fit with the internal business processes of our applicants.

Just as an example, applicants are also then submitting electronically sort of going paperless within their internal business operations and yet they still need sometimes to circulate, draft documents internally for approvals and signatures and et cetera. So, there still need to be ability for them to print a PDF and et cetera.

So obviously, electronic systems have to meet the needs of our applicants as well as CMS doing the application intake.

So, we're hoping for great success with that. And we're excited about it and look forward to making announcements later year as we move towards a wider, broader implementation of electronic application taking.

And we thank you all for your patience and waiting for that change in our system. I think that's really big news.

Fourth item on the list of six is providing more detailed responses to applicants in order to provide greater transparency and to assist and understanding CMS's decision making and rationale.

We are constantly working towards that and finding an acceptable mix of providing information that's enough. We've actually had request in the past that – to not provide too much information. So, we are always trying to meet the needs of our stakeholders and get it right and provide the exact amount of information that we need and the rationale that we need. And so, we've been working towards that for a long time.

We have on our website and some of you if you look at our new documents, our HCPCS procedures document, includes and really has included sample decisions and decision rationales that relate to our decision criteria and – which provide an understanding of the types of decisions we make and the types of rationale that we provide.

And as we move along if any of you have any comments specifically on the nature of that information, those types of responses, and level of information, and this decision rationale we'd be happy to hear it.

We know that you need enough information in order to know whether or not to apply again if an application is – doesn't result in the new code requested and information that might help understand what might need to be different in a subsequent application. And we are working on that always and happy to take input on that.

The fifth item on our listed six changes is providing for a greater transparency and public input by providing for remote participation in HCPCS public meetings.

So, previously, our public meetings have been for in-person attendance – in-person participation I should say. We have published the public meeting content on YouTube and we've live streamed. But we haven't previously had a way for applicants or others to provide presentations for example remotely or to ask questions remotely without being at CMS in our building, in our auditorium.

So, CMS has a means to enable that. And we plan to employ that for our upcoming coding cycle which should make it easier for people to participate more cost effective as they wouldn't necessarily have to travel and et cetera. So, we look forward to that.

And we are also – the sixth item and last item on our list of changes for 2019-2020 is that we're increasing transparency by including an archive of past year's files on CMS's website. In particular, I think this refers to files that we've published at the end of the – every – the coding cycle that include nature of the applications that CMS considered for the coding cycle together with additional information that includes our preliminary coding recommendation, a brief summary of applicant comments if there were any at the public meeting, and CMS's final coding recommendations.

And we've published that in two formats and sort of a spreadsheet format and also in a narrative format on CMS's website. And so, that's a pretty rich detailed document that describes pretty much everything that went on in the coding cycle for the year across all the external applications that we received.

And we've only started publishing that – I want to say this is our fourth year, might be third, but I think it's our fourth year. And it's a huge bulk of content. And so, we've been replacing the prior years' content with the current year's content.

We've received a request to publish just continuously and leave the prior years' content on our website in addition to publishing the current year's content so that we build sort of an archive of current and prior decisions and code applications and the information surrounding those.

So, we've began to do that. So, we'll be developing a rich archive of HCPCS coding information as we move along.

And let's see if I have anything else. So, I just wanted to say that as I mentioned, CMS is always interested in improving processes. And we've taken great pride in that. And our HCPCS level two coding process has been used as an example by other code set maintainers in terms of transparency, in terms of efficiency in bringing a process to having an entire cycle within a year that it includes a process for reconsideration.

And so, we like to take the lead. We're very interested in your comments and your questions about this year's changes and additional input regarding developing additional improvements in the coming years.

And with that, I will turn it over to (Lisa) or whomever will be asking for questions.

Operator: Thank you. As a reminder ladies and gentlemen, if you would like to ask a question, please press star then one on your telephone keypad. If you would like to withdraw your question, please press the pound key. Please limit your questions to one question and one follow-up to allow other participants time for questions. If you require any further follow-up, you may press star one again to rejoin the queue.

Your first question comes from the line of John McInnes from Arnold & Porter. Your line is open.

John McInnes: Yes, hi, thank you. So, first, I'd like to say I greatly appreciate the efforts by CCPG and HCPCS. I kind of want to go back to – I just make a suggestion and this is not so much the HCPCS process but sort of the consequences of a

sister group at CMS and sort of what they do with the HCPCS codes that the work group creates.

And some of the consequences I think this is – this is important and could be to some extent undermining some of the good work that the HCPCS work group does. So, with regard to drug applications, when a J-code is granted, typically one of the things that is evaluated is physician office utilization.

And if a J-code is granted, first it's just relying on a C-code for HOPD and ASC use. The work group will determine that the physician office utilization is sufficient and that's part of the evaluation and that's part of the information that's provided. And when that's decided, J-code is granted.

And there's been several situations where the HCPCS work group creates a J-code. But then, the hospital mandatory policy group does not list that J-code on ASP pricing file even though ASP is submitted to the agency. And I fully understand and appreciate that this is not necessarily squarely within CCPGs policy area. And I've discussed with (HAPC).

I just bring this to the attention of CCPG and the HCPCS work group because I think that in some cases when the J-code is created that additional step is really necessary in order for – as Laurence summarized very nicely at the beginning - the full benefit of these codes to physicians that want to use the drugs in the physician office setting and the patients who could have the drug administered in that less costly site of service.

And it's not a lot of drugs frankly of the whole list. But it is not insignificant number of drugs that sort of that last step is for whatever reason I don't fully understand it but it is not done. And I think that I might be worthwhile – I mean, I know when I was at the agency there was always discussion about kind of breaking down the silo walls and discussing some of the – how these policies interact.

If you might maybe ask the (HAPC) – your (HAPC) colleagues about that. And perhaps look into that. I think that would be very helpful to a lot of the

drug companies that do get a J-code and find that their code is not listed in the ASP file. And that was my comment and my request. So, thank you.

Laurence Wilson: Thank you, (John). And we will certainly share that with the part B drug policy team.

Operator: And again, if you'd like to ask a question that's star one on your telephone keypad.

Our next question comes from the line of Amanda Cassidy from Arnold & Porter. Your line is open.

Amanda Cassidy: Hi. Thank you very much for this open door forum for making of (assignments) to the process. I just wanted to clarify one number that appears in the application and to ask a quick question.

First of all, to make sure that I understood correctly, we're only required now to submit 25 and not 35 or rather a total of 36 applications. It looks like that number was revised in the 2019 application. And I want to make sure that that's correct.

And then secondly, there's also a statement that says that applicants need to provide documentation of the FDA determination. And this appears in the list and it suggested that FDA determination might be something different from the FDA approval.

And just wanted to understand if like for a drug that has received an FDA approval letter if that suffices those for the FDA approval and the FDA determination. Thank you.

Cindy Hake: OK. Thank you, Amanda. It's yes and yes. So, the FDA determination is the approval if that's what the FDA determination is. And 25 is accurate. That's not a typo for this year. And hopefully, in the future, we'll bring that to zero copies, right, with electronic application submissions. Thank you very much.

Operator: Our next question comes from the line of Chris Jacobs from Genteel. Your line is open.

Chris Jacobs: Thank you. This is not drug related. It's durable medical device. How do you handle a product such as ours not to go in long winded about our product? But we have a vacuum blood draw system that there is no code for because it is brand new. I mean, a ton of patents. And in fact, the only FDA cleared device of its type it allows you to – it's for people with diabetes. You put it against your skin. You push a button. And it uses vacuum instead of hard lancing to draw blood up.

Now, the closest thing would be a lancer. And so, we've put in the A-code. How do you get maybe into the E-code or just you might say off the record advice how we could file for that? We tried once and it was just – it was squished into the A-code which is not really representative of what we do.

Cindy Hake: OK. Thank you, Mr. Jacobs. I'm very familiar with your product. And I do remember your application. And I – off the top of my head and I don't know if Joel Kaiser might want to say something or not.

But typically, the level two HCPCS code – and I should've mentioned this at the very beginning, so, I'm very glad that you brought this point up. It makes perfect sense here.

HCPCS codes represent categories of similar items and it's not – and is not intended to be a universal listing of every product and make and model on the market. So, as you look at our decision criteria, you see how items maybe gathered into an existing code category.

But the – when I get questions such as yours, I typically refer them to the insurers and who's jurisdiction claims are filed because – while CMS maintains the code set and what reviews new technology and make sure that that is included in the code sets so this could be updated and meet the needs of providers and beneficiaries, we aren't charged with actually assigning individual products to existing codes. That's something that insurers do.

And so, if it were me, I would contact the insurers be it Medicare, contractors, state Medicaid agency, private insurer in whose jurisdiction I would be submitting a claim and ask them how the device should be coded on an application coming in to them.

So, insurers have the necessary flexibility to assign individual products to existing codes as they deem appropriate and as is consistent with their programs and policies.

In order to get a new code, then that kind of information is what's outlined in our decision tree. I don't know what else to tell you other than to – I believe your decision letter referred you back to the insurers.

I don't know if you had had an opportunity to have this conversation. But if you haven't, you might want to start there.

Chris Jacobs: Understood. And I think we all like the idea of new and exciting health improving technologies. And I'm just hoping we can introduce this in a way that doesn't stifle new developments because new developments are what make things better.

Cindy Hake: You are right. Thank you very much. You're exactly right which is why we're interested in having a very responsive process and code set. Thank you.

Chris Jacobs: I was really applying to the wrong people rather than the wrong way.

Operator: And again, if you'd like to ask a question, that's star one on your telephone keypad.

Our next question comes from the line of John Carlsen from Convente. Your line is open.

John Carlsen: Hi. My question relates to coding for biosimilars. And I was wondering if you have any kind of special guidance or suggestions regarding how biosimilar manufacturer should go about requesting a code.

I know that over the last few years, many biosimilars have received Q-codes that have been part of the quarterly HCPCS files which I assume is outside of the standard annual process. However, there have been biosimilars that have gone through the annual process including a couple this year that were issued codes through that process.

So, I'm just wondering if you have any – if you can speak to the approach that biosimilar manufacturer should take if they're interested in getting a code for their product. Or, if it's not possible to address that on the call today if that's something that CMS could consider doing in the future.

Operator: We have no further questions in queue. I'll turn the call back to the presenters.

Cindy Hake: I'm sorry, I began talking to the (mute) in answering John Carlsen's question. So, it's Cindy Hake. John, I just want to thank you for bringing up the example of biosimilars because that's a great example of CMS exercising its flexibility in coding sooner than the next annual update.

And so, we've made use of quarterly updates up until now to code sooner when there's a need to do so. It seems that sometimes there's a quarterly process that applies to the biosimilars. And as you mentioned, it seems that other times the applications go through the entire annual processing.

I believe that the difference in the background is only that for some of those biosimilars, FDA clearance was still pending. And in these instances, CMS they have converted this to internal request in order to have a mechanism to code quickly rather than waiting for reapplication in the next annual update.

So, that FDA clearance timing does affect obviously timing of publication. And we're acutely aware at CMS of the need to code sooner for certain items and something that we are and have been considering. Certainly don't have any answer for you today, John. But it was a great example and a good question.

And if you or if anyone on the line wants to submit additional questions or give us your input in writing so that we can have it and gather it for future consideration even after today's call, you can e-mail us at hcpcs@cms.hhs.gov and give us a written record of your questions and we'll maintain them for consideration.

Operator: Our next question comes from the line of Vision Lan from Navigant Consulting. Your line is open.

Vision Lan from Navigant Consulting, your line is open.

OK. And we have no further questions in queue.

Laurence Wilson: And this is Laurence Wilson. I just wanted to thank everyone for joining the call today. And as Cindy mentioned, we do have the HCPCS mailbox open for any further input on the process as it exists today for any suggestions for future changes.

Again, thank you very much for joining us today.

Operator: This concludes today's conference call. You may now disconnect.

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