

Centers for Medicare & Medicaid Services
Questions and Answers
Open Door Forum: End Stage Renal Disease
Tuesday, December 10, 2024

1. Question: I represent the National Forum of ESRD Networks. I'm the Co-Chairperson of that patient organization within the forum. And I first want to begin by thanking you all for everything that you do for kidney patients. And I had a comment/question in reference to the phosphate binders going into the bundle on January 1. As a 35-year kidney patient, I've been taking phosphate binders for most of those 35 years except for the six years that I had a kidney transplant. My concern with the transplant, with the bundle payment for the binders is that in some facilities, yes it will increase access for patients, and it'll probably increase access for all patients. However, in some of our smaller facilities, dispensing those phosphate binders may become a burden for the facility. And in addition to that, I am afraid as a patient that there may be some unintended circumstances behind the binders going into the bundle. For example, there are some patients that take two different types of binders to control their phosphorus levels. And I see it happening already that binders are being switched from two binders to one and if they're going into the cheaper binders, for example, calcium acetate, which is one of the cheapest ones. And we know that studies show that large levels of calcium is harmful to kidney patients. So, I'm concerned about the long-term effects of these calcium acetate binders being used because they're the cheapest and the unintended harm that may take place as a result of those. And I was wondering if CMS is concerned about that. Are we going to study that, and are we going to study what the effects of patient's long term with all of this calcium in our system is going to be?
 - a. Answer: The first has to do with dispensing may become a burden for smaller facilities. Now keep in mind that this has been on the books that we were going to do this since 2016 and what we have told, and we've sent out guidance on this, and it also included this in the final rule, that these smaller facilities, they can either provide themselves if they choose to, or they can do it under arrangement. And so, with that, we feel, and we've investigated this, that there's an ample opportunity for the patients to obtain the phosphate binders, and it really shouldn't be any different than them obtaining it before, when they had it through Part D. The advantage being, is now about 20% of the people have access to it that didn't have it before. And the second one that you mentioned has to do with the unintended consequences about the two different types. We have provided guidance about how to go ahead and have the ESRD facilities put the—if patients are taking two different types of binders, putting that on the claim that they will be reimbursed. Now keep in mind that the—what the patient is prescribed and what their plan of care is, is between their nephrologist and the patient. CMS by law is not allowed to practice medicine. And so if there is a problem, what we are

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going to do is we have an abundant amount of information that we have been collecting for years and years and years about phosphate binders and the outcomes that we see in patients, whether it's, you know, has to do with cardiac or bone and mineral metabolism, breaks, MACE (major adverse cardiovascular event) events, all of those. We have all of that information as it stands now and in past years. We will be closely monitoring it and looking at the different populations and subpopulations of payment—patients who receive different phosphate binders. And if there's a change, we're going to be looking at that also and monitoring that. And if we see that, we are certainly going to send that information to the appropriate divisions and components so it can be more thoroughly investigated.

i. Question: Will there be a quality measure on phosphorus levels in patients?

1. Answer: We are exploring options for a new bone and mineral disorder measure and are always pursuing opportunities to expand and enhance our measure set.

2. Question: Our recent comment letter went through the litany of new drugs for which TDAPA has failed to provide meaningful access to patients. In the preamble to the rule, you acknowledge unintended consequences of bundling new drugs, but you say you are counting on physicians to prescribe those drugs even though practically speaking, the cost of the new drugs comes out of the physician's pockets. I just want to say that I regularly receive announcements from CMS assuring beneficiaries will get access to new Part B and Part D drugs for diseases like sickle cell or even obesity. But I've never seen a press release trumpeting a TDAPA drug. And I'm assuming the reason for that is that you know that dialysis patients are unlikely to get these drugs. In three decades of working on public policy, I've never seen a worse case of groupthink than the enthusiasm for rigid bundling and the denial that there are trade-offs, and the trade-off is the possibility that any patient who differs from the average patient who needs an expensive treatment is not going to get it. My question is, has your group briefed the CMS administrators on the trade-offs inherent in the dialysis bundle and offered them either the last two, any options other than this current policy that is not delivering these drugs to patients?

a. Answer: Yes, and answer to your question, yes, we brief the administrators. We have routinely expressed our desire to match payment with resource use, and part of the reason for having the bundle to begin with is because there was an abuse in anemia management drugs. So, we wanted to go ahead and provide these functional categories for different—for nephrologists to have this armamentarium of drugs to use for patients. Not every patient needs every drug in every functional category. So, we wanted to provide flexibility, and in doing so, in addition to which we had to do that within the framework of what section 1881(b)(14) allows us to do, and that is we have to have a single payment. Now we have discussed many opportunities of perhaps looking at different aspects of

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our payment system including, you know, rebasing. And so, my suggestion would be to you, but we can't do that. CMS is not allowed to dictate policy. We don't tell Congress what to do. Congress tells us what to do. And so, it would seem that an ability to rebase, because we haven't done it in a very, very long time, would help many problems with not only drugs, but with TDAPA and TPNIES and other various aspects of this. We have to go ahead and do what Congress tells us to do in a budget neutral fashion. And so that's why we have the system set up the system set up the way that we do. you should not infer that we don't expect patients are going to receive TDAPA drugs. We absolutely expect that we should receive TDAPA drugs when it's appropriate. And I'm not really certain whether you're talking about any of the drugs that have recently received, you know, TDAPA. If it was any of the new drugs or if you're talking about TDAPA for phosphate binders, but it just in principle, the payment policy for TDAPA is based on average sales price. So, your other comment about the cost of drugs for TDAPA coming out of the, don't remember if you said it was a dialysis facility's pocket or a physician's pocket. I'm not really sure that I follow that, and I just want to make sure that you're aware that the TDAPA policy is—there is an add-on payment under the TDAPA, which is based on average sales price.

i. Comment from participant: I certainly understand that. I mean the problem is that the doctors are in joint ventures with the dialysis clinic. So, they are—it's almost a form of capitation in the sense that the money is spread across all patients rather than following the individual patient with special needs. And I just wish that there could be a little bit more creativity on the agency's part to figure out how to get these drugs to patients. Because getting Congress to do anything, as you know, is very difficult, and there's a score involved, and it would just be a lot easier if CMS could resolve this problem for patients.

1. Answer from CMS: So TDAPA is paid on a utilization basis, so the claims billed and TDAPA is paid for the claim.

a. Comment from participant: Yes. But the doctors are anticipating a post-TDAPA period that's not going to have an adequate payment. So, they're anticipating that they're not going to deliver the drug in the first place because then they have to withdraw it.

i. Answer from CMS: That makes sense. That clarifies the comment. I think what I would encourage, ongoing dialogue. This is kind a good dovetail into sort of what I want to say later about the future of these Open Door Forums, just ongoing dialogue about ideas that the community has for—for—making revisions in the payment system. CMS

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has solicited comments as readers of the rule will know about making revisions to the case-mix adjustments and collecting the types of data that would be necessary to understand the drivers of— better understand the drivers of cost and make those kinds of revisions. So, in addition to, as I mentioned earlier, the outlier adjustment, which recognizes costlier patients and makes an adjustment for those patients whose treatment is costlier, we would strongly encourage dialogue from the community here on how we might recognize those types of things and potential revisions in the future.

3. Question: The first is regarding the new wage index table. I just want to make sure as I'm reading this to load into my billing system that it is read left to right including the 24 and the 25 columns. Is that correct?
 - a. Answer: That's correct. I think you're talking about the crosswalk that's on the website. The far left column is FIPS (Federal Information Processing Series) state and county codes. What that tells you is for a given FIPS state and county code, it was in CBSA (Core-Based Statistical Areas) or state code whatever in 2024. In 2025, the delineations have changed. It is a different CBSA or state code.
 - i. Question: OK. I just wanted to make sure because one of mine so far in my list has been changed. Second, for the composite rate items that are moving to outlier, the first communication had a hundred pages of NDCs (National Drug Codes) and drugs that will be moving to outlier. Does that also include the composite rate injectables that we've been given to our patients such as heparin, mannitol, glucose, that whole list that we've seen before. Does the outlier now include both the orals and the injectables or just the orals that were included in the outlier communication?
 1. Answer: The outlier includes both the orals and the injectables that are composite rate drugs. The change request I think you're referring to I think the document you're referring to is coming from the transmittal. That includes the oral NDCs and HCPCS (Healthcare Common Procedure Coding System) ASP pricing will be available later this month. It typically comes at the last couple weeks of the quarter. And once the ASP file is made available, then those prices will be available.
 - a. Question: Will heparin, mannitol, glucose, and everything else that is on that list, those will be included in outlier going forward?
 - i. Answer: Yes.

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1. Question: Then my final question was regarding the LVPA, the two-tiered system. Will we be notified which tier each clinic falls in with our attestation approvals, or is this something that we're going to have to make our determinations ourselves?
 - a. Answer: The criteria for which tier the facility falls in are clearly laid out in the change request. CMS is not dictating which tier the facilities fall in.

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