

WEBVTT

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00:00:00.000 --> 00:00:01.510

Zehra Hussain: A mask in the

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00:00:01.540 --> 00:00:03.719

Zehra Hussain: in Substitutes Town Hall,

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00:00:03.900 --> 00:00:32.389

Zehra Hussain: and today you can see we have some a lot of faces and a lot of names, and we will actually begin shortly. But we wanted to note that the participants do not have the ability to share their screen or turn on their video only be panelists and the panelists you see here are actually interested parties who have indicated that they wanted to present, and they will remain off of camera, and they will remain muted until it is time to hear from them.

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00:00:32.420 --> 00:00:41.269

Zehra Hussain: So we will get started in about two to three minutes. We are still waiting on some Cms personnel to help on. But thank you all for joining, and we will begin surely

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00:05:23.270 --> 00:05:41.060

Zehra Hussain: again. Just want to welcome you all, and thank you for joining the Cms. In Substitutes Town Hall. I apologize for the delay. We have one of our deputy directors that are just running a little bit behind due to some other scheduling conflicts. But we'll we'll be um getting started in about the next few minutes or so so. Thank you

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00:06:46.170 --> 00:06:53.690

Zehra Hussain: all right. Well, we will go ahead and get started. Now thank you again. Everyone for your patience and I apologize for the delay.

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00:06:53.700 --> 00:07:11.090

Zehra Hussain: Welcome to centers for Medicare and Medicaid services. Skin substitutes Town Hall. My name is Zara Hussain, and I am with the division of practitioner services which is responsible for the physician. Fee Schedule Pfs proposed and final rules. I will be the moderator for today's Town Hall

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00:07:11.170 --> 00:07:22.300

Zehra Hussain: today's skin substitutes. Town Hall is an opportunity for Cms to obtain feedback from interested parties on changes to skin substitute policies and procedures under the Pfs.

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00:07:22.310 --> 00:07:33.689

Zehra Hussain: Specifically, Cms is seeking additional information from interested parties to help inform a proposal that can achieve equitable payment for all skin substitute products under the Pfs.

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00:07:33.820 --> 00:07:49.930

Zehra Hussain: As a result, Cms. Tailored Today's Town Hall discussion to the following questions: Number one: What should we consider as part of Cms efforts to ensure consistent, fair, and appropriate payment for services and products

across different settings of care.

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00:07:49.940 --> 00:08:05.569

Zehra Hussain: Number two. How could we ensure that valuation under the Pfs adequately accounts for variability and relevant resource costs of different skin steps to products as supplies within the practice, expense, relative value, unit or Pe Rv. Methodology.

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00:08:05.730 --> 00:08:21.970

Zehra Hussain: Number three are there similarly resourced groups of products services that could inform how payment might be stratified without risking access to services. And lastly, number four. What should we consider as alternatives regarding any potential changes to terminology

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00:08:22.180 --> 00:08:38.749

Zehra Hussain: and as written on the Cms. And Substitutes Town Hall invitation? We have asked interested parties to indicate if they were interested in providing a response to any of these questions. Today we will hear from various interested parties that will present their response on these questions

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00:08:38.760 --> 00:08:54.599

Zehra Hussain: due to the limited time we have today. Cms. Will not be responding individually to these presentations or answering questions from these presentations we will do our best to get through all presentations today. Each speaker will have no more than five minutes to present their responses.

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00:08:54.610 --> 00:09:00.570

Zehra Hussain: We are keeping an eye on the time, and we politely ask those speaking to finish remarks at time.

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00:09:01.430 --> 00:09:18.179

Zehra Hussain: Additionally, Cms notes that we were not able to provide everyone with the opportunity to present, and as a result we request those who are not able to present their responses to these questions to please, submit them to Medicare Physician Fee schedule at Cms. Hhs.

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00:09:18.560 --> 00:09:33.479

Zehra Hussain: Today's skin substitutes Town Hall is being recorded and closed. Captioning is also available. Please do not speak. If you object to the recording. Once the recording is made available, we will contact participants with information on how to access the recording for Today's Town Hall.

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00:09:33.820 --> 00:09:48.990

Zehra Hussain: Also, this call is not for Press Press are welcome to listen to Today's Town Hall, but press questions need to be directed to the Press Office's resource on the Cms. Hhs website, or sent to press at Cms. Hhs.

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00:09:49.250 --> 00:10:03.359

Zehra Hussain: Today's agenda will begin with a summary on proposed and final changes to skin substitute products under the Pfs. For Cy two thousand and twenty three, followed by remarks from the Hospital and Ambulatory Policy Group Deputy Director Ryan Howe,

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00:10:03.370 --> 00:10:18.430

Zehra Hussain: after which I will present a brief overview on the Pr view methodology. Finally, we will hear the presentations from interested parties, and if we have any remaining time we will allow presentations from interested parties that are listed as an alternate presenter.

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00:10:18.810 --> 00:10:32.769

Zehra Hussain: Now, to start us off, I would like to summarize the changes we propose for skin substitute products in the cy two thousand and twenty-three pfs. For both world, as well as discuss what was finalized in the cy two thousand and twenty-three pfs. Final

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00:10:33.350 --> 00:10:48.889

Zehra Hussain: in the cy two thousand and twenty-three Pfs. Proposed rule. We proposed several changes to our policies for skin substitute products to streamline the coding, billing and payment rules and to establish consistency in how we code and pay for these products across various settings.

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00:10:48.900 --> 00:11:09.180

Zehra Hussain: Specifically, cms proposed to change the terminology of skin substitutes to moon care management products in order to actively affect how clinicians use these products to provide a more consistent and transparent approach to quoting for these products, and to treat and pay for these products as incident two supplies under the Pfs. Beginning on January the first two thousand and twenty-four

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00:11:09.190 --> 00:11:14.350

Zehra Hussain: after reviewing comments received on the why two thousand and twenty three Pfs. Proposed rule. The

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00:11:14.360 --> 00:11:32.870

Zehra Hussain: we understand that it would be beneficial to provide interested parties more opportunity to comment on the specific details of changes in terminology, coding, and payment mechanisms prior to finalizing a specific date. When the transition to more appropriate and consistent payment and coding for these products will be completed.

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00:11:32.880 --> 00:11:50.760

Zehra Hussain: Therefore, in the Cy. Two thousand and twenty-three pfs. Final rule, Cms. Stated, we would not finalize our proposals for payment and terminology, and instead work with interested parties during a town hall as an opportunity to discuss changes in terminology and to achieve a transition to equitable payment for like products.

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00:11:50.770 --> 00:11:56.100

Zehra Hussain: With that i'll turn it over to Ryan Howe, the deputy director for his opening remarks.

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00:12:01.420 --> 00:12:07.090

Ryan Howe: Afternoon, Everybody or good Good morning.

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00:12:07.100 --> 00:12:15.109

Ryan Howe: Trust that you can hear me, Zehra, and you please let me know. Yeah, Okay, great. I I wanted to thank everybody for the

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00:12:15.120 --> 00:12:35.100

Ryan Howe: for joining us today, as has been noted, and as we noted in the final Bfs rule we recognize the importance especially based on the possible comments we would be on providing more of an opportunity to give us feedback on approaches to achieving the equitable payment

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00:12:35.110 --> 00:12:53.310

Ryan Howe: for all. Ah, all of the skin substitute products. So, as part of that effort, we are conducting this Town Hall to learn more directly from you about your perspectives and concerns with regarding potential changes to how some can subscribe. Products are paid,

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00:12:53.320 --> 00:13:03.169

Ryan Howe: and you receive feedback on how to treat all the skin, substitute products in a consistent manner, without compromising coverage for quality of care for Medicare Beneficiary.

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00:13:03.180 --> 00:13:20.800

Ryan Howe: Again, we appreciate all of the helpful comments received on the rule, and we understand many of the concerns, and that it includes the request for more details on how it's been posted. Product would be paid at the supply under the position fee schedule, as well as

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00:13:20.810 --> 00:13:39.660

Ryan Howe: more of an opportunity to discuss with changes in any terminology. And that's why the focus is there. Today We look forward to hearing more of your thoughts on these topics, which will inform our thinking in the future, including in terms of the development of any proposed policy,

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00:13:39.670 --> 00:13:54.869

Ryan Howe: but again be open for comments after that as well. So we thank you again for joining. I look forward to hearing the presentations and the ongoing collaboration and feedback, and i'll end it back to our moderators here.

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00:13:56.570 --> 00:13:57.930

Zehra Hussain: Thank you, Ryan,

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00:13:57.940 --> 00:14:26.970

Zehra Hussain: and before I go into the next agenda item. I just wanted to reiterate to some of the attendees that you might see a lot of names on the screen today, and that is because we will be hearing from these interested parties later on. During today's Town Hall, and for any interested party that is joining. Now, just a reminder. Please remain on mute, and please turn off your video until it is your time to present, and I will indicate individually um given the presentation work

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00:14:26.980 --> 00:14:31.050

Zehra Hussain: when it is time for your interested party or organization to present,

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00:14:31.870 --> 00:14:46.809

Zehra Hussain: and with that we will move on to the next agenda item, which is a presentation or a brief overview on the P. E. Rvu Methodology and Chris or Devon. Can you please confirm that you can see my screen?

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00:14:49.820 --> 00:14:50.960
Yes,

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00:14:50.970 --> 00:14:52.890
Kris Corwin: yes, we can see your screen

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00:14:54.850 --> 00:14:56.890
so as a quick disclaimer.

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00:14:56.900 --> 00:15:09.120
Zehra Hussain: This presentation was prepared as a service to the public, and it's not intended to grant rights or impose obligations. This presentation may contain references or links to statutes, regulations, or other policy materials.

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00:15:09.130 --> 00:15:24.800
Zehra Hussain: The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations, and we encourage participants to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents.

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00:15:25.300 --> 00:15:42.029
Zehra Hussain: Now this presentation will cover a variety of items. First, we will briefly touch base on Rbu and its different components. Then we will go into the main focus, which is the practice expense. Ah, Rbu! And what comprises of it, which is the direct costs and indirect costs,

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00:15:42.040 --> 00:15:53.910
Zehra Hussain: and specifically we'll be mainly tackling direct costs and things that are in the direct costs, such as supply costs, as well as providing an example where we all can follow along easily,

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00:15:53.920 --> 00:16:13.239
Zehra Hussain: and then we'll. We also be discussing the Invoice Commission process, as well as providing a example, calculation of what a final p our view might look like. We will also be talking about how we might consider a skin substitute as a supply, and then, lastly, we will wrap up with other means of pricing under the Pfs.

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00:16:14.500 --> 00:16:21.939
Zehra Hussain: Now, in order to understand the pr view methodology, it's important to see how it relates to the total. Rv. You

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00:16:21.960 --> 00:16:39.210
Zehra Hussain: and the Medicare physician P. Schedule utilizes an Rbu or a relative value unit to reflect the relative resource costs associated with a specific service, and as seen in the diagram. The total Rbu is actually broken up into three different components. There is the work Rv. You

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00:16:39.220 --> 00:16:42.120
Zehra Hussain: the practice expense, or P. Rv. You

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00:16:42.200 --> 00:16:51.459

Zehra Hussain: the malpractice Rb. Or Mp. Rv. And each of these individual Rb. Use account for a certain percentage of the total Rbu,

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00:16:51.470 --> 00:17:08.439

Zehra Hussain: and specifically within the practice expense. Ah, Rbu, there is a differentiation between facility and non-facility in the yield to separate B or means. I will be discussing this further in detail later on in my presentation, And because we're mainly focusing on the Pr view for today

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00:17:08.450 --> 00:17:28.390

Zehra Hussain: to dive in a little bit deeper, there are actually two different components of pe. There is the direct costs and indirect costs, and the direct cost reflects a practitioners Clinical labor supplies equipment and indirect costs, reflective practitioners overhead. So things like administration nonclinical labor or rent,

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00:17:28.400 --> 00:17:47.820

Zehra Hussain: and I will be mainly focusing on direct costs. But to touch briefly on indirect costs as mentioned previously. These are items related to anything overhead. So non-clinical labor ran utilities and indirect costs are typically allocated to services based on work and direct costs,

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00:17:47.830 --> 00:17:53.929

Zehra Hussain: and they are adjusted, based on the indirect cost shares of the specialties that provide much service.

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00:17:54.300 --> 00:18:01.349

Zehra Hussain: Now, to go into direct costs. Direct costs are related to clinical labor supplies, equipment,

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00:18:01.360 --> 00:18:20.949

Zehra Hussain: and how to determine a direct P Inputs. Is through a variety of ways, one of which is the American Medical Association, has a specialty society known as Ne. Brook, and they host meetings that occur several times throughout the year, and provide Cms. With recommendations on direct P Inputs. For each code.

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00:18:20.960 --> 00:18:38.730

Zehra Hussain: C. Andms also receives recommendations and cost information throughout the year, and may address these revisions during the rule-making process. And this seeks to show that the result of a direct P. Input is actually derived from a variety of sources, so it could be rough recommendations, as well as other various cost data,

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00:18:39.140 --> 00:18:48.450

Zehra Hussain: and to put direct costs into perspective. We wanted to showcase an example, and this is actually sourced from a public use file.

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00:18:48.460 --> 00:19:12.950

Zehra Hussain: And, for example, we have here code, one zero zero five, and the description is fine needle aspiration, biopsy with ultrasound guidance. First lesion, and really here I wanted to showcase um with the red circle that there is a differentiation between the non-facility Rvs and the facility our muse, and we will be mainly focusing on P. Our means

for this specific exam.

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00:19:13.280 --> 00:19:32.800

Zehra Hussain: Now, when we look at the direct costs. For the same example, we can see that it's further broken down into three different costs. So we have. First, the labor costs the supply cost, and the equipment cost, and the sum of all of these yields the direct costs, and that is what's circled and run;

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00:19:33.040 --> 00:19:45.999

Zehra Hussain: and although calculated in the same manner. The costs differ between non-facility and facility, because services furnished within facilities receive a separate payment through the inpatient or outpatient payments,

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00:19:48.160 --> 00:20:04.549

Zehra Hussain: and here it's another example of the breakdown of the direct costs for the exact same code, so the non-facility, facility for labor is it being highlighted in green, as well as the supply cost and equipment costs which are respectively red and perfect.

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00:20:06.050 --> 00:20:11.309

Zehra Hussain: To look it a little bit further, we're going to be looking at the supply costs. So

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00:20:12.200 --> 00:20:28.000

Zehra Hussain: So here is the supply detail and a great way to view. It is as if it was like an itemized receipt. So here we have the details of what exactly goes into a supply cost, and this is for the exact same example.

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00:20:28.010 --> 00:20:42.289

Zehra Hussain: So for the code, one hundred and five, we have the category kit pack for the row number one pack minimum, which is the description as well as the price and the quantity between non facility and facility,

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00:20:42.300 --> 00:20:51.099

Zehra Hussain: and really to get the supply cost detail. It's the sum of price times, the quantity, and that will yield the supply cost

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00:20:51.110 --> 00:21:04.389

Zehra Hussain: and drawing your attention to the source on this table. It shows that the source is rock. However, Cms actually uses a variety of sources to determine things like supply costs and equipment costs,

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00:21:04.400 --> 00:21:22.310

Zehra Hussain: and we would like to note that in the why two thousand and eleven Pfs final rule to update supply and equipment prices through an invoice submission process requires pricing data indicative of the typical market price of the supply or equipment item in question to update this price,

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00:21:22.320 --> 00:21:29.390

Zehra Hussain: and we encourage interested parties to reference the Pfs rules to find more information on our pricing information process.

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00:21:29.400 --> 00:21:38.120

Zehra Hussain: Interested parties are encouraged to submit invoices with their public commons, even if it's outside the notice and common rule-making process at this email address,

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00:21:39.200 --> 00:21:58.390

Zehra Hussain: and to tie in all of the materials that was discussed. Really, this just showcases that it is so many different factors that can yield a final P. Rbu Um. And really the final pe Rv. You times the conversion factor will yield the dollar amount, and this is for the exact same code.

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00:22:01.040 --> 00:22:15.219

Zehra Hussain: And when we want to consider a skin substitute as a supply within that pr view methodology. To give a hypothetical example, let's say, we have code zero, one, two, three, four application of skin substitute graph.

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00:22:15.230 --> 00:22:29.919

Zehra Hussain: So we would add their associated cost to the direct P Inputs. For the service with which the product is furnished. So, for example, we would consider, what is the labor involved for this code? What are the supplies involved for the code, and what equipment is involved in the code.

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00:22:29.930 --> 00:22:44.929

Zehra Hussain: Then the some of that would be added to the indirect cost to yield the P Rb. For that specific code. However, it's important to keep in mind that we do this for other services. But there are other factors in the Pfs rate, setting methodology that can adjust the pricing.

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00:22:44.940 --> 00:22:54.960

Zehra Hussain: So, for example, even though we have here code zero, one, two, three, four is Pr. View. It's not the end, as it will be added to other Rvs within the total Rm. Equation,

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00:22:57.470 --> 00:23:20.239

Zehra Hussain: and there are other means of pricing under the Pfs. So we note that when the Pfs rate setting model methodology does not reflect relative resource costs for a specific code. There are other means to achieve this under the Pfs. And those could include crosswalking and Mac Pricing and Mac Pricing is essentially allowing a Medicare administrative contractor to set the price within their jurisdiction;

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00:23:20.850 --> 00:23:32.160

Zehra Hussain: and lastly, to wrap up. I just wanted to point out that the data I used for my example, in this presentation anyone can actually access the same exact data. There are plenty of other codes

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00:23:32.170 --> 00:23:43.839

Zehra Hussain: to dive into you. You could also go into more depth regarding the Rbu methodology, and that is available on the Pfs website underneath the related links section below,

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00:23:45.530 --> 00:23:54.040

Zehra Hussain: and that concludes my presentation. Thank you all for listening in on the overview of the Pe Rbu methodology

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00:23:59.570 --> 00:24:06.829

Zehra Hussain: that it will begin to transition into our presenter portion from the interested parties,

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00:24:06.960 --> 00:24:16.189

Zehra Hussain: and before we begin to hear from them, I would like to just reiterate a few guidelines for these presentations, which was previously communicated to our interested parties.

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00:24:16.200 --> 00:24:35.969

Zehra Hussain: Each presentation is limited to five minutes, and I will keep time, and when an interested start party starts to begin speaking, that is, when your time will begin. I will politely ask presenters to conclude their remarks at time, and I will also provide speakers with the one one minute warning in the chat box. So please be mindful of the chat role you are presenting,

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00:24:36.030 --> 00:24:51.469

Zehra Hussain: and as the presenters may have noticed, all of the presenters are now listed on the screen, I will individually call each interested party in the presentation order that was sent out, and what it is your organization's turn to present. Please unmute your mic, and you may turn on your camera if you choose.

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00:24:51.480 --> 00:25:06.479

Zehra Hussain: At the conclusion of the five minutes. Please mute your mic and turn off your camera so that the next speaker may begin. If time allows, we will begin to call upon interested parties that were alternate presenters. If your organization is an alternate presenter. Please be ready with your presentation.

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00:25:06.630 --> 00:25:20.259

Zehra Hussain: And lastly, the Q. And a chat box is available for our presenters; and if there are any logistical questions or problems. Please direct those to the Q. And A. Box. My colleague, Chris Coron, will be Fielding inquiries in the Q. And A. Chat box.

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00:25:20.610 --> 00:25:25.259

Zehra Hussain: And now, without further ado, we will begin with our first presenter,

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00:25:25.590 --> 00:25:31.330

Zehra Hussain: Paul Rudolph. Whenever you are ready, please feel free to unmute and share your screen,

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00:25:50.200 --> 00:25:51.430

so I believe

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00:25:51.610 --> 00:25:53.490

all is not on

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00:25:56.620 --> 00:25:59.449

so to not delay. Oh,

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00:25:59.750 --> 00:26:18.549

Kris Corwin: Sarah, I just promoted Paul, and there may be a leg. But yeah, yeah, I just. I just got the um. I just got the promotion here, so thank you very much. I'm going to have to share my screen here, and I hope hopefully, it'll be the the right one,

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00:26:18.690 --> 00:26:21.010

Paul Rudolf: and I will. Um!

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00:26:21.330 --> 00:26:22.680

Paul Rudolf: Ah,

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00:26:24.810 --> 00:26:27.690

Paul Rudolf: can you? Can you see the President first slide,

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00:26:29.350 --> 00:26:30.870

Zehra Hussain: I know?

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00:26:31.480 --> 00:26:33.050

Paul Rudolf: Can you see it Now

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00:26:36.290 --> 00:26:37.370

try.

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00:26:37.380 --> 00:26:38.180

Paul Rudolf: Thank you.

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00:26:38.430 --> 00:26:43.540

Paul Rudolf: It should say it should say, Oh, I see. Hold on, I

101

00:26:43.740 --> 00:26:53.409

Zehra Hussain: There you go. We can see it. You see it now. Okay, so let me um. Do you see it now? Is it in slideshow? Mode? Yes, now it's in presenter.

102

00:26:53.420 --> 00:27:04.619

Paul Rudolf: Okay, Great. Why, I know you can probably see the next slide. But okay, I'm going to go ahead and let me just start right now. So i'm Paul Rudolph.

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00:27:04.630 --> 00:27:27.089

Paul Rudolf: I am representing organogenesis and manufacturer of skin substitutes, and we will be addressing Cms questions, one, two, and three as a threshold matter. I want to point out that skin substitutes are an invaluable part of the Armenarium for treating difficult to heal chronic wounds, and they have been shown to reduce the incidence of major

lower extremity Amputations,

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00:27:27.100 --> 00:27:56.870

Paul Rudolf: therefore, as a general matter. Organogenesis recommends that Cms. Continue to make separate payment for student substitutes in the Physician office until Cms. Can demonstrate through rule, making that Bumley will not affect quality of care, access to care for Medicare beneficiaries, or disproportionately affect underserved patient populations. With respect to question one in any rule making, we request that Cms. Solicit comments on the effect of any proposal on the ability of physician offices to continue to offer,

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00:27:56.880 --> 00:28:26.810

Paul Rudolf: and substitutes to medicare beneficiaries and solicit comments, and whether the proposal is likely to shift care back to the hospital setting, and would hospitals be able to handle the patient low. A couple of slides here showing the difficulty of accurately bungling skin substitutes. So I don't know if you can see my cursor. But you can see here this is the amount of student substitutes that are that are billed foreign claims. There are over sixteen thousand claims that have seven centimeters of skin substitution.

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00:28:26.820 --> 00:28:39.689

Paul Rudolf: Build. Every skin substitute is built per square centimeter. There are over fourteen thousand claims where they're sixteen square centimeters filled, and so on and so forth. You can see the huge variability of the size of wood

107

00:28:39.700 --> 00:29:00.449

Paul Rudolf: going to be a real challenge, we think, for Medicare to be able to appropriately package skin substitutes in a way that pays appropriately and fairly across all these wound sides. The same thing is true at the cost. This is how much Medicare is paying for skin substitutes right now separately over twenty five thousand claims, two thousand dollars over

108

00:29:00.460 --> 00:29:22.710

Paul Rudolf: ten thousand claims, seven thousand dollars, and also eight thousand dollars. Again pointing out how hard it's going to be to pay accurately, and this, by the way, is for Cbt code, one, five, two hundred and seventy five, which is the application of skin substitutes mostly to the feed first, twenty, five square centimeters. So with respect to the Rv. Your calculations in any rule making, we ask that Cms.

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00:29:22.720 --> 00:29:52.540

Paul Rudolf: Discuss all the options. They considered the reasons why one option was proposed, and another was not. And very importantly, one of the assumptions made for the inputs, for skin substitutes, in other words, is the input based on the most common use can substitute. Is it a weight average of all the products here? How does Cns decide to bundle in twelve square centimeters versus fifteen square centimeters. This has to really be discussed in detail, and there's an interesting point for a base code like the one I just discovered this this discussed.

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00:29:52.550 --> 00:30:18.770

Paul Rudolf: That base code can be built alone with an add on code. If it's built alone, the size of the wound can be anywhere from one to twenty, five square centimeters. So how much is the Cms going to put in that? However, it's still with an add on. Then all twenty, five square centimeters were used, and the payment for the base code should include twenty five square centimeters of skin substitute, which basically means there could be two payments associated with the base codes.

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00:30:18.780 --> 00:30:42.369

Paul Rudolf: Very importantly. How are these costs going to be updated every year? What data is seeing that's going to use what will be submitted to make sure that over time, and as soon as substitutes new ones come on the market, old ones lead. How will the Costs always be appropriate. How the amounts be updated, and how the Cms going to be able to know that It's not creating inadvertent Consequences like what happened in the op-d,

112

00:30:42.380 --> 00:31:11.790

Paul Rudolf: or to give it Incentives to just use the cheapest product possible, even if it's not clinically appropriate for patients, and again reiterating the quality of care stuff here. We do not believe that there are similar groups of products or services that could really inform payment gear. This is really a case of first impression. We don't believe that the Pps funding methodology was was has been successful in many ways. Cms. Has had to change policies. We don't really think it serves as a mom. We like to avoid those problems.

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00:31:11.800 --> 00:31:19.990

Paul Rudolf: So in summary we asked that Cns fully lay out a year by year plan what's going to happen every year?

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00:31:20.000 --> 00:31:47.400

Paul Rudolf: The methodology for pricing understanding how these proposals going to affect equity, quality, and access, and we point out also that for separate payments. He and this has talked about separate payment made by the Max. Well, Cms should specify what that pain is going to be based on is going to be based on ah invoices, and how can it be uniform across all? Ah, jurisdictions! We think that's also be a tick with a problem. But Cms. Did not ask

115

00:31:47.610 --> 00:31:56.289

Paul Rudolf: for comments on that. But organogenesis is planning to submit written comments after this Town Hall is over, and with that I'm. Concluding,

116

00:31:58.200 --> 00:31:59.189

Thank you, Paul.

117

00:31:59.200 --> 00:32:03.010

Zehra Hussain: You had eight seconds remaining, so we appreciate the timeliness.

118

00:32:03.360 --> 00:32:15.840

Zehra Hussain: Yeah, I practiced it five times to make sure I can get it in under five minutes. It's a great way to to start the discussion. So thank you, Paul, and if you don't mind uh please stop sharing your screen, and we will move on to our next presenter.

119

00:32:15.980 --> 00:32:19.830

Zehra Hussain: Our next presenter is Um, Miss Stephanie Clay,

120

00:32:45.780 --> 00:32:49.160

Kris Corwin: in either the attendee or panelist list.

121

00:32:49.500 --> 00:32:54.929

Zehra Hussain: Thanks for confirming Chris. We will go ahead and move on to Dr. Paul Kesselman.

122

00:33:00.840 --> 00:33:02.489

Paul Kesselman: Can you hear me?

123

00:33:02.870 --> 00:33:03.790

Kris Corwin: We can.

124

00:33:03.800 --> 00:33:26.929

Paul Kesselman: Okay, Thank you very much for giving us the opportunity to respond. Ah, just as a brief background. I i'm a practicing pediatrician. I've been practicing for over forty years. I have been involved with home care since the day I finished my postgraduate training, I was involved in committees with empire, blue crystal shield, and other third-party. Max.

125

00:33:26.940 --> 00:33:41.919

Paul Kesselman: Ah! Before they were called Max in terms of when these skin substitute products first came on, and i'd like to say that I believe the Lcds and Lcas do a really good job of restricting who can get them, and when they can get them.

126

00:33:42.540 --> 00:33:54.999

Paul Kesselman: The problem, as I see that's just been mentioned by the previous speaker is that you have such a wide array of products right now. Some are in it's relatively inexpensive, some are more costly,

127

00:33:55.010 --> 00:34:05.000

Paul Kesselman: but to give an average payment will disincentivize certainly the use of more effective products that may be more expensive for specific patients

128

00:34:05.200 --> 00:34:15.409

Paul Kesselman: ultimately resulting in patients having lack of healing and wounds that recur and ending up in the hospital.

129

00:34:15.420 --> 00:34:43.120

Paul Kesselman: The other possibility is, if the physician wants to use a more effective uh um Sorry a more expensive product that would match that patient's clinical scenario, they would be forced to put the patient in the hospital, resulting in higher costs overall as we've been seeing with opd type stuff now, so I I believe that this is an endeavor that is likely to fail. It's going to end up costing more money in the long run, and I believe

130

00:34:43.130 --> 00:34:54.339

Paul Kesselman: that patients Ah! If you bundle payments. The other problem, I see, is with a lot of these patients who are diabetics, especially foot ulceration patients.

131

00:34:54.350 --> 00:35:06.529

Paul Kesselman: Ah, these these patients end up healing, and then they re ulcerate again. How does Cms plan to bundle payments for different episodes of care,

132

00:35:06.630 --> 00:35:19.170

Paul Kesselman: as we see on the Dme side, which same are similar as it's going to be a similar type scenario, where a right foot ulcer on the first metatarsal head, planner, aspect, heels, and then recurs, or on a different site on the same foot.

133

00:35:19.420 --> 00:35:39.129

Paul Kesselman: The other issue is sizing Size here does matter uh larger ulcerations cost more money uh and to, if if a less expensive product is not available on that size, and you have to order two or three in terms of a quantity that will end up ultimately costing Cms more money.

134

00:35:39.240 --> 00:35:50.310

Paul Kesselman: So I think I think doing a better job with the Lcds. And the Lcas is A. Is a far more effective job than than

135

00:35:50.700 --> 00:35:55.750

Paul Kesselman: we're literally changing the entire spectrum of the way. This is going to be paid.

136

00:35:56.160 --> 00:36:00.660

Paul Kesselman: The last issue I want to talk about is

137

00:36:00.980 --> 00:36:04.670

Paul Kesselman: having all of these won't care treatments

138

00:36:04.680 --> 00:36:31.159

Paul Kesselman: used Ah, using one specific type of terminology to encompass all of them. So we're talking about throwing in surgical dressings and pneumatic compressive devices and all sorts of other things. Under the umbrella of home care management. You have different Macs paying for these different services, and it's only, I think, going to add to the confusion of the wounded care team as to who bills what? When?

139

00:36:31.290 --> 00:36:32.600

Paul Kesselman: Um!

140

00:36:32.850 --> 00:36:40.969

Paul Kesselman: Just another notion that I think is just just misguided, and I would urge you to reconsider

141

00:36:41.570 --> 00:36:46.190

Paul Kesselman: this whole scenario and meet with the

142

00:36:46.360 --> 00:37:04.279

Paul Kesselman: interested providers as we go along. We all want to see the Medicare Trust Fund protecting. I'm. A Medicare beneficiary I want, and a relatively young one. I want to make sure that the Medicare Trust Fund is well preserved. Not taking advantage of,

143

00:37:04.290 --> 00:37:17.460

Paul Kesselman: I do auditing. I see lots of audits for mooncare products, and I think that those cases where there is abuse there should be recruitment. There are other ways to so

144

00:37:17.610 --> 00:37:26.990

Paul Kesselman: stem the tide of reimbursement in Ah, in scenarios where, whether It' inappropriate, and it would urge Cms to consider

145

00:37:27.000 --> 00:37:31.680

Paul Kesselman: other avenues other than bundle payments. Thank you very much.

146

00:37:34.160 --> 00:37:36.279

Zehra Hussain: Thank you, Dr. Paul Kesselman.

147

00:37:36.860 --> 00:37:44.110

Zehra Hussain: We will now move on to our next presenter from the Alliance of Moon Care stakeholders. Marcia.

148

00:37:44.950 --> 00:38:14.810

Marcia Nusgart: Good afternoon. My name is Marsha Nascar, and I'm. The Ceo of the Alliance of women care stakeholders. We appreciate the opportunity to provide the alliance comments from you for this meeting today? I'm. Answering both questions, one and four today, and then providing recommendations. The agency first asked, What should we consider as part of Cms's efforts to ensure consistent, fair, and appropriate payment for services and products across different settings of care. In order to help answer this question, we really need to have more information on the

149

00:38:14.820 --> 00:38:44.590

Marcia Nusgart: agency, on Cms's intent goals or criteria for packaging skin substitutes in the physician's office providing form feedback. However, we do not believe that Cms. Should package skin substitutes in the physician of office, as the agency does now in the hospital outpatient departments. Since we stated in our September O. Pps commas packaging has not worked well for the agency for the patients or for the hospital outpatient departments. In addition to significant flaws in the fema methodology.

150

00:38:44.600 --> 00:39:14.580

Marcia Nusgart: There have been issues with patient access to care as well as limiting clinicians choice of products. For several years the Cms advisory panel on hospital outpatient payment, have agreed with our two recommendations to create some of the to to correct some of the flaws in the system. Yet Cms has not adopted these important recommendations, often citing incorrect information as the rationale for the rejection of these recommendations. Finally, Alliance members have created models to learn if packaging could be

151

00:39:14.590 --> 00:39:33.189

Marcia Nusgart: that way accomplished in the physician's office without impacting patient access. Their conclusions were that passion, packaging does not work in the physician's office until cms can show their modeling and impact analysis. We're very concerned about packaging in the Physician Office and the impact they'll make on patient access.

152

00:39:33.200 --> 00:39:44.029

Marcia Nusgart: So regarding the terminology question, We also do not agree with nomenclature in the proposed rule. Mooncare management products. It's way too broad a term, and incorporates more than just the product

153

00:39:44.040 --> 00:40:13.860

Marcia Nusgart: category of skin substitutes. Given that the terminology does not fix the pay the payment issue, the alliance will only say that we continue to support the term cellular and or tissue-based products for skin wounds or ctps, as a terminology that the alliance should adopt. If there is a name, change at all, we'll provide additional comments about this at a later time. So there's three recommendations that we would like the agency to look to Number One as we stayed in our September. O. Pps

154

00:40:13.870 --> 00:40:43.550

Marcia Nusgart: Commons of the Agency. Given that not much information is known about Cms's Intent Goals, or criteria for packaging skin substitutes in the physician office the Alliance recommends that the agency not issue a proposed rule in this rule, making cycle, but rather put forward a framework document similar to what the agency did recently for the five hundred and five to be drugs. This framework documents should offer stakeholders an explanation, criteria, standards, et cetera, which will be helpful, will allow for State

155

00:40:43.560 --> 00:40:46.720

to have a more meaningful dialogue with the agency

156

00:40:46.820 --> 00:41:10.529

Marcia Nusgart: number two. While the Alliance appreciates that Samus is holding this Town Hall meeting, we believe the agency is not allowing enough time for meaningful comments to be provided. Therefore, after Cms. Publishes this frameworks document, the agency should hold another Town Hall meeting this time for a full day, in which we can actually have a dialogue with the agency related to the framework

157

00:41:10.540 --> 00:41:40.000

Marcia Nusgart: Number three, since the agency is in the process of revamping or revising the Medicare position of be scheduled. We do not think that now is the time to be making significant payment changes, since the new Medicare Fee Schedule comment has not yet been released. In the interim the Alliance supports and strongly believes that Cms. Should continue this long steaming policy, recognizing, providing separate payments for those products under the asp methodology described in the Substitute Security Act, we recommend having all skin substitute companies

158

00:41:40.010 --> 00:42:09.370

Marcia Nusgart: to submit asp pricing to the agency. However, in order for the submission of Asp to work, the agency must provide enforcement reporting, and all the companies asp data must be published in the asp data file. In our recent comments the Alliance provide the agency with data that showed when asps were utilized, Medicare saved money. The provided data also demonstrated that the payment per unit actually decreased by five percent for products listed on the asp file,

159

00:42:09.380 --> 00:42:36.309

Marcia Nusgart: while the payment per unit for for products not listed increased fifty, nine percent per unit. Similarly, as the Alliance is already provided to the agency from two thousand and nineteen to twenty twenty payments for skin substitute products list on the asp file increased by two. However, payments for products not listed on the asp file increase five hundred and ninety seven percent for two hundred and forty, three million dollars in two thousand and twenty.

160

00:42:36.320 --> 00:42:49.190

Marcia Nusgart: Finally, we appreciate that this past year Cms. Has invited the Alliance to educated staff on ctps this past year, and we welcome the opportunity to serve in this capacity in the future. Thank you so much for your time.

161

00:42:50.900 --> 00:42:57.689

Zehra Hussain: Thank you, Marcia, and apologies for mispronouncing your name earlier, and you were also remaining with two seconds that we are doing great on.

162

00:42:57.700 --> 00:43:04.020

Zehra Hussain: We tried, we tried. It was like all I worked it. Thank you. Thank you. Everyone

163

00:43:04.560 --> 00:43:14.029

Zehra Hussain: all right. The next presenter is from the coalition of room care manufacturers. When you are ready, please unmute, and if you want, you can share your screen as well.

164

00:43:14.040 --> 00:43:43.799

Karen Ravitz: Great? Thank you so much, and good afternoon. I hope you can hear me. My name is Karen rabbits, and I am the healthcare policy adviser for the coalition of we care manufacturers. The coalition represents leading manufacturers of wound care products used by medicare beneficiaries for the treatment of wounds, including skin substitutes. Our members have a vested interest in ensuring that whatever policy objective Cms has, and whatever policy it goes forward with are created in a sound manner, and do not negatively impact patient access to those

165

00:43:43.810 --> 00:44:01.010

Karen Ravitz: to these products which are known to reduce infection and amputation, and patients with both diabetic foot ulcers and Venous ulcers. Loss of limb, or even life, is not something to be taken lightly. Cms really does need to get this right. The implications are too significant not to

166

00:44:01.020 --> 00:44:30.909

Karen Ravitz: the coalition. Thanks the agency for holding this Town Hall meeting, but with all due respect the agency still has not put out substantive information on the proposal to package skin substitutes in the Physician office, yet has put forward these four questions, in which stakeholders are left to provide hypothetical remarks in less than ideal timeframes to address them. Any one of these questions warrants more than five minutes to provide substantive feedback, let alone four questions in which we are provided, a total of five minutes to address all without substantive and necessary

167

00:44:30.920 --> 00:44:53.649

Karen Ravitz: information provided by the agency. This doesn't really seem to be a constructive use of time. But the Alliance does believe that the agency needs to be more transparent, and provide more information to stakeholders before any rule making can take place. The coalition agrees with the previous speaker, and also recommends that Cms. Issue a framework document prior to any rule making,

168

00:44:53.660 --> 00:45:22.600

Karen Ravitz: and afterwards hold another longer Town Hall meeting. We also agree with the comments just moments ago stated, and the issues for Cms to consider that were presented by both Dr. Rudolph and Ms. Nuscard. In response to

the questions posed for the first question, Cms indicated that the reason for the proposal to package skin substitutes in the position office setting was its desire to have a consistent payment approach between the Physician office and the hospital outpatient setting.

169

00:45:22.610 --> 00:45:52.509

Karen Ravitz: However, these payment systems are different and packaging in the Physician office for this product sector, as we've already heard, will be very challenging. Furthermore, packaging of skin substitutes has not worked well in the hospital outpatient setting, and has been revised multiple times over the years. In fact, Cms has recognized. There are issues that have tried to address them over the years by making multiple revisions to their methodology, and in putting forth at least four proposals for alternative payment methodologies over the past five years,

170

00:45:52.520 --> 00:46:05.089

Karen Ravitz: in order to have a more effective system. So why would Cms try to emulate and be consistent with a system that Hasn't worked and is still evolving it? Doesn't make sense, and one that we're not in support of.

171

00:46:05.100 --> 00:46:22.470

Karen Ravitz: If Cms is interested in a consistent payment approach that will not impact patient access, but will provide cost savings to the Medicare Trust Fund. The coalition recommends the agency, use the asp plus six percent and publish all products and their pricing on the Medicare party pricing data file over the next two to three years

172

00:46:22.480 --> 00:46:29.090

Karen Ravitz: before any substantive changes are made. The framework is already in place, so implementation would be very easy

173

00:46:29.100 --> 00:46:34.089

Karen Ravitz: asp would allow for pricing consistency and achieve Cms's goal of reading,

174

00:46:34.100 --> 00:46:52.280

Karen Ravitz: reducing out of Pocket Co. Payments and Cms. Would not be paying based on list or invoice pricing, but rather on vetted sales. Price, inclusive of discounts, using asp can achieve cost, savings which other speakers have already addressed. The coalition believes that publishing any reported asp creates a level

175

00:46:52.290 --> 00:47:22.280

Karen Ravitz: field for manufacturers, prevents over billing, decreases medicare beneficiary financial responsibility ensures clinicians select products based on clinical efficacy and assures transparency in response to the second question by setting cost thresholds in the hospital. Outpatient setting, Cms. Drove artificial const inflation. This is not an appropriate criteria. But what is what supply code with Cms create here? What are the characteristics? More information is needed from the agency, as we do not believe that there are

176

00:47:22.290 --> 00:47:52.280

Karen Ravitz: is consistent, equitable criteria that is appropriate for a unified payment rate for these products; that the uses of these products vary and are chosen based on multiple factors, including, but not limited to the type and size of the wound, the intended use and the product type. Therefore there would be significant variability and resource costs within the practice expense, methodology, and Cms would need to have too many levels of reimbursement to accommodate this variation, and for packaging to work the coalition supports the turn, cellular and or tissue

177

00:47:52.290 --> 00:48:22.250

Karen Ravitz: to-based products for skin wounds or ctps, and believes this nomenclature along with the standard set by the aspn incorporates all products currently, or that will enter the marketplace. And finally, from a procedural perspective. I'm wondering if the agency is going to make public any comments that are submitted in writing that those that we're not able to speak today, and what the mechanism is for the general public to submit Comments as nothing has been published. I appreciate the opportunity to provide our feedback to the agency, and thank you.

178

00:48:22.260 --> 00:48:23.160

How much?

179

00:48:24.530 --> 00:48:26.650

Zehra Hussain: Thank you, Karen, for your remarks.

180

00:48:27.130 --> 00:48:31.309

Zehra Hussain: The next speaker is donna from integral Life sciences.

181

00:48:42.330 --> 00:49:02.679

Donna Cartwright: Good afternoon. My name is Donna Cartwright. I'm. A senior director of health Policy and reimbursement for Integral Life sciences, corporations in tiger life, sciences, manufacturers, many types of skin substitutes. Regarding question one. It is very difficult to answer this question, as H. O. Pps and asc payments or package Currently,

182

00:49:02.690 --> 00:49:18.850

Donna Cartwright: however, the Medicare physician's fee schedule is not historically prior to two thousand and fourteen skin substitutes were paid separately in all venues. That is, the only time that payment was consistent, fair, and appropriate across all venues of care.

183

00:49:18.860 --> 00:49:28.289

Donna Cartwright: With the event of packaging in H. O. Pps. We have learned over the years that this methodology has been inconsistent over time, and should not be considered

184

00:49:29.060 --> 00:49:39.460

Donna Cartwright: with regard to question two; and Tiger believes it's difficult to accurately assess cost of skin substitute products by using the practice, expense, methodology.

185

00:49:39.710 --> 00:49:56.369

Donna Cartwright: The uses of these products vary by size of blue, the intended uses, as well as the different product types, making it difficult to assess what a typical service would be which is a necessary element of the practice, expense, calculation.

186

00:49:56.380 --> 00:50:13.990

Donna Cartwright: We also believe that there may be unintended. Consequences of redistributing these costs over the various cpt codes as they are outside the budget. Neutral process, integral has and remains willing to offer thoughtful responses to the questions such as this. However,

187

00:50:14.000 --> 00:50:40.590

Donna Cartwright: we believe that it would be very helpful if Cms. Were to publish a document on the Cms website that outlines the agency vision on how skin substitute products could be brought within the peer-review methodology given the complexity of the direct and indirect cost the public would benefit greatly if Cms. Did so, and we would then be in a better position to offer meaningful thoughts on this important question.

188

00:50:40.910 --> 00:51:07.559

Donna Cartwright: While we understand the desire for consistent and appropriate payment across different settings. We think it is paramount that positions are able to use the products they believe appropriate for their patients, and that beneficiary access is not compromised with different statutory payment structures for different settings. Consistency across settings of care may be challenging, but ensuring patient access should not be.

189

00:51:08.640 --> 00:51:20.820

Donna Cartwright: As for question, four Cms. Should not ignore the Cpt. Guidance on this issue. Skin substitute applications are clearly situated in the surgery Section regarding skin Graphs

190

00:51:21.000 --> 00:51:36.769

Donna Cartwright: change of this terminology may create confusion from a coding perspective. If the terminology remains the same. But in lieu of that we would support the ah adoption of cellular and tissue-based products consistent with the asm standards.

191

00:51:36.780 --> 00:51:46.150

Donna Cartwright: Thank you for hosting this town hall and we hope to see more concrete information from Cms. As I mentioned, so that we can better contribute to this dialogue.

192

00:51:47.890 --> 00:51:48.970

Donna Cartwright: That's it.

193

00:51:49.570 --> 00:51:51.829

Zehra Hussain: Thank you, Dona, for your remarks.

194

00:51:52.520 --> 00:51:58.560

Zehra Hussain: We will now move on to the next speaker, Mr. Abdul Jalil Mccowey.

195

00:52:05.130 --> 00:52:06.439

Kris Corwin: It's Shira

196

00:52:07.680 --> 00:52:09.580

Kris Corwin: Don't. See

197

00:52:11.580 --> 00:52:13.810

Kris Corwin: that attendee anywhere.

198

00:52:14.130 --> 00:52:16.969

Kris Corwin: Either on the attendee list or the panelists list

199

00:52:18.200 --> 00:52:18.790

are We

200

00:52:18.800 --> 00:52:25.989

Zehra Hussain: We will move on to the next speaker, and they are from the organization. Hc: A healthcare mountain Division.

201

00:52:28.310 --> 00:52:34.319

William Tettelbach: Yeah, just give me. I'm gonna share my screen real quick. Let me get online here

202

00:52:38.870 --> 00:52:41.060

William Tettelbach: all right, Can you? Can you see everything

203

00:52:41.500 --> 00:52:42.590

Kris Corwin: if we can?

204

00:52:42.600 --> 00:53:11.489

William Tettelbach: Fantastic, All right. So thank you again for giving us the time to speak today on these topics just a little bit on my background. My name is Uh Bill Tuttlebach. Uh been in room care for over twenty you know twenty-one years. I've had the ability to actually uh be the system director for in around healthcare, when we created the Mo in hypervisor service line I had twenty-two hospitals, and over ten out facing clinics. Uh that we ran with this. I am currently the executive medical director,

205

00:53:11.500 --> 00:53:25.379

William Tettelbach: overwhelming and hyperbaric service line with Hca and the mountain division, so that includes Alaska. I know in Utah to be transparent. I am the past medical officer, a chief medical officer at my medics. But

206

00:53:25.590 --> 00:53:41.209

William Tettelbach: my ah! My current role is ah with Hca and I'm. Also a Cac member with the Iridian and health developer wound. Ah Woundcare, Lcd: So this is one of the areas I

207

00:53:41.220 --> 00:53:53.200

William Tettelbach: really have our feelings towards, especially with my patient care. Now, the first question basically I wanted to reiterate everything that has been said already.

208

00:53:53.210 --> 00:54:21.860

William Tettelbach: Work in the H. You know Pd. Setting Uh, you know we've been working with a bundle rate, you know, you know, since two thousand and fourteen going onward. But in the physician's office the asp plus six percent has been established, but really has never been truly enforced, where all the products having in Asd, or being a uh

administrative model. So I really don't think we've ever really realized or had a chance to create or get the data

209

00:54:21.870 --> 00:54:51.670

William Tettelbach: to validate the cost impact on this when it actually is being ah having the oversight. Now I think really what we have here is something where the twenty first century Cures Act could help to guide us in the sense of making medical based decisions, where, if we are finally establishing an asp for all commercially available skin substitutes. Then we should be collecting data over the next two to three years. Analyze this, and then sort of compare the two models that have been put in place

210

00:54:51.710 --> 00:55:21.669

William Tettelbach: versus the package and asp, I think, is what what's been reiterated. We're going to see that Actually, there's uh, probably more cost savings that actually can be uh attained under asd model. That's actually in force. Now, we touched on large wounds. We know that ten percent of uh medicare patients have who's over greater than twenty-five square centimeters. This actually is an access issue in each in the O. HpD setting we can't treat these rooms under a bundle of payment. They're too big. We can't appropriately cover them according to the instructions or user parameters

211

00:55:21.680 --> 00:55:51.449

William Tettelbach: for use, and we actually collaborate with the physician's office to send these patients for appropriate treatment where we can't work with them. So this is going to basically compromise. I think a patient care system with a dual system that's in place, and maybe one or the other is better. But we need to collect data on that before we make this move again, I've had the opportunity to recently publish data on this. You mentioned this. There's other data, but we know that when you're using student substitutes in these lower extremes of patients or diabetic.

212

00:55:51.480 --> 00:56:14.899

William Tettelbach: You know your outcomes are better. You actually, when you're following the parameters for use or instruction for use, you can cut and minor and major amputations by fifty percent compared to those who don't get these products. We also know It's cost effective. We published on that. We know that those who get treated with the skin substitute within the first year can have at least three thousand, plus or three thousand six hundred hours

213

00:56:14.910 --> 00:56:40.090

William Tettelbach: direct cost, savings, and up to five thousand and five years. When modeling, we know we improve outpatient for our patients quality of life. We know that when you put this in a population level of a million patients. So that's about six thousand patients who are at risk for developing rooms. That's over twenty million dollars annually that can be saved by utilizing this appropriately, so restricting access to be a a major detriment.

214

00:56:40.100 --> 00:56:44.660

William Tettelbach: Now, again on question two, we're talking about valuation under, you know the the feast,

215

00:56:44.670 --> 00:57:07.790

William Tettelbach: and but you have this label that's a supply. This is not in. Substitutes are really not supplies. There are three hundred and sixty-one products mixed in here. They're clinically applied by clinicians. They integrate into the room, not really under a supply matrix. But again, when you talk about variability, the sp model inherently takes care of this. So why not actually give it time to work?

216

00:57:07.800 --> 00:57:13.859

William Tettelbach: Now, when it comes to terminology? We've been given skin substitutes In the seventys we get in

ctps, and this

217

00:57:13.870 --> 00:57:42.110

William Tettelbach: two thousand and sixteen You're proposing a new one. But actually there are tail wells that got together. They're going to ah publish a consensus paper. Ah! And to ah regenerative tissues they come up, I think, with a nice umbrella name, cellular aceler, and major likes products or camps. This actually entails synthetics and anything else that probably can umbrella, and in future market I think better than what's already there. So it's kind of like, you know. All right better. This may be best,

218

00:57:42.120 --> 00:58:03.530

William Tettelbach: but clearly better than what is out there. So again, I think we need to give the asp model a chance to collect the data and compare according to the twenty first century Cures Act. Again. The other questions I don't think, are necessary, and as impactful as determining how we're going to manage this payment process today in this meeting. Thank you.

219

00:58:04.910 --> 00:58:06.049

Thank you.

220

00:58:09.250 --> 00:58:10.899

William Tettelbach: Let me try it.

221

00:58:10.910 --> 00:58:15.029

William Tettelbach: Let me try to get my share here undone.

222

00:58:15.070 --> 00:58:22.479

Zehra Hussain: Thank you. And and while he's doing that, the next presenter is the Kara from George Washington University Hospital.

223

00:58:23.680 --> 00:58:32.859

Kara Couch: Good afternoon. Thank you very much. My name is Kara Couch, and I am the Director of Lone Care Services at the George Washington

224

00:58:35.270 --> 00:58:46.290

Kara Couch: Research Professor of Surgery at the School of Medicine and Health Studies at George Washington University. I've been practicing in lone care as a nurse practitioner for twenty years in the Dc. Veteran region.

225

00:58:46.300 --> 00:59:04.579

Kara Couch: I am answering questions one and four today, and then providing recommendations, starting with question four, I support the use of the term cellular and or tissue-based products, for skin wounds or ctps instead of skin substitutes, as it more accurately describes the products being used as such. I would use this term throughout my presentation.

226

00:59:04.590 --> 00:59:15.479

Kara Couch: With respect to question one, the agency asks, What should we consider as part of Cms efforts to ensure

consistent, fair, and appropriate payment for services and products across different service lines?

227

00:59:15.490 --> 00:59:44.060

Kara Couch: Since the new Hospital, Ops. Was enacted in two thousand and fourteen. It's become clear that it's still a greatly flawed payment system which has created issues and access to care and inequalities In the treatment of in the District of Columbia the vast majority of home care outpatient are treated in hospital, outpatient provider departments. This is Washington hospital center

228

00:59:44.070 --> 00:59:49.310

Kara Couch: ctps are a very important tool in our armamentarium. To close these wounds faster,

229

00:59:49.320 --> 01:00:19.279

Kara Couch: to reduce negative outcomes, such as osteomyelitis, overexposure to antibiotics and women amputations. On June twenty, seventh, two thousand and twenty two, I spoke at the alliance of one year stakeholders, educational and service on Ctps for students with Cms and I raised these points. The physician offices and Pvd's much purchased, must purchase the appropriate size. Ctp. Regardless of the in atomic locations which applied the physician fee schedule Hayes position offices to purchase the appropriate site

230

01:00:19.290 --> 01:00:33.610

Kara Couch: I, Ctp. By paying her square center and purchased, and to perform the application to the entire wound surface area by paying for the add on procedures when required. This payment must be maintained in order for positions to continue to purchase and use these,

231

01:00:33.620 --> 01:01:01.350

Kara Couch: the outpatient uh the Okps does not pay provider-based departments to purchase the appropriate I ctp, because the full cost is not incorporated in the base application phones it also did not add it to pay for the application of sixty piece to wounds or ulcers between twenty-five and ninety-nine square centimeters or brainer than one hundred square centimeters, because those add on codes are packaged, and it does not addictly pay for wounds or ulcers. Um! Of a hundred square centimeters, one smaller in the common location.

232

01:01:01.360 --> 01:01:13.140

Kara Couch: So in the hospital allocation department it's cost prohibitive to pay for ctps and wounds between twenty, five and ninety nine per centimeters for greater than one hundred centimeters on smaller an atomic location,

233

01:01:13.150 --> 01:01:21.430

Kara Couch: because larger the moon by surface area, and the longer the wound has been present is a key factor for having an extended period of healing

234

01:01:21.440 --> 01:01:37.870

Kara Couch: in these patients will require multiple applications for ctps to close the room in a sustained, progressive manner. However, I have dozens of patients in my practice. Now, with wounds that fall into this category, and I cannot effectively treat them in my clinic due to untenable class constraints.

235

01:01:37.880 --> 01:01:52.510

Kara Couch: Further, we are paid differently, based on where the room is located on the body, which does not make

sense. A large abdominal woman can be as challenging to heal as a scalp or a diabetic wound. But this coverage distinction, these patients do not perceive an equitable distribution of care.

236

01:01:52.520 --> 01:02:13.089

Kara Couch: How does an Hpd Provider overcome company's financial limitations. These patients must undergo their Ctp application in the operating room which exposes the patients to unnecessary anesthesia post record of complications and can negatively impact their quality of life by having to spend a day in the hospital rather than attending a simple clinic appointment for the same procedure.

237

01:02:13.100 --> 01:02:26.360

Kara Couch: This only adds to the cost of the system, and places additional burden on the Medicare Trust. This does not occur in patients who are receiving care and physicians offices which currently maintain an effortable payment for Buddhist purchase and U. Ctps on their patients.

238

01:02:26.660 --> 01:02:37.710

Kara Couch: Patients need to be able to receive the appropriate product to treat their rooms. The clinicians should be able to have the choice of product they need to invest, to use their patients or choose the best products on their primary.

239

01:02:37.720 --> 01:02:56.789

Kara Couch: These are my recommendations we heard earlier from other speakers. Cms. Is to provide more detail or info on what you're doing in order to provide more meaningful comments. I agree with the issuance of a framework document to understand what the Agency's intentions are, as well as the criteria and otherported information, so we can get the most effective comment on the detailed framework.

240

01:02:56.800 --> 01:02:59.889

Kara Couch: Everything we know. That's far as merely hypothetical.

241

01:02:59.900 --> 01:03:07.289

Kara Couch: If Cms. Is really interested in a consistent approach and saving the trust fund you can re-establish consistent policy by referring

242

01:03:07.300 --> 01:03:28.289

Kara Couch: converting to separate payment for student substitutes, as you did, prior to packaging them in two thousand and fourteen, and preserve or utilize as pricing. I suggest that Cms use asp, pricing and publish all products in a part B pricing data file for two years while you're renaming. This accurately submitted, the asp lends itself to a level playing. Thank you for your time.

243

01:03:32.060 --> 01:03:33.209

Thank you.

244

01:03:39.370 --> 01:03:54.070

Tim Hunter: Good afternoon. My name is Tim Hunter, and I serve as the Vice President for reimbursement and governor of affairs for bio tissue. We want to thank Cms for hosting this forum and for soliciting feedback from stakeholders, so they can better inform your policy decisions.

245

01:03:54.620 --> 01:04:20.390

Tim Hunter: Our current products that are used in the treatment of diabetic. But ulcers and related ulcers are marketed as human tissue derived products under section three hundred and sixty, one. Ah! But additionally, we are also pursuing a biological license application for the treatment of diabetic buttons that extend to bone, ligament, or tendon. Ah! Including Dfus with osteomyelitis, and have two base, three clinical studies completing enrollment right now

246

01:04:20.400 --> 01:04:26.819

Tim Hunter: for the purposes of this presentation. I'm. Going to focus primarily on question four, and question one.

247

01:04:27.580 --> 01:04:36.730

Tim Hunter: With respect to the terminology, we think that the name of the classified group is less important than the composition and the definition of the products that make up that group.

248

01:04:36.840 --> 01:04:55.579

Tim Hunter: Ah! Currently available products or wound coverings, regardless of whether the products regulated as a human tissue or an animal-direct product, a synthetic device, or some other type of device cleared as a five thousand K or Pm. A product. And so we think that any terminology and its related definition should be limited

249

01:04:55.590 --> 01:05:00.350

to these types of products, these human and animal-driven tissues and medical devices,

250

01:05:00.440 --> 01:05:12.199

Tim Hunter: the terminology and its definition should exclude the term biologicals, which has been used in the past to avoid confusion with next-generation products that will be approved through the bla process,

251

01:05:12.210 --> 01:05:40.210

Tim Hunter: and I think that see mystic, a really good first step in the twenty twenty three position be scheduled, proposed rule when they noted the difference between their current class of products that they call skin substitutes, and and those products that are approved by the Fda through the Andnda or Vla processes. Ah! And so, as as soon as travels with ah! This issue moving forward. Ah! We believe that any terminology change, and the the related definition should also discontinue the use of the term biological,

252

01:05:40.280 --> 01:05:45.799

Tim Hunter: and continue to explicitly exclude drugs and biologics from that definition.

253

01:05:46.540 --> 01:05:53.229

Tim Hunter: I think this fills over also to the payment methodology any future action that Cms has.

254

01:05:53.310 --> 01:06:08.420

Tim Hunter: If you have decides to take for the skin, substitute class, or whatever terminology you you determine to use moving forward. It also should be limited to those products that are currently available, those human and animal, direct issues and medical devices,

255

01:06:08.430 --> 01:06:15.089

Tim Hunter: and again continue to exclude Vla and nda products,

256

01:06:15.240 --> 01:06:28.829

Tim Hunter: and I again in the proposed rule. Cms: I I think, did a good job of of ah stating that that it with any proposal to bundle skin substitutes, or ah assume a different payment. Methodology

257

01:06:29.020 --> 01:06:44.449

Tim Hunter: would exclude these these Bla and the Nba products, and we would want to similarly make sure that any future action that is related to payment. Methodology continues to honor this difference between wound coverings and and biologics and drugs.

258

01:06:44.530 --> 01:06:53.189

Tim Hunter: And finally, as you think about this across settings of care. We want to make sure that that those distinctions are maintained,

259

01:06:53.200 --> 01:07:09.600

Tim Hunter: and we thank Cms very much for the opportunity to ah to comment, and we welcome the opportunity to work with you in the future as to try to think not only of the current class of products that are available to treat. Ah, you know these patients, but also the future brothers. So thank you.

260

01:07:12.110 --> 01:07:13.240

Thank you.

261

01:07:14.520 --> 01:07:17.309

Zehra Hussain: The next presenter is colleen

262

01:07:21.310 --> 01:07:23.840

Colleen DeSantis: great. Thank you.

263

01:07:24.460 --> 01:07:26.650

Colleen DeSantis: Let me know when you can see my screen

264

01:07:27.110 --> 01:07:28.450

we can see it

265

01:07:32.060 --> 01:07:40.320

Colleen DeSantis: all right. Hello! My name is Kelly de Fantis. I'm the Vice president of reimbursement and health policy for my medics. Thank you for the opportunity to present today.

266

01:07:40.330 --> 01:07:56.480

Colleen DeSantis: I'm going to be addressing the first question. Chronic non-healing wounds are complex and extremely difficult to heal positions, pain, flexibility, and treatment, protocols and products as individual patients will respond.

Different different treatments, based on their comorbidities doing size and location.

267

01:07:56.490 --> 01:08:07.450

Colleen DeSantis: Larger wounds in particular, are most risk of infection and amputation, and a payment methodology that does not appropriately reimburse for these patients can be detrimental to medicare beneficiaries

268

01:08:07.510 --> 01:08:24.030

Colleen DeSantis: packaging skin substitutes in a provider office will no doubt drive larger wounds to costly inpatient states. We're not being treated at all. We saw this in ambulatory surgical centers, whereby the package reimbursement was half of Ah, of the hospital outpatient, and consequently patients were not seen in a setting

269

01:08:24.040 --> 01:08:31.760

Colleen DeSantis: appropriate payment and cost can be controlled by an asp. Methodology, while preserving patient access in a physician office for student substitute treatment.

270

01:08:32.279 --> 01:08:50.130

Colleen DeSantis: Access to this important treatment is especially concerning for patients in a large room. To illustrate this, we analyze the two thousand and twenty one Medicare party claims for symptoms to procedure codes. Eleven percent of the two thousand and twenty one. Medicare claims submitted by physician offices were coded with procedures over twenty five centimeters.

271

01:08:50.140 --> 01:08:56.719

This patient population would not be adequately reimbursed with a bundled rate in the hospital patient setting or physician office.

272

01:08:56.729 --> 01:09:15.119

Colleen DeSantis: However, we further analyze the claim to determine that an additional subset of rooms, thirteen to twenty five centimeters, are also at risk, as they may not be viable in physician office setting with the package payment methodology. Many patients have multiple loops that are built with the total number of units per anatomical location,

273

01:09:16.290 --> 01:09:36.589

Colleen DeSantis: as you are aware, in twenty twenty one. The compality appropriation is acts intended to require all manufacturers to report asc as of twenty twenty, two to provide a full disclosure of product pricing, and also to establish a mechanism to generate significant savings for Medicare programs to the establishment of asp-based payment rates that more closely aligned with actual market cost of products

274

01:09:37.240 --> 01:09:53.300

Colleen DeSantis: to further demonstrate we reviewed as t-listed products in Nania c. Products for symptoms in Medicare claimed data, we found we are a significant cost increases for products not received on the asp file as represented in the graph to the right.

275

01:09:53.310 --> 01:10:03.219

Colleen DeSantis: Medicare claims Data reveals then, for since those substitutes that were listed on the national file actually decreased from twenty to two thousand and twenty to two thousand and twenty one.

276

01:10:03.980 --> 01:10:21.639

Colleen DeSantis: Similarly, Medicare per unit cost for non asc listed products. Escalated data confirms that a per unit cost for products not on the national file has drastically escalated year after year. This underscores the importance of publishing refer to Esp. Based payment rates for some skin substitute products.

277

01:10:22.240 --> 01:10:39.639

Colleen DeSantis: The spirit asp reporting and reimbursement practices under Part B have not gone unnoticed. Menpac previously documented nearly an identical pricing behaviors with respect to holy arnic acid products covered under part B. And recommended Congress In their June two thousand and nineteen report,

278

01:10:42.030 --> 01:11:00.619

Colleen DeSantis: Kalia got a product decrease in Medicare costs after a required asp reporting and listing on the national file. In Q. Two of twenty, twenty, two seven products were added to the national file with a substantial decrease in reimbursement rate from wholesale acquisition cost payment methodology to asp plus six percent within one quarter.

279

01:11:00.710 --> 01:11:12.449

Colleen DeSantis: Only recently has Cms. Added forty, one students to the asp file effect of January first, two thousand and twenty three. In addition, the Oig published two reports on Education and Oversight of Ac, reporting,

280

01:11:12.840 --> 01:11:23.909

Colleen DeSantis: as demonstrated by the Aj. Products when added to the asp, file Medicare payment rates, the same substitute products significantly decrease from Q. Four to two thousand and twenty two to this quarter, when added to the file

281

01:11:24.520 --> 01:11:43.430

Colleen DeSantis: in a summary. We strongly encourage Cms to give the ac pricing methodology time to remedy abuses in the same substitute industry and demonstrate cost savings in this category. The underlying cost control issue today relates to product pricing versus service. Pricing. An asp method can address the desire to put cost control,

282

01:11:49.890 --> 01:12:05.560

Colleen DeSantis: can't see reimbursement could potentially save the Medicare Trust Fund twenty to fifty percent annually for skin substitute product stream bursts in the position office, setting asp reimbursement would allow position, flexibility to treat large complex car to deal wounds in an office setting with many product options.

283

01:12:05.600 --> 01:12:16.289

Colleen DeSantis: Implementation of package Methodology is counter to the important Cms efforts to advance health, equity, and does not serve Medicare beneficiaries, including minority as intended.

284

01:12:16.410 --> 01:12:17.500

Colleen DeSantis: Thank you,

285

01:12:21.980 --> 01:12:23.570

thank you, Colleen.

286

01:12:24.300 --> 01:12:28.009

Zehra Hussain: The next speaker is from Stanford. Help,

287

01:12:29.660 --> 01:12:44.799

Emily Greenstein: Hi! Thank you. My name is Emily Greenstein, and I'm. A certified wounded Oscar Nurse, practitioner at Stanford. Health in Fargo, North Dakota Sanford Health is a Health Care Enterprise spanning North Dakota, South Dakota, Minnesota, and Montana.

288

01:12:44.810 --> 01:12:55.340

Emily Greenstein: The hospital in Fargo is a nine hundred bed level, one trauma center. I currently run the outpatient We care center there, and on average we see around four hundred visits per month.

289

01:12:55.520 --> 01:13:07.599

Emily Greenstein: We all know that the rate of diabetes in the Us. And worldwide is on the rise. The number of Americans with diagnosed diabetes is projected to increase one hundred and sixty, five percent

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01:13:07.610 --> 01:13:16.300

Emily Greenstein: from eleven million in two thousand, with a prevalence of four percent to twenty, nine million in two thousand and fifty, with a prevalence of seven point, two percent,

291

01:13:16.310 --> 01:13:45.259

Emily Greenstein: as we know. With this increase will come an increase in the prevalence of wounds based on many studies that have been conducted. We know that skin substitutes have been shown to decrease amputation, rates, decrease infection rates and improve healing time in diabetic patients. As such, any movement to bundle the use of these products can have a direct impact on the access for these patients, and therefore can possibly increase amputation. Rates increase infection rates,

292

01:13:45.270 --> 01:13:58.189

Emily Greenstein: and possibly lead to the loss of life. Cms needs to get this right for my patients and all patients with chronic wounds. There are a couple of topics that I would like to address today related to the issues that have been presented.

293

01:13:58.200 --> 01:14:08.889

Emily Greenstein: First, clinicians need to be able to use their clinical judgment when selecting products to treat patients with wounds. Not all patients will respond the same to each treatment.

294

01:14:08.900 --> 01:14:23.670

Emily Greenstein: Multiple products and multiple sizes are needed to choose from. These products are not simple dressings. They are not gauze. They are advanced therapeutic agents to help put this into context. If I am treating the patient with high blood pressure,

295

01:14:23.680 --> 01:14:42.860

Emily Greenstein: I will look at a rope of drugs that has been improved and designed to lower their blood pressure. I will then select the correct medication based on the patient's physical exam, their metabolic history, their lifestyle, and

my past clinical experience selecting a can substitute. My patient is no different than selecting a medication for them

296

01:14:42.870 --> 01:15:01.790

Emily Greenstein: as a clinician. I need to use my clinical judgment to choose the best product for my patient. The individuality of my patient lends itself and necessitates the individuality of the choice of product, whether a skin substitute or a prescription. Drug packaging will not afford me the opportunity to make these choices.

297

01:15:01.800 --> 01:15:31.569

Emily Greenstein: The next concern I would like to address is packaging up these products in two thousand and fourteen. The bundling payments for zoom substitute started in the Ocd department. I have seen firsthand the impact that packaging can have with all the add on politicians with larger ones have been limited access to these products. The grouping by price does not lend itself to effective bundling by costs and creating categories Doesn't lend itself to an effective payment system or care of patients when they show up in, not be

298

01:15:31.580 --> 01:15:32.670

a Pd.

299

01:15:32.680 --> 01:16:00.349

Emily Greenstein: Furthermore, once the property went into effect, why a range of products costs decreased significantly. Products that placed into low-cost buckets were not being utilized as much because facilities such as mine were losing money when utilizing them. Furthermore, Cms needed artificial inflation or movement for all products to go into a high cost bucket because of these things atop's no longer have a wide range of products to choose from a cost perspective.

300

01:16:00.360 --> 01:16:29.680

Emily Greenstein: My facility, like many and others, work on a formula, and each product that is brought in goes through a value and analysis committee. This committee weighs the clinical effectiveness costs amount of projected use and reimbursement for each product. Not all products that come in the same size. An example of this facility might go with Product A. Because it has ten sizes, but isn't the cheapest harvest, choosing for less waste. This concept will also need to be taken into consideration when Cms. Is trying to make a practice deal for the Pfs.

301

01:16:29.690 --> 01:16:37.149

Emily Greenstein: My concern is that Cms. Has not put out much information on their proposal to package skin substitutes in the Physician office setting.

302

01:16:37.160 --> 01:17:04.770

Emily Greenstein: Like others who have already commented, I agree that a framework document is needed before any proposed rule can be issued. A framework will help clinicians to a better. Understand the agency's thinking before the further future role making takes place. I can only remark on what I have seen, which has been very little by the agency, even though my setting is at age of me. There are position-based offices that exist in my system. This includes podiatry and dermatology, all who utilized in substitutes on a daily basis to effectively treat their patients

303

01:17:04.780 --> 01:17:16.400

Emily Greenstein: i'm afraid that Cms. Begins to pack a skin substitute in a position office setting. Patients will no longer be able to receive the appropriate products, treat their wounds before the navy could easily impact their care, and ultimately outcomes

304

01:17:16.410 --> 01:17:36.370

Emily Greenstein: to summarize, based on what we have seen. After the changes were made in Hiv setting, packaging in the Physician office setting could have severe impacts on access to skin substitutes which will impact patient care, loss of limbs, and possibly loss of life. Because of this as a clinician, I do not support the packaging of been substitutes in the Physician office setting. Thank you,

305

01:17:39.400 --> 01:17:40.929

Zehra Hussain: thank you, Emily.

306

01:17:41.440 --> 01:17:46.179

Zehra Hussain: We will now move on to the next speaker, Mr. Chris Broderick.

307

01:17:48.280 --> 01:17:50.559

Chris Broderick: Thank you. Can you all hear me?

308

01:17:50.930 --> 01:17:51.990

Yes,

309

01:17:52.810 --> 01:18:02.239

Chris Broderick: good afternoon, and thank you for the opportunity to speak on this call today. My name is Chris Broderick and I'm. A Ceo of Miraculous Therapeutics,

310

01:18:02.660 --> 01:18:16.180

Chris Broderick: a little background on Merit Chris. We are a biological drug development company that is running a multi-center phase, two clinical trial for phenostasis, ulcers and developing precision. One healing therapeutics.

311

01:18:16.240 --> 01:18:20.909

Chris Broderick: We also commercially provide amniotic alligraph products to the market

312

01:18:21.000 --> 01:18:34.410

Chris Broderick: My discussion today is aimed at the first question, What Cms should consider as part of its effort to ensure consistent, fair, and appropriate payment for services and products across different settings of care.

313

01:18:34.610 --> 01:18:45.309

Chris Broderick: I would first like to share our opinion of the proposed bundling of skin substitutes, and then provide a recommended methodology to be considered for adoption by Cms.

314

01:18:46.430 --> 01:18:56.940

Chris Broderick: Following numerous discussions with health care, providers, caregivers, and other stakeholders in the Wind care space. The current hospital outpatient department has caused patients with large

315

01:18:56.980 --> 01:19:02.199

Chris Broderick: complex wounds to have a limited access in the treatments they receive.

316

01:19:02.290 --> 01:19:10.530

Chris Broderick: Health care. Providers also have limited choices on what technologies they utilize, due to cost restrictions and financial limitations.

317

01:19:11.020 --> 01:19:24.459

Chris Broderick: The bundling in the hospital outpatient department approach is contrary to the twenty first Century Cures Act, which was signed into legislation, with the intention to increase choice and access for patients and providers.

318

01:19:24.610 --> 01:19:35.180

Chris Broderick: Therefore Cms. Should not proceed with a bundle payment methodology, as it previously proposed. As this would hinder patient access and provider choice.

319

01:19:35.470 --> 01:19:55.030

Chris Broderick: Inside of this we recommend that Cms preserve and follow Asp for at least twenty four months, and during that twenty four month period of continuing to follow asp. We believe Cms should design and propose a framework of bundling skin substitutes using a tiered-based approach,

320

01:19:55.040 --> 01:20:01.019

Chris Broderick: such that payment. Bundling would be based on the wound, size and complexity.

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01:20:01.030 --> 01:20:15.500

Chris Broderick: For example, complexity can be defined by host complications, such as comorbidities that interfere with wound healing and wound complications such as severity, ischemia, wound area, and or patient age.

322

01:20:15.780 --> 01:20:25.579

Chris Broderick: Such an approach would be somewhat comparable to the evolution of the Drg. System, which was introduced to correct the expenditure burden on Medicare.

323

01:20:26.670 --> 01:20:42.659

Chris Broderick: Thus the Cms engineered framework, somewhat like the Drg model that pays based on the severity of patient diagnosis, should be considered, and a bundled, tiered-based approach; for when care, products and services would be the best way to move forward

324

01:20:42.930 --> 01:20:45.080

Chris Broderick: in our organization's. Belief

325

01:20:45.200 --> 01:21:01.189

Chris Broderick: in such a model. Payments based on wound complexity would allow for more resources, such that more complex wounds with multiple comorbidities and a large area would be allowed access to more resources, and would result

326

01:21:01.720 --> 01:21:07.250

Chris Broderick: positive outcomes as compared to smaller, easier to heal chronic ones.

327

01:21:07.300 --> 01:21:23.780

Chris Broderick: Under this tiered bundling approach. We would propose also that Cms consider adopting this methodology for both a clinical setting as well as the outpatient setting, and we believe that increased choices and access for patients and providers would be optimal of this methodology.

328

01:21:24.590 --> 01:21:39.430

Chris Broderick: This approach is stopped by our organization to be to the benefit of patients, providers, and cms We additionally feel that this tiered-based bundling approach would improve the sustainability of the Medicare Part B Trust Fund,

329

01:21:40.330 --> 01:21:51.350

Chris Broderick: similar to the Alliance for wound-care stakeholders and the coalition for woundcare manufacturers we agree that a framework document to be developed and presented to

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01:21:51.360 --> 01:22:03.739

Chris Broderick: the community to provide um any meaningful comments they have, and an opportunity to hold another Town Hall to address such comments would be much appreciated.

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01:22:04.090 --> 01:22:05.540

Chris Broderick: Thank you for the time.

332

01:22:09.920 --> 01:22:11.090

Thank you.

333

01:22:12.100 --> 01:22:16.819

Zehra Hussain: The next speaker is from the organization. Admin.

334

01:22:20.070 --> 01:22:29.620

Tara Burke: Good afternoon. My name is Tara Burke, vice President of Payment and Healthcare delivery policy at the Advanced Medical Technology Association for Avenue

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01:22:29.700 --> 01:22:36.620

Tara Burke: Abdomen is the National Trade Association. We're representing manufacturers of medical devices and diagnostic products.

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01:22:36.640 --> 01:22:42.650

Tara Burke: We appreciate the opportunity to present today, and we'll be providing responses to each of the four questions.

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01:22:43.200 --> 01:22:52.960

Tara Burke: Cms. First asks what should be considered to ensure a consistent, fair, and appropriate payment for services and products across different settings of care.

338

01:22:52.970 --> 01:23:04.430

Tara Burke: Cms. Had a consistent policy for skin substitutes across the Pfs and Ops prior to two thousand and fourteen, when all these products were paid separately, using the same methodology as biological

339

01:23:04.630 --> 01:23:15.020

Tara Burke: beginning in two thousand and fourteen cms. Institutional policy of packaging skin substitutes under the Okps, while continuing continuing a separate payment under the Pms

340

01:23:16.060 --> 01:23:23.679

Tara Burke: Cms. Should re-establish that consistent policy by reverting to separate payment for skin substitutes, as it did prior to two thousand and fourteen.

341

01:23:23.690 --> 01:23:38.200

Tara Burke: Such consistency would actually be improved today relative to two thousand and fourteen, as a Social Security Act now requires asp reporting effect of January first, of two thousand and twenty, two for products that are payable under the part as a drug are biological.

342

01:23:38.980 --> 01:23:47.770

Tara Burke: Regarding Cms. The second question, it would be incredibly difficult to accurately assess the cost of skin substitute products by using pe methodology.

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01:23:47.970 --> 01:23:57.589

Tara Burke: The uses of these products vary immensely, and change based on the size of the wound, the intended use and the product type making it difficult to attest a typical service.

344

01:23:57.860 --> 01:24:05.680

Tara Burke: There are simply an insufficient number of cpt codes available to recognize the variability and resource costs within the pe methodology.

345

01:24:05.690 --> 01:24:16.559

Tara Burke: Moreover, the incorporation of skin substitute products across the Pfs could result in an unpredictable redistribution of funds to or from other unrelated Pfs services.

346

01:24:16.700 --> 01:24:23.420

Tara Burke: Such dramatic changes in reimbursement will have a major impact on the ability of physicians to deliver these important services.

347

01:24:23.430 --> 01:24:29.099

Tara Burke: For these reasons, alammed, recommends that Cms not bundled skin, substitute products under the Cfs.

348

01:24:29.740 --> 01:24:46.600

Tara Burke: If Cms. Does move forward, Adam, and recommend Cms delay bundling these products under the Pfs until Cms. Can propose a framework for P. E. Rbus for the relevant codes inclusive of skin substitutes, explain how it would develop those Ah Rvs in a step by step, fashion,

349

01:24:46.610 --> 01:24:51.710

Tara Burke: making supporting information available to the public, and allow time for meaningful comment.

350

01:24:52.030 --> 01:25:06.869

Tara Burke: The situation with skin substitute codes could be viewed similarly to the drug administration. Codes, drug and masturbation codes recognize the resource costs associated with administering drug or biologic, but the drug or biologic itself has paid separately.

351

01:25:06.970 --> 01:25:16.699

Tara Burke: There would be no way to bundle the drug or biologic into the drug administration codes, because a different product product among hundreds, could be used for each administration.

352

01:25:16.860 --> 01:25:33.680

Tara Burke: Similarly, there are well over one hundred different skin substitute products to use with two groups of adults in substitute application codes. The skin substitute application is describing the service of the position, which is an analogous to the the drug administration,

353

01:25:33.690 --> 01:25:39.409

Tara Burke: while the skin substitute itself would be paid separately. Again, analogous to the drug or biologic

354

01:25:39.420 --> 01:25:48.790

Tara Burke: packaging or bundling skin substitutes in the application. Codes makes no more sense than doing the same for drugs or biologics with the drug administration codes.

355

01:25:49.180 --> 01:26:01.950

Tara Burke: Lastly, Cms. Asks for alternatives to consider regarding any potential changes to terminology as a foundational issue. Abomin does not believe that the term skin substitutes is problematic or confusing.

356

01:26:01.960 --> 01:26:12.300

Tara Burke: Indeed, what seems most confusing is, it's a part from a phrase skin substitute that has been used for years, and remains pertinent and pertinent. So Cbt codes

357

01:26:12.850 --> 01:26:19.419

Tara Burke: aamet opposes the proposal to replace the term skin substitutes with home care, management, or wool-care management products.

358

01:26:19.750 --> 01:26:36.109

Tara Burke: If Cms does replace the term out of bed, recommends the term cellular and or tissue-based products for ctps

this term will better achieve Cms's goal of more accurately describing the entire suite of products, but without the possible misinterpretation as other medical products or services,

359

01:26:36.730 --> 01:26:40.990

Tara Burke: this term would not only better align with the Fda categorization and review

360

01:26:41.000 --> 01:26:46.519

Tara Burke: process for these products. It would align with the astm international definition of a Ctp.

361

01:26:46.870 --> 01:26:49.389

Tara Burke: Thank you for the opportunity to speak today.

362

01:26:54.090 --> 01:26:55.699

Zehra Hussain: Thank you. Admin.

363

01:26:55.870 --> 01:26:58.880

Zehra Hussain: The next presenter is Stewart.

364

01:27:02.150 --> 01:27:16.870

Stuart Langbein: Hello. My name is Stuart Langman and I'm. Speaking on behalf of my client contact triad Life Sciences. I will address some questions at Cms pose, but i'll first speak to some broader policy points in this in substitute space.

365

01:27:16.880 --> 01:27:43.249

Stuart Langbein: Overarchingly we urge Cms. To act to ensure that its current and future policies in gender a level playing field across can substitute products for the past twelve months from both a coding and payment standpoint. Cms. Has and continues to treat some skin, substitute products that function similarly, and have similar indications in a different manner from others which has created a commercially commercial environment that's badly unfair.

366

01:27:43.260 --> 01:28:03.259

Stuart Langbein: There is a set of products for which Cms. Has been assigned a codes, and is paying for these products differently than other very similar products. In addition, some sheets can substitute products like https, or they are able to proceed through the quarterly epics code application process where others, like xenographs, are

367

01:28:03.270 --> 01:28:13.640

Stuart Langbein: forced to go through the longer process for non-drawn non-biological products despite the fact that xenographs undergrow greater regulatory scrutiny by the Fda.

368

01:28:13.710 --> 01:28:32.530

Stuart Langbein: All skin substitute products, regardless of how they regulated, should proceed through the quarterly ethics process. These are examples of how Cms is currently treating similar skin substitute products differently, and these inconsistencies should end immediately because they're stifling healthy commercial competition.

369

01:28:32.710 --> 01:29:02.169

Stuart Langbein: We appreciate that Cms wants to have consistent and fair payments for the first question. It pose, consistency, and fairness could be promoted if Cms. Were to end the artificial distinctions that it has created among skin substitute products from a payment perspective. Cms has indicated that products with a codes or supplies and supplies are priced by maps. Yet some of these products are regulated by the Fda in the same way as products with Q. Codes, and that are including the Asd

370

01:29:02.180 --> 01:29:15.779

Stuart Langbein: payment limit file. There's no justification for paying for these products under a different methodology. This would be a good place, for Cms. To further its efforts to ensure consistent and fair payment across products.

371

01:29:15.940 --> 01:29:35.030

Stuart Langbein: See us, asks in the second question, How it can ensure that valuation under the Pfs. Adequately accounts for variability and relative resource cost. As others have said, this question is very difficult to address. When Cms. Has provided so little detail about how it works in substitute products into the fees get?

372

01:29:35.040 --> 01:29:47.660

Stuart Langbein: Is it a thought to include skin substitute products as practice expenses into current Cbt codes. What does Cmf believe it could use to gauge the resources? The position expands for skin substitute products

373

01:29:47.720 --> 01:30:01.130

Stuart Langbein: given the cost of skin substitute products and the interrelationship between direct practice expenses and indirect practice expenses. What would the impact of significant added direct expenses have on the indirect

374

01:30:01.140 --> 01:30:08.490

Stuart Langbein: Also, what are Cms's plans for other major Pfs reforms that Cms. And its contractors have been working on.

375

01:30:08.500 --> 01:30:19.279

Stuart Langbein: Given the interconnectedness in this payment system. If other changes are made. What the public may say now could be impractical or infeasible. After Pfs reforms

376

01:30:19.290 --> 01:30:29.309

Stuart Langbein: the public could contribute much more to this discussion. If Cms were to provide some details on how it believes it could coal-skinned substitute products into the pfs,

377

01:30:29.320 --> 01:30:39.339

Stuart Langbein: We urge Cms to flesh out some details, to then take comments from the public ahead of the release of any proposed rule that would alter payments for skin substitute products.

378

01:30:39.570 --> 01:30:55.240

Stuart Langbein: With regard to terminology. Convent tech is amenable to a change in terminology, but recommends that c. Must not use wound, care, management, or wound care management products, because these phrases are likely to generate a great deal of confusion among providers and other payers.

379

01:30:55.250 --> 01:31:00.330

Stuart Langbein: A particular concern is the misalignment of terminology used between the graphs,

380

01:31:00.340 --> 01:31:20.670

Stuart Langbein: procedure, Cpt. Codes, one, five two hundred and seventy, one to one, five, two, seven, eight, and the idea of woundcare management, Many of the products with A and Q codes are required to be built alongside a skin graph procedure code in this series, and the code language for all of these codes refers to application of a skin substitute.

381

01:31:20.680 --> 01:31:28.770

Stuart Langbein: Providers may be confused. If Cms. Uses wound care, management product with the pertinent cpt codes used skin substitutes,

382

01:31:28.840 --> 01:31:52.620

Stuart Langbein: we look forward to Ah, to Cms, sharing more information about what it believes is feasible for skin substitute products under the Pfs, after which we certainly could share more concrete ideas, however, in keeping with Cms's objective to promote consistency and fairness. We encourage Cms to take more immediate action by one, allowing all skin substitutes

383

01:31:52.630 --> 01:32:09.030

Stuart Langbein: to proceed through the quarterly hex process and two paying for all skin substitutes under the same methodology. Now, while the agency considers potentially broader changes to payments for skin substitutes in the future, Thank you very much for the opportunity to speak.

384

01:32:12.020 --> 01:32:13.960

Zehra Hussain: Thank you for your remarks.

385

01:32:14.770 --> 01:32:21.029

Zehra Hussain: The next speaker is from applied policy. Who will be presenting on behalf of Stensis.

386

01:32:22.090 --> 01:32:44.119

William Rogers: Hi! Thanks for the chance to speak briefly today. This afternoon my comments are going to be in response to the first question concerning consistent, fair and appropriate payment. Um, I'm. Dr. Way, Rogers, chief medical officer for applied policy, which is a health care consultancy located in Alexandria, Virginia, and we are representing our client stems

387

01:32:44.130 --> 01:32:52.690

William Rogers: which manufactures, a product called excel stem moon powder, which is an Fda. Five hundred and onek approved extracellular matrix

388

01:32:52.700 --> 01:33:00.019

William Rogers: skin substitute, composed of cosine collagen and multiple ecm components which is indicated for the management of moves.

389

01:33:00.830 --> 01:33:18.290

William Rogers: The term-skinned substitute has been used by cms and other payers to define a group of products used to cover non-healing wounds in order to stimulate and support the healing process, while most skin substitutes are manufactured in a sheet form. There are fda approved skin substitutes that are manufactured in a power.

390

01:33:18.520 --> 01:33:38.320

William Rogers: The sheet form is well suited to wounds with a smooth service, but wounds with an irregular surface are most efficiently treated with a particular or powered forms can substitute, since the sheets tend to tent up on the high points of the Moon Service, preventing them from adhering and contacting the low points on the Moon service.

391

01:33:38.650 --> 01:33:48.229

William Rogers: The skin substitute graph codes, fifteen, two hundred and seventy, one to one thousand two hundred and seventy eight may only be used to describe the application of sheet-skinned substitute products

392

01:33:48.250 --> 01:33:59.679

William Rogers: payment for the skin substitute is made under the hospital operation, perspective payment system, or under the medicare physician fee schedule, as we've discussed when they're used in a non-facility setting

393

01:33:59.740 --> 01:34:15.849

William Rogers: when a clinician elects to use a powder form in the substitute, for instance, because the moon has an irregular surface. The codes, one thousand two hundred and seventy, one to one thousand, two hundred and seventy eight may not be used, and as a result there's no way for the position or facility to recover the cost of the product.

394

01:34:15.860 --> 01:34:30.599

William Rogers: We would ask that Cms. Address this barrier to optimal care out of some chronic wounds by permitting clinicians who need a powdered skin substitute to treat a particular wound, to recover the cost of the powdered product used to treat that wound.

395

01:34:30.610 --> 01:34:34.799

William Rogers: That's all I needed to say about that. Thank you for the opportunity to speak.

396

01:34:38.050 --> 01:34:39.160

Thank you.

397

01:34:40.560 --> 01:34:43.899

Zehra Hussain: The next speaker is from Smith and nephew

398

01:35:05.110 --> 01:35:09.249

Kris Corwin: see that Mark is off mute. So, Mark, when you're ready

399

01:35:28.240 --> 01:35:29.789

a mark we cannot hear

400

01:35:29.800 --> 01:35:36.559

Zehra Hussain: you. So if you're experiencing any technical difficulties, could you let us know in the panel. Chat, please.

401

01:35:50.640 --> 01:35:51.889

Yeah, no, we cannot

402

01:35:51.900 --> 01:35:52.910

hear you.

403

01:36:12.110 --> 01:36:24.259

Zehra Hussain: I did try out joining again, and in the meantime to not waste any time we'll move on to the next speaker, and then we'll circle back to you. But, mark, we'll have my colleague, Chris, help you out.

404

01:36:25.240 --> 01:36:29.610

Zehra Hussain: So the next speaker is from life, net health.

405

01:36:44.300 --> 01:36:51.020

Kris Corwin: But there are a life net poc is not on point of contact, neither.

406

01:36:52.000 --> 01:36:53.039

Thank you.

407

01:36:53.930 --> 01:36:59.069

Then the next speaker is from forefront. Strategic partners.

408

01:37:04.050 --> 01:37:10.439

Brenda Boschetto: Hi, everyone! My name is Brenda O'connell, and today I am going to be

409

01:37:10.900 --> 01:37:25.719

Brenda Boschetto: talking a little bit about skin substitutes, and some of the questions that Um Cms has asked for interesting parties to consider. So can you all see my screen?

410

01:37:26.410 --> 01:37:27.289

Kris Corwin: We can.

411

01:37:27.300 --> 01:37:28.809

Brenda Boschetto: Yeah, Okay, perfect.

412

01:37:28.980 --> 01:37:54.919

Brenda Boschetto: So we are going to respond to the first question regarding Cms's request for feedback. What should we consider as part of Cms's efforts to ensure consistent, fair, and appropriate payment for services, products across

different settings of care and um, provided what is just an outline of what we will talk about today, and in order to stay within the five minute timeframe. I will just go to the next slide.

413

01:37:55.500 --> 01:38:19.630

Brenda Boschetto: So we heard a lot today about different types of payment methodologies, and what Cms is considering, or has proposed in the prior proposed rules. And currently, Ah Medica pays for ah physician payment for skin substitutes in the office setting based on an asp, methodology, back neurology or invoice. And

414

01:38:19.640 --> 01:38:34.560

Brenda Boschetto: uh, what we found is that this creates a disparity of payment um to providers when they're providing those services depending on the type of skin substitute, and whether it reports asp or is payable based on invoice.

415

01:38:34.570 --> 01:38:43.229

Brenda Boschetto: We heard earlier people talking about the Consolidated Appropriations act of two thousand and twenty one requiring manufacturers of

416

01:38:43.240 --> 01:39:07.549

Brenda Boschetto: R. B. Drugs and biologicals that do not have a medicaid drug rebate report to report Asp to Cms. And that requirement was beginning at twenty twenty-two, but we found in the proposed air file rules, and in some of the communication was there are some ambiguities related to asp reporting requirements,

417

01:39:07.640 --> 01:39:36.670

Brenda Boschetto: and so, as Cms. Moves forward with different payment proposals, considering either sticking with a separate payment for physician office payment, or moving towards a bundle payment. We do believe that if the asp payment methodology is concerned that these impunities ambiguities, need to be clarified, for example, sub skin substitute manufacturers for asp to Cms. Some do not,

418

01:39:36.680 --> 01:39:45.050

Brenda Boschetto: and it's unclear, whether manufacturers of synthetic skin substitute products which are typically approved

419

01:39:45.060 --> 01:40:06.910

Brenda Boschetto: by a five ten K or a Pm. A. Are required to report asp, and what we recommend is that Cms. Address these ambiguities and provide their directions, so that manufacturers and distributors um understand what they're reporting with are depending on the type of skin substitute that they have

420

01:40:07.790 --> 01:40:25.320

Brenda Boschetto: um Also, in response to that same question, we really think it's important that cms clarify um the nomenclature and the terminology as it starts proposing these different Um ah payment methodologies.

421

01:40:25.330 --> 01:40:45.589

Brenda Boschetto: I read in some of the prior proposed rules. Discussion of ah describing skin substitutes as food care products as opposed to just skin substitutes, and we believe it's really important that, as Cms proposes, these new policies that there is clear um

422

01:40:45.600 --> 01:41:01.760

Brenda Boschetto: explanations and clarification regarding their terminology, so that uh manufacturers, distributors, and providers understand what is included within a specific category of products.

423

01:41:02.810 --> 01:41:10.450

Brenda Boschetto: And finally, one thing that we think is really important is education. So as Cms

424

01:41:11.070 --> 01:41:20.570

Brenda Boschetto: works to possibly modify language and nomenclature relating to skin substitutes and or woundcare products.

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01:41:20.580 --> 01:41:49.619

Brenda Boschetto: Um, We think it's really important to publish that information and explain that to the Provider community to the manufacturer, community um, as well as so as these new proposals come out and and become finalized, we think it's important that Cms. Collaborate with Am. A Ct. Um. To ensure that these communications get out to the provider community and manufacture.

426

01:41:49.680 --> 01:42:14.619

Brenda Boschetto: So we would suggest that Cms. Collaborate with Ama Cpp. Um. In regard to the outreach and educational opportunities uh, by creating communications such as meddler matters, articles, and or Cp. Assistant articles, to ensure that all the appropriate stakeholders are aware of the changes.

427

01:42:15.210 --> 01:42:17.400

Brenda Boschetto: Thank you So much for your time.

428

01:42:21.840 --> 01:42:23.339

Zehra Hussain: Thank you, Brenda,

429

01:42:23.600 --> 01:42:40.219

Zehra Hussain: and we did receive um in the Q. And a chat that a life net did not wish to present at this time, and we will wait for Mark to join with audio. But we can test it out now. Real quick, Mark, if you're able to

430

01:42:40.320 --> 01:42:41.530

Zehra Hussain: unmute

431

01:42:41.950 --> 01:42:43.270

at this time

432

01:42:44.140 --> 01:42:47.090

Mark Olmstead: the Tsar. I'm going to try that now. Can everybody hear me?

433

01:42:47.100 --> 01:42:51.340

Mark Olmstead: Yes, we can hear you. Oh, great, fantastic! Thank you so much.

434

01:42:51.410 --> 01:42:53.449

Mark Olmstead: Apologize for the delay.

435

01:42:54.090 --> 01:43:09.909

Mark Olmstead: So on behalf of Smith and Nephew, we'd like to thank Cms for the opportunity to partake in the skin substitute Town Hall. My name is Mark Olmsted. I am the senior director of market Access and reimbursement. We're providing answers to two responses of the questions, number three and four.

436

01:43:11.380 --> 01:43:16.390

Mark Olmstead: So we are aligned with Cms. That in the Physician office

437

01:43:16.400 --> 01:43:18.270

Mark Olmstead: appropriate payment there

438

01:43:18.510 --> 01:43:27.190

Mark Olmstead: appropriate payment policy should be correlated to coverage of solutions with strong evidence and reimbursed on an asp basis.

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01:43:27.290 --> 01:43:40.800

Mark Olmstead: Cms and three Medicare administrative contractors have current skin substitute proposals, limiting coverage to products with strong evidence in various stages of final role In commentary, as we speak,

440

01:43:41.030 --> 01:43:47.630

Mark Olmstead: differentiating skincepts with clinical benefits should not be treated like basic commodities in administration or reimbursement

441

01:43:48.820 --> 01:44:05.710

Mark Olmstead: in any payment consideration. We are cms to consider the effective changes and the underserved patients that we've heard about in prior discussions this morning and this afternoon, including those for minorities, lower income households, and those with comorbidities of diabetes and obesity.

442

01:44:05.860 --> 01:44:22.859

Mark Olmstead: Cms. Implemented what Congress legislated through the Consolidated Appropriations Act of twenty twenty one, and I gave the opportunity for manufacturers of Part B drugs and biologics to submit and skin substitutes the asp information effect of January of twenty twenty two.

443

01:44:22.990 --> 01:44:25.969

Mark Olmstead: We recommend that this payment methodology

444

01:44:26.140 --> 01:44:37.339

Mark Olmstead: be the payment methodology for the Physician office, and that it pay for all skin substitutes based on

asp over the next several years to minimize disruption

445

01:44:37.350 --> 01:44:52.820

Brenda Boschetto: ensure continued access to advanced therapies, reduce Medicare spending and beneficiary cost, sharing, and give so much time to implement and evaluate how a universally applied asp approach would align with agency policy goals,

446

01:44:52.830 --> 01:45:11.870

Mark Olmstead: and we commend lastly, Cms. For adding forty, one cpts the list of new products, with asps as of January, the twentieth, twenty, three with fifty seven now boosting transparency. Lastly, in regards to change in the terminology, we don't believe at this time, and are aligned with previous speakers.

447

01:45:11.880 --> 01:45:29.989

Mark Olmstead: Medicare should consider aligning with the Fda and label skin substitutes as cellular and or tissue-based products c to bes and wound care management products will just cause more confusion mixing high-value products with the lowest cost products based on intended use and diminishing public health protection.

448

01:45:30.100 --> 01:45:34.550

Mark Olmstead: We thank you for the opportunity to speak today, and I'm turning it back over to you.

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01:45:37.280 --> 01:45:39.590

Zehra Hussain: Thank you, Mark, for your remarks.

450

01:45:40.060 --> 01:45:43.270

Zehra Hussain: The next speaker is from Northwell. Health.

451

01:45:43.800 --> 01:45:45.859

Alisha Oropallo: Good afternoon. Can you hear me?

452

01:45:46.330 --> 01:45:47.840

Zehra Hussain: Yes, we can hear you

453

01:45:47.850 --> 01:46:17.599

Alisha Oropallo: great um i'm. Dr. Alicia or Apollo. I'm. A professor of surgery at the dotted in Barbara Zucker School of Medicine at Hoshu University at Northwell health, and we're located here in New York. I've been practicing for over fifteen years in lone care and as a vascular surgeon and director of a busy, outpatient position room center, and we see approximately ten thousand patient office visits per year. I'm. Involved in many of the day to day needs of the patients,

454

01:46:17.610 --> 01:46:20.569

Alisha Oropallo: as well as the administrative aspect of won't care.

455

01:46:20.860 --> 01:46:34.630

Alisha Oropallo: I agree that with the recommendations from the prior speakers there is definitely a need for Cms to

provide greater detail, and should issue a framework document prior to any rule making, so that all stakeholders will have subsequent

456

01:46:34.640 --> 01:46:56.690

Alisha Oropallo: information to review and provide feedback. I also agree that with many of the other presenters that Cms should use is deep pricing, plus six, to publish and publish all the asp in the Medicare part. The data file to ensure not only transparency, but, as others mentioned, cost savings to the Medicare program,

457

01:46:56.700 --> 01:47:14.790

Alisha Oropallo: it's important for Cms to recognize that when they are aiming for a consistent approach. Physician practices are different from the hospital-based practices and packaging will impact our ability to continue to provide this valuable and successful treatment to our patients.

458

01:47:14.800 --> 01:47:30.479

Alisha Oropallo: First we purchase products prior to any reimbursement being made. It is already a huge expense that we undertake, but at the same time we do this because we know that these products work. They are very effective in treating our patients.

459

01:47:30.490 --> 01:47:59.630

Alisha Oropallo: Additionally, we are reimbursed for the product and separately for the application of the product. If we are not reimbursed adequately, we will not be able to continue the use of these products and use them for our patients creating an access to care problem for most of our vulnerable patients that I personally treat. We also have different resources available. Our staffing, model and workflow are different, and our expenses are different from the hospital based practices.

460

01:47:59.640 --> 01:48:14.469

Alisha Oropallo: But these resources are now impaired with packaging. This will affect the downstream care of patients, and may lead to parent purchasing of some products over others due to the reimbursement rather than what's best for the patient

461

01:48:14.500 --> 01:48:22.080

Alisha Oropallo: will be important, and how we are able to provide the treatment to all which is the greatest concern that I have.

462

01:48:22.090 --> 01:48:31.590

Alisha Oropallo: It's important to recognize that there are many different types of products and many different sizes of products. Each product has its own intended use,

463

01:48:31.600 --> 01:48:54.350

Alisha Oropallo: and there is considerable variability in the prices of these products. As a result, a funnel payment, where the variation with the variation of the products and the product, size and cost, will limit my ability to choose the most effective product for each individual patient under my care, because of the funnel payment which will likely impact the ability to treat these patients,

464

01:48:54.360 --> 01:49:08.890

Alisha Oropallo: and especially with those with larger sized worlds. I cannot see how packaging can be accomplished without limiting access. Increasing infection rates, increasing amputations, and then sadly increasing the loss of life.

465

01:49:08.900 --> 01:49:18.560

Alisha Oropallo: Cms has not created any modeling to show that packaging will be effective, or what impact these changes will make on my patients that I treat every day.

466

01:49:18.570 --> 01:49:46.629

Alisha Oropallo: My patients are comprised of a diverse population in New York with different needs, including the integ of population. They have multiple permitted comorbidities and rely on me to heal their works. And I need to continue to to do so Again, I agree with the prior suggestion that framework document is needed prior to any rule, making and products should report the asp price in plus six percent, and all asp should be published in the carpet pricing data file.

467

01:49:46.640 --> 01:50:02.790

Alisha Oropallo: This will continue to allow clinicians to choose the best product to treat their patients, being transparent in the data file and having additional framework, are essential for advancing this process. I appreciate Cms giving me the opportunity to speak.

468

01:50:06.580 --> 01:50:07.760

Zehra Hussain: Thank you.

469

01:50:07.950 --> 01:50:18.760

Zehra Hussain: And I did receive board that life. Net health wants to present. So my apologies for misinterpreting that um Chris, did we get both of them as panelists

470

01:50:19.520 --> 01:50:21.480

Kris Corwin: we did in.

471

01:50:21.850 --> 01:50:35.390

Kris Corwin: I am, and I think I can speak out. Yeah, and and forgive me, Allen, before you begin. Can you just identify yourself? I just have to switch your registered under a different name. So just to keep that transcript. Ah,

472

01:50:35.400 --> 01:50:36.490

Alan Stanley: here,

473

01:50:36.500 --> 01:50:43.689

Kris Corwin: yeah, Bud Brain originally did the registration but switch the speaker to me. So thank you. I'll make that change.

474

01:50:43.700 --> 01:50:53.350

Alan Stanley: No problem. That's fine. Um! My name is Alan Staley. I'm the Vp. And you know, manager for wound and surgical reconstruction for life, net health.

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01:50:53.920 --> 01:51:00.419

Alan Stanley: We are a nonprofit tissue bank located in Virginia Beach Virginia,

476

01:51:01.310 --> 01:51:09.249

Alan Stanley: with respect to. We're going to respond to questions one and four only with respect to question number one life net health,

477

01:51:09.260 --> 01:51:29.759

Alan Stanley: not believe our products or many of the other products noted here are incident to supplies, and to that end, should the agency decide to bundles can substitute payments in the position, office setting, we have several parameters and qualifications for such bundling follow

478

01:51:29.770 --> 01:51:36.999

Alan Stanley: that would reflect the nature and value of these products. While still accomplishing Cms's goal to bundle payment,

479

01:51:37.260 --> 01:51:48.889

Brenda Boschetto: we believe that a bundle payment system designed along such parameters will help create treatment. Parity across different sites of service, eliminate the current disparate financial incentives that certain marketers

480

01:51:50.150 --> 01:51:57.500

Alan Stanley: of skin substitutes offered to provide in the Physician Office site of service and reduced cost to the Medicare program.

481

01:51:57.580 --> 01:52:05.550

Alan Stanley: Recommended qualifications and parameters for bundling payment are as follows: One Since skin substitutes are not the

482

01:52:05.680 --> 01:52:18.090

Alan Stanley: supplies incident to the procedure to add on payments for treatment for wounds larger than twenty five square centimeters should be provided for each additional twenty, five square centimeters

483

01:52:18.100 --> 01:52:20.920

Alan Stanley: over the first twenty five square centimeters the

484

01:52:21.060 --> 01:52:35.349

Alan Stanley: and this should be in the pos. Eleven site of service bundle payment is applicable in the future, and additionally it should be added to the pos. Twenty, one, and twenty two sites of service.

485

01:52:36.080 --> 01:52:49.979

Alan Stanley: We recommend establishing a working committee to identify and limit the number of applications that's in substitutes. This would help physicians and providers use more clinically effective products

486

01:52:50.160 --> 01:53:03.189

Alan Stanley: in previous feedback to Cms. We have stated that there is clinical literature literature supporting a limit of four applications in a twelve week period, and with no more than twelve applications per year

487

01:53:03.590 --> 01:53:12.910

Alan Stanley: eliminate the payment of wholesale acquisition, cost whack and invoice plus six,

488

01:53:12.930 --> 01:53:21.109

Alan Stanley: which is subject to abuse, and is currently obviously we believe the problem that Cms. Is trying to address here.

489

01:53:21.610 --> 01:53:38.870

Alan Stanley: Eliminate the subjective asp reporting of some manufacturers. A number of speakers have referred to this. There is vagueness in the current language, and we would recommend that Cms. Clarify and make it very clear

490

01:53:39.840 --> 01:53:45.760

that asp is required by all of these products being reimbursed

491

01:53:45.860 --> 01:53:59.020

Alan Stanley: in these sites of service alternatively regarding question Number one. If Cms. Finds that the implementation of a bundled payment rate in Tos eleven is not practical, giving current guidelines and rules

492

01:53:59.030 --> 01:54:09.969

Alan Stanley: and Cms should make absolutely clear that all ctps, including all synthetic products, must report asp associated with outpatient usage, and use providers

493

01:54:10.160 --> 01:54:17.240

Alan Stanley: clarifying current language as discussed and and referenced in a recent Allij report

494

01:54:17.250 --> 01:54:24.120

Alan Stanley: and disallow reimbursement associated with whack and invoice with these ctps.

495

01:54:25.930 --> 01:54:45.829

Alan Stanley: Lastly, with respect to your question number four life. Net health recommends use of the term of cellular and or tissue-based products, as defined by as tm the place of the term skin substitutes. This term has thoroughly been vetted and agreed upon by the alliance of moon care. Stakeholders over

496

01:54:45.860 --> 01:54:54.510

Alan Stanley: many years reflects industry, consensus, and has been defined by the asm as a term,

497

01:54:54.580 --> 01:54:57.149

Alan Stanley: and that completes our Commons. Thank you.

498

01:54:59.980 --> 01:55:01.880

Zehra Hussain: Thank you. Life net help.

499

01:55:02.260 --> 01:55:07.070

Zehra Hussain: The next speaker is from the American Association of Tissue banks,

500

01:55:13.820 --> 01:55:15.649

Zehra Hussain: and we can see your screen.

501

01:55:22.360 --> 01:55:25.290

Marc Pearce: Good afternoon and thank you for the opportunity.

502

01:55:29.040 --> 01:55:30.190

Marc Pearce: Excuse me,

503

01:55:32.010 --> 01:55:40.939

Marc Pearce: good afternoon and thank you for the opportunity to offer input on this important topic. My name is Mark Pierce, and I am the President and Ceo of the American Association of Tissue Banks.

504

01:55:40.970 --> 01:55:52.449

Marc Pearce: Atvs are a professional nonprofit, scientific and educational organization and its membership totals more than one hundred and twenty accredited tissue banks and over six thousand five hundred individual members

505

01:55:53.550 --> 01:56:09.759

Marc Pearce: to begin. I'd like to start with question. Four regarding potential changes in terminology Atv. Recommends using the term cellular and or tissue based products. Ctds for skin wounds consistent with this recommendation i'll use this terminology through the rest of my State.

506

01:56:10.510 --> 01:56:20.820

Marc Pearce: In response to question, one Atb appreciates Cms interest in aligning payments across settings of care, and we believe that there are several factors that Cms. Should take into consideration.

507

01:56:20.830 --> 01:56:41.549

Marc Pearce: These include one, the demonstrated clinical value of ctps for skin wounds. Compared with the standard of care. Two. The need to ensure payment is sufficient to cover costs, regardless of setting, and that payment accommodates variability in terms of the size amount of the product used, the number of applications required, and the cost of administration,

508

01:56:41.730 --> 01:56:49.569

Marc Pearce: the feasibility of consistent and fair payment across settings, when each setting is subject to its own separate payment system.

509

01:56:49.580 --> 01:57:06.800

Marc Pearce: Atv is particularly concerned that a payment for ctps for skin work is folded into Medicare physician, c. Schedule Pfs payments for these products would be inappropriately constrained under the Pfs. Relative to payments under the outpatient prospective payment system, opps

510

01:57:06.810 --> 01:57:31.850

Marc Pearce: for individual patient needs and the importance of allowing providers to select from a wide array of products based on patient needs give the potential for average sales, rice, asp-based reimbursement to achieve the the goals of consistent fair and appropriate payment in Q. One of two thousand and twenty three Cms. Started to publish asps across a wider range of products.

511

01:57:31.860 --> 01:57:40.630

Marc Pearce: This enhanced transparency could drive down costs while preserving innovation and access. And Cms should give this process more time.

512

01:57:40.640 --> 01:58:10.589

Marc Pearce: Six, Finally, and most importantly, the need for transparency, certainty, and reasonable timeliness in any payment. Transition, restructure and payment requires Cmos to clearly detail data used, including asp for individual ctps. The methodology used to translate asp data for pricing under a revised payment frame, and the final prices that would apply. Cms. Should also provide a reasonable time frame for stakeholders to plan and implement this.

513

01:58:10.600 --> 01:58:11.860

It changes

514

01:58:13.520 --> 01:58:28.909

Marc Pearce: for question. Two Cms. Asked how it would ensure that valuation, and the Psf. Adequately accounts for variability and relative resource cost for a different skin substitute products as supplies within pe rd.

515

01:58:29.090 --> 01:58:47.140

Marc Pearce: Atb strongly objects to the premise of this question, which assumes that ctps for skin should be considered incidental to supplies captured within the Pe Rdv. Methodology. Cpts for skin roots are medical products that are critical in supporting the treatment of certain

516

01:58:47.180 --> 01:59:03.359

Marc Pearce: numerous trials have proven that ctps for skin rooms are significantly more effective in supporting the healing awards, such as diabetic football serves versus standard of care. The standard of care includes treating wounds with actual supplies currently categorized under a codes

517

01:59:03.910 --> 01:59:15.489

Marc Pearce: incorporating ctps for scamboats into the P. E. Rvu. Methodology would also have ramifications for physician payments due to the constraints on payments that apply under the Pfs.

518

01:59:15.500 --> 01:59:42.750

Marc Pearce: This includes Budget neutrality, requirements that apply both to the overall pool of P. E. Rv. Use as well

as the Pfs Rv. You changes overall, notably budget Neutrality Adjustments have led to negative payment updates under the Pfs for the last three years. Additionally, Pfs updates are not meaningfully tied to inflation. Rather the Pfs receive zero or little inflationary updates based on current.

519

01:59:42.760 --> 01:59:52.219

Marc Pearce: These factors of Psf. Would result in payments for precision services, not keeping pace with increases in the cost of ctps for skin wounds over time.

520

01:59:52.230 --> 02:00:13.219

Marc Pearce: They would also result in payment. Differentials between office settings paid under the Psf. And outpatient hospital settings paid under the Medicare Ops, which could restrict access in office settings and shift services to more expensive outpatient hospital settings. For these reasons we urge Cms to abandon consideration of this option.

521

02:00:13.670 --> 02:00:16.160

Marc Pearce: Thank you for considering these comments.

522

02:00:20.490 --> 02:00:21.770

Zehra Hussain: Thank you. Mark,

523

02:00:25.300 --> 02:00:34.860

Zehra Hussain: and our next presenter is Dr. Jeffrey Carter. And mark if you don't mind. Just please stop sharing your screen. Thank you.

524

02:00:37.700 --> 02:00:41.750

Jeffrey Carter: Good morning. Thank you for the opportunity to to present today

525

02:00:42.510 --> 02:01:00.190

Jeffrey Carter: Burns, surgeon in New Orleans, the medical director of the Bernstein, or the member of it, and also serve as an officer and board member of the Aba. And I'm. A physician that sits on the one of the larger Gpo panels. So I have a unique perspective How this affects not only our patients, but also our providers and our health care systems

526

02:01:00.200 --> 02:01:05.349

Jeffrey Carter: primarily coming from the burned perspective of how this affects us across the different things of care,

527

02:01:05.430 --> 02:01:32.780

Jeffrey Carter: and it's important to kind of a little bit of a background. Burns and and house kids up to you. You can tell for them in presenters Here there's different compositions and cost of benefits. Risk of them acutely. We use these for both function cosmetics, and in Burns we have such large wounds of it occasionally that we'll have to use these to cover when they don't have enough skin left behind to treat their wounds, or in smaller wounds to maybe cover something that's not masked or enough to support a skin graph bone in them. For example,

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02:01:32.790 --> 02:01:37.929

Jeffrey Carter: in the chronic setting we commonly use these skin substitutes to reconstruct or improve burn scars.

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02:01:38.640 --> 02:01:46.800

Jeffrey Carter: It's important to look at the use of these. And so what we were able to do is pull data from Rbs, and you can see here that in the primary code,

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02:01:46.810 --> 02:02:00.329

Jeffrey Carter: you know Burns make up only about nine percent. But when you look at it the atom codes we make up over our almost sixty percent of the total usage, meaning that if our ones are much larger than the ones treated by pediatricist or the chronic wound physicians,

531

02:02:00.340 --> 02:02:16.899

Jeffrey Carter: and it's important for us to be able to acknowledge that even in the outpatient setting, like a one percent or two percent burn, can still be several hundred square centimeters. So as these coaches come into review, and as this process goes into review, it's important for us to be able to be supported for our larger wounds.

532

02:02:18.070 --> 02:02:31.739

Jeffrey Carter: This is an example of the percent. Tbsa. You can see here on the left that the vast majority of Burns are actually small. They're under twenty percent Tbsa. But even a one or two or ten percent. Tbsa can be two thousand per centimeters, as you can see over here on the side.

533

02:02:32.240 --> 02:02:53.760

Jeffrey Carter: This has been a real challenge for burn centers in the nineteen seventy S. Where there's over one hundred and eighty, and now we're down to about one hundred and thirty burn centers in the country. It's only two percent of the hospitals in the entire country have a burn center of the eighty two thousand members of the American College of Surgeons. There's only two hundred and fifty Burns visuals left in the U. S. Where there's many doctors that care for small burns. There's very few of us that manage the most complex Burns and Apa verified branches like myself.

534

02:02:54.120 --> 02:03:17.650

Jeffrey Carter: Our request is to acknowledge that in these large wounds, like a review we recently did, we averaged close to two thousand centimeters, and these can vary greatly from us in one day of eighteen or two centimeters. We use these not only as temporary, but also for permanent coverage, and the cost varies dramatically. But we look at retail prices that can be over two hundred and forty dollars per centimeter.

535

02:03:18.100 --> 02:03:32.540

Jeffrey Carter: This is the captions of our patients. I work with a community that has the high amount of uninsured or underinsured population patients, and you can see that while we use these in different settings, no one can really afford this type without the appropriate support.

536

02:03:32.580 --> 02:03:50.530

Jeffrey Carter: Here you can see what their reimbursement is for these wounds, and while it might work for smaller ones, this does not work at all for larger wounds. We truly need a payment mechanism that accommodates this, so that we can provide care for small burns in the outpatient setting, and how people get back to their homes and back to their families, and not have to be admitted for inpatient care,

537

02:03:50.540 --> 02:03:55.430

especially as the number of burned centers in burned beds and surgeons goes down.

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02:03:55.880 --> 02:04:14.209

Jeffrey Carter: So what we're requesting here is that you know physician offices receive the payment they need based upon the room size, and that while we don't adequately get paid for this as you do this, please still support these larger wounds. I appreciate the opportunity to present today and look, and, in fact, and be of additional systems in the future. Provide to do that. Thank you.

539

02:04:17.730 --> 02:04:20.270

Zehra Hussain: Thank you, Dr. Carter, for your remarks.

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02:04:20.620 --> 02:04:24.029

Zehra Hussain: The next speaker is from regenerative lots.

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02:04:26.350 --> 02:04:48.739

Beeben Russell: Well, thank you. Everyone for having us. Uh I'm. I'm. With Virginia labs. We manufacturer can sell tissue products here in Pensacola, Florida. I'm actually gonna uh bring on outside council uh Rob Castle Um and I guess for the transcript and correction there is to be in Russell's in here on panelists. Um, so that will be Rob speaking and Rob, Can you get on here with us.

542

02:04:51.530 --> 02:04:53.620

Beeben Russell: Make sure he can't first right.

543

02:04:57.730 --> 02:04:59.799

Kris Corwin: Bear with me just a moment

544

02:05:00.070 --> 02:05:01.300

Kris Corwin: in November.

545

02:05:02.430 --> 02:05:05.789

Beeben Russell: I know he's got phone and computers in front of them so

546

02:05:07.690 --> 02:05:12.800

Kris Corwin: and even figured me. But can you go ahead and spell out Rob's full name?

547

02:05:12.810 --> 02:05:21.790

Kris Corwin: Yeah, So it's Robert and Robe Dart Castle. And then just how it sounds.

548

02:05:21.800 --> 02:05:22.630

Thank you

549

02:05:35.130 --> 02:05:36.200

Kris Corwin: great.

550

02:05:37.280 --> 02:05:38.389

Kris Corwin: Please proceed

551

02:05:41.000 --> 02:05:44.450

Beeben Russell: saying a technical issue dialing in by phone. Now,

552

02:05:46.160 --> 02:05:47.240

just it.

553

02:05:47.270 --> 02:05:51.280

Beeben Russell: Let me tell you what phone number he's probably going to be calling on. That'll help you.

554

02:05:51.380 --> 02:05:58.700

Kris Corwin: Yes, please, if you can just direct message to me. So we don't include it in the transcript. I mean, I can take that out later. But

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02:05:59.460 --> 02:06:06.799

Kris Corwin: um excuse me, Stephan, if he calls in. You cannot promote him to a panelist.

556

02:06:06.990 --> 02:06:08.099

Okay,

557

02:06:08.910 --> 02:06:11.289

Kris Corwin: but, Devon, I can open up the line,

558

02:06:11.310 --> 02:06:14.480

Kris Corwin: right? Or we could. Yes, you can.

559

02:06:15.170 --> 02:06:16.930

Beeben Russell: Okay, perfect.

560

02:06:20.010 --> 02:06:21.360

Thank you very much.

561

02:06:21.370 --> 02:06:32.789

Rob Castle: Yeah, we can hear you. Great. Thank you. Our first one is Rob Chas: I'm. Here to have Max, Sire Virginia the last uh we really appreciate the opportunity to present today.

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02:06:32.800 --> 02:06:41.559

Rob Castle: I'll talk about a very interesting uh transfer presenter. So, in particular infection with comments to questions

Number one and number two.

563

02:06:42.050 --> 02:06:46.349

Rob Castle: We greatly agree with you to clamp a lot of data.

564

02:06:46.450 --> 02:07:03.270

Rob Castle: It's pretty much surrounded. The use of asp reporting, and we agree with the presenter who discussed the confusion that the ambiguities and then only in our opinion non-compliance with asp recorded requirements

565

02:07:03.400 --> 02:07:23.800

Rob Castle: um. We know this is a good opportunity for Cms to push forward to reverse the asp reporter requirements, specifically products that, not satisfied with the requirements not be eligible for re embarrassment. Those parties who do not need their regulatory obligations should not be able to benefit from their non-compliance.

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02:07:23.810 --> 02:07:29.569

Rob Castle: Most of the manufacturers and distribution. Networks have overly admitted that they gained the system as far

567

02:07:29.580 --> 02:07:46.339

Rob Castle: to see if the risk companies are allowed to monitor previously due to lack of feeding, and the consequences are sufficient to their non-compliance. Some manufacturers have actually adopted an understanding of business model. The pay for fines for Niagara Falls is a cost of business,

568

02:07:46.350 --> 02:07:57.899

Rob Castle: and they can also make more about sending graphs to the to provide a rebates and paying the funds in the well. If you actually put the asp given the effects of pricing the compliance has to stop

569

02:07:57.950 --> 02:08:14.289

Rob Castle: that has to start and does emerge he in our opinion right Now a non-compliant company can talk about whatever they want to hear, and they're the battery's one who bears the grunt of the malc compliance from that manufacturer as such.

570

02:08:14.440 --> 02:08:32.970

Rob Castle: Ah! We support the use of asp in the the Physician office center. We certainly ah agree that there needs to be a more stringent requirement and more ah consequence for fairly compiler those important requirements where they view through ambiguity or through intentional

571

02:08:33.190 --> 02:08:47.519

Rob Castle: of decision-making further we agree with Mr. Mccallum's point earlier, Probably the collection of data, and the need for further analysis, both in terms of as we drive work towards value-based care

572

02:08:47.530 --> 02:09:01.599

Rob Castle: to achieve the same, we want to tie the script as more of our manufacturers with our distribution teams, while we've improved the outcomes of database characterized each manufacturer should have the needs of the means by

which to collect the data and products and applications.

573

02:09:01.610 --> 02:09:21.410

Rob Castle: There's a consistent battery that to discern which products are effective and the degree to which they are effective, so it can be aggregated and analyzed to determine efficacy very, very easily and through simple requirements from Cms. As a preferred to by reimbursement of policy. But that's the data aggregation for publication outcome transparency,

574

02:09:21.420 --> 02:09:32.549

Rob Castle: rising, transparency and effectiveness. With a better understanding of lift and outcomes, we can truly begin to actually assess what products secure truly drives an outcomes and value-based model.

575

02:09:32.760 --> 02:09:36.130

Uh, thank you for your time to present today, and we hope you have a great day.

576

02:09:36.540 --> 02:10:06.529

Beeben Russell: This is the closing remarks. I think it's just easy to say this is a complicated topic, and a lot of people brought really really great arguments here and a lot of data, but I think it's important to look on some of the common sense because it gets lost in some of this. Um. You know the prices are exorberant. There are people running away from Asp, and the Science Fair has already been one on this. These drafts work. We know this Um. But understanding which companies are producing ongoing, patient-based graphs, meaning that this is not

577

02:10:06.540 --> 02:10:23.479

Beeben Russell: my cherry-pick to ongoing. Data. This is relative to real patients that are covered and walking in and covered by Medicare, and the data is actually concurrent. Almost everyday patients. Manufacturers should be responsible to report that, as well as pricing to show that they are observing the pain. Thank you.

578

02:10:26.800 --> 02:10:28.889

Zehra Hussain: Thank you. Regenerative labs.

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02:10:29.940 --> 02:10:34.559

Zehra Hussain: The next speaker is from the American Medical Association.

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02:10:36.380 --> 02:10:39.500

Jennifer Hananoki: Good afternoon. Can you hear me? Yes, we can hear you

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02:10:39.600 --> 02:10:54.790

Jennifer Hananoki: right. I'm. Jennifer Han Noki I'm. The Assistant Director of Federal Affairs at the American Medical Association. Thank you to Cms for holding this town hall and offering the Ama an opportunity to provide on skin substitutes

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02:10:55.210 --> 02:11:13.640

Jennifer Hananoki: related to potential of solutions regarding evaluation in the Physician office. Setting, as we understand it, the issue is primarily around the granularity it costs between separate supplies in this area, and there are

more opera mechanisms for cms to address this underlying issue.

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02:11:13.650 --> 02:11:27.930

Jennifer Hananoki: The Ama and the Ama Specialty Society, relative value, Update committee or Iraq have consistently over many years, requested that Cms pay separately for high cost flies that are greater than five hundred dollars.

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02:11:27.940 --> 02:11:43.550

Jennifer Hananoki: High Variability and supply costs can greet distortions and inadequate payment. Under the existing practice practice expense model. The rvrbs, the A. May recommends that Cms definitely identify and pay for high cost

585

02:11:43.560 --> 02:11:49.740

Jennifer Hananoki: supplies priced at more than five hundred dollars. Using an appropriate hick fix code.

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02:11:49.980 --> 02:11:56.700

Jennifer Hananoki: The pricing of these supplies should be based on a transparent process where items are annually reviewed and updated.

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02:11:57.630 --> 02:12:16.289

Jennifer Hananoki: An analogy in this area is Cms's current payment policy for paying separately for split and cast supplies under current Cms policy. Pick picks, cue codes are utilized for separate payment of the necessary supplies along with the Cbt code for cast traffic procedures. This allows for price to

588

02:12:16.300 --> 02:12:23.330

Jennifer Hananoki: granularity across many different types of supplies. While maintaining consistency for the actual procedure recording

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02:12:23.950 --> 02:12:41.989

Jennifer Hananoki: related to terminology. We believe that the definitions listed in the Cbt code set. Guidelines adequately describe skin substitute services creating deviations for these definitions, especially for primarily cost-related reasons could create fusion across health care,

590

02:12:42.260 --> 02:12:51.190

Jennifer Hananoki: changing the terminology to boom management would differ from Cp. To nomenclature, and cause confusion and inconsistent reporting.

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02:12:51.610 --> 02:13:00.289

Jennifer Hananoki: However, the Cpc guidelines and reporting for skin substitutes are clear, and they do not include the application of non-graphical dressings,

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02:13:00.300 --> 02:13:06.589

Jennifer Hananoki: for example, gel powder, ointment so, or liquid, or injected skin substitutes.

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02:13:06.600 --> 02:13:11.569

Jennifer Hananoki: And those items should not be lung together and catch all terminology, such as food management.

594

02:13:12.720 --> 02:13:16.480

Jennifer Hananoki: Thank you again for your time and for your attention to our comments.

595

02:13:19.690 --> 02:13:21.940

Zehra Hussain: Thank you to the ama.

596

02:13:22.740 --> 02:13:27.960

Zehra Hussain: The next speaker is representing the American Pediatric Medical Association.

597

02:13:29.700 --> 02:13:31.690

Edward Prikaszczyk: Yeah, Hi, Hi. Can you hear me?

598

02:13:31.700 --> 02:13:51.340

Edward Prikaszczyk: Yeah, Okay, Thank you. Yeah. My name is Edward for, and I represent the American Pediatric Medical Association. I am of the diam stress, and have been in practice for almost forty years, and have my skin substitute uh products uh across a lot of different settings

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02:13:51.350 --> 02:14:19.430

Edward Prikaszczyk: uh, including a room center, my office and and in the inpatient setting in the operating over the years. I've seen a lot of changes in current. Uh, also seen a lot of suggested changes, and and I want to thank Cms for for having this Town Hall meeting, so that our voices can be heard, and they can be rendered on this very complex issue, and also very expensive issue as well.

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02:14:19.440 --> 02:14:41.440

Edward Prikaszczyk: Um, My comments will be directed at uh uh, regarding questions one, two, and and three in regards to question number one. The uh Apa believes that bubble payments for these products risk creating a situation where payment patients may be limited in receiving the larger sized products when they are needed.

601

02:14:41.450 --> 02:14:55.289

Edward Prikaszczyk: Having bubbled payments for skin substitutes could create a cost and reimbursement differential that would result in limiting or eliminating access to substitutes in an office setting.

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02:14:55.480 --> 02:15:06.789

Edward Prikaszczyk: Uh, Also, care uh uh! Could be shifted to the hospital, or with the obvious increasing cost of care uh to to a Cms. And then Medicare.

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02:15:06.800 --> 02:15:17.310

Edward Prikaszczyk: We have seen this happen in the Agl Pd. Setting along with associated poor outcomes due to a lack of access to

604

02:15:17.330 --> 02:15:24.950

Edward Prikaszczyk: some of the larger size to products. In regards to a question number two,

605

02:15:25.340 --> 02:15:30.780

Edward Prikaszczyk: and the evaluation under the Pfs practice expense. Rv: You,

606

02:15:30.790 --> 02:15:38.050

Edward Prikaszczyk: Cms. Would need to have many levels of reimbursement for skin substitute products due to the variability in costs

607

02:15:38.060 --> 02:15:57.329

Edward Prikaszczyk: based on size and the actual product itself. Across the board Bubble payments for these products risk creating a situation where patients may be limited in receiving the larger size products when they are needed. We can't foresee a Method to account for the cost of our ability within the practice.

608

02:15:57.340 --> 02:16:14.010

Edward Prikaszczyk: The Two-tier and Hlpd reimbursement model will not work across the board, since it has not worked in the age. Or Pd. Setting. The net result of this would limit access to care and potentially compromise station, health, as well as increase the amputation rates.

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02:16:14.190 --> 02:16:28.209

Edward Prikaszczyk: In regards to question number three. The only comparison that we could make was to the Hlpd setting, where the two-tiered approach is used,

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02:16:28.220 --> 02:16:43.110

Edward Prikaszczyk: and the two chair system failed to account for size differential, and did have an impact on patient access to appropriate world care. As many of the other presenters have said as well.

611

02:16:43.160 --> 02:17:06.230

Edward Prikaszczyk: Um. So in the in summary we are opposed to the valuation of these products under the practice expense. Um rbu ah suggestion by by Cms. Ah! And and ah! Probably a more appropriate approach would be to use as a asp less six percent due to the variability costs

612

02:17:06.240 --> 02:17:21.929

Edward Prikaszczyk: uh having choices on the products used by the clinician and allowing access to care uh in an office setting and preserving this very valuable uh a place of struggles. Thank you for areas.

613

02:17:24.950 --> 02:17:27.210

Zehra Hussain: Thank you for your remarks,

614

02:17:27.219 --> 02:17:42.440

Zehra Hussain: and the next presenter has indicated. They will no longer be presenting at this Town Hall, and before I move on to our final speaker for the presentation, we actually have some time available to get into our alternate presenters,

615

02:17:42.450 --> 02:17:58.550

Zehra Hussain: and if you are an alternate presenter I will have my colleagues and the zoom moderator promote you as a panelist, and we will call upon you. But it is not required if you do not wish to speak, or if you did not have on time available to create a presentation or remarks.

616

02:17:58.629 --> 02:18:05.630

Zehra Hussain: So with that we'll move on to our final presenter on this list, and there are from wound care plus.

617

02:18:19.160 --> 02:18:19.889

See your screen,

618

02:18:19.900 --> 02:18:21.830

but we cannot hear. You

619

02:18:29.920 --> 02:18:31.619

might be doubly muted.

620

02:18:43.600 --> 02:18:44.689

Yeah, we cannot hear you,

621

02:18:44.700 --> 02:18:49.330

Zehra Hussain: Devon. Is there a way where we can have Martha dialed in?

622

02:19:01.820 --> 02:19:05.940

Zehra Hussain: We do this in the chat. Okay, perfect.

623

02:19:25.450 --> 02:19:32.600

Zehra Hussain: So the Devon is going to put in the call and information in the chat so hopefully you'll be able to dial in

624

02:19:42.120 --> 02:19:53.190

Zehra Hussain: as doing that, to prepare the next speaker on our alternate list. It will be a Dr. Carpenter. So after Martha gives her remarks, we will move on to you.

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02:19:54.280 --> 02:20:06.590

Zehra Hussain: Um, but actually yes, um. In the meantime, let's just go ahead and move on to Dr. Carpenter. So, Martha, if you don't mind. Ah, stop sharing your screen, and then we will circle back to you after we troubleshoot. So Dr. Carpenter, when you are ready.

626

02:20:07.290 --> 02:20:25.870

Shaun Carpenter: Thank you. I appreciate it. Thank you for giving me this opportunity. I'm glad to see some other positions and clinicians on this call. Um, Thank you, Dr. Carter, for your comments from Burn center right here in New Orleans and Lsu I'm, Dr. Sean, Carpenter, I'm, the chief medical officer of

627

02:20:25.880 --> 02:20:33.139

Shaun Carpenter: women care associates. We have private office phone centers and We also have hospital-based phone centers.

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02:20:33.390 --> 02:20:36.119

Shaun Carpenter: We are on both sides on a practicing position.

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02:20:36.190 --> 02:20:44.710

Shaun Carpenter: Sports are fine emergency medicine. I've been practicing. We medicine for the last twenty years. So I feel like I have a unique perspective.

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02:20:44.720 --> 02:21:04.069

Shaun Carpenter: I hope that in addition to the five minutes that we get in these presentations that Cnn. Will allow patients to present. We Haven't heard from eight patients. Yet these patients who have been denied care because of the current bundled Hp. E. Policy, and then those patients who receive care because of the ability to treat larger wounds in the private offices.

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02:21:04.080 --> 02:21:22.650

Shaun Carpenter: I would just like to say that the bundled system in Hiv's having worked in the Hpd Moon Center for twenty years, has been an abject failure, as it pertains to treating our most at-risk patients essentially the bundled system

632

02:21:22.660 --> 02:21:42.279

Shaun Carpenter: creates a adverse or perverse incentive to treat wounds. The size of this dye so essentially a patient with a one square, senior wound. Ah is treated where, as a patient with a thirty square centimeter wound cannot be treated in the Hpd. One of my colleagues earlier. It said that

633

02:21:42.290 --> 02:21:54.469

Shaun Carpenter: ten percent of wounds were twenty five square centimeters, and greater. I can tell you that in our ten thousand patient practice here in Louisiana, Mississippi, that our average one size is twenty, eight plus seven years.

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02:21:54.480 --> 02:22:04.500

Shaun Carpenter: The average number of applications it takes to heal some of these patients of seven applications per patient. I think that going down to four applications per square per patient

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02:22:04.550 --> 02:22:13.309

Shaun Carpenter: will effectively discriminate against patients with large wounds. You can't possibly treat a wound as big as my hand with four applications.

636

02:22:13.380 --> 02:22:31.470

Shaun Carpenter: Our population of ten thousand patients, Three percent of those patients receive skin substitutes, but those are the highest risk. Patients, Mississippi and Louisiana has the highest rate of diabetes, obesity, amputations in the entire country. Those patients overwhelmingly reside in the rural settings. So

637

02:22:31.480 --> 02:22:49.489

Shaun Carpenter: ah! You don't find a gopds very often in the rural setting. Hospitals can't afford to have a clinic. Patients have nowhere to get treated, and their only option to get treated is with a private moon center or a private office. I would hope that Cms. Would want to

638

02:22:51.050 --> 02:23:03.250

Shaun Carpenter: increase the number of private moon centers that reach out to these rural populations and not decimate them. The current proposal. It would be akin to telling hospitals that hyper Barracks reimbursement

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02:23:03.280 --> 02:23:17.710

Shaun Carpenter: is going to be significantly cut or eliminated, and therefore you would effectively close your hospital-based loon centers, because Cms is essentially attached. The viability of a hospital-based wound center. The Hyper barracks.

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02:23:17.720 --> 02:23:27.709

Shaun Carpenter: I don't think anybody wants to see hospital and centers close, and I don't think anybody wants to see private room centers close. We should be treating more patients, not fewer.

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02:23:27.720 --> 02:23:28.900

Shaun Carpenter: I think that

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02:23:29.030 --> 02:23:34.440

Shaun Carpenter: Cms needs to decide if they agree with the science that

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02:23:35.420 --> 02:23:41.990

Shaun Carpenter: skin substitutes are beneficial to patients and help patients we should be expanding the coverage of the

644

02:23:42.060 --> 02:23:48.700

Shaun Carpenter: substitutes to these at-risk patients not limiting the access.

645

02:23:51.050 --> 02:23:52.440

Shaun Carpenter: I think that

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02:23:52.730 --> 02:24:07.039

Shaun Carpenter: by emulating the bundles in the private office we will only reduce care for these minority patients. Really, what needs to happen is that the Hpds should be reimbursed per square centimeter, so that all patients can receive

647

02:24:07.050 --> 02:24:16.919

Shaun Carpenter: the needed skin substitutes, regardless of how large, or how small their wounds are. I don't think that the policy should be determining who gets treated, and who does it i'll close in saying that

648

02:24:16.990 --> 02:24:36.259

Shaun Carpenter: African-americans in our in our ten thousand patient population everyone's are fifty, four percent larger than the Caucasian Americans. They're twice as likely to get amputations. And I think that any decisions that Cms makes should be reviewed by the office of minority health that Cms currently has, and we need to make sure that we're not further

649

02:24:36.270 --> 02:24:54.179

Shaun Carpenter: creating a disparity gap in health care treatment for these patients. Thank you very much for the time to present, and I hope we have more time in the future to have a robust discussion, and I sincerely hope that this decision is pushed off to two thousand and twenty five, so that we can all make a rational, logical decision to help our patients. Thank you.

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02:24:58.040 --> 02:24:59.850

Thank you, Dr. Carpenter.

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02:25:01.800 --> 02:25:07.659

Zehra Hussain: So now we'll circle back to Martha to see if you were able to dial in.

652

02:25:08.060 --> 02:25:10.390

Zehra Hussain: So if we want to just test that real quick,

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02:25:20.800 --> 02:25:21.690

you're speaking, Martha,

654

02:25:21.700 --> 02:25:23.959

Zehra Hussain: or not able to hear you still.

655

02:25:40.520 --> 02:25:49.480

Zehra Hussain: So it looks like she still might have some technical difficulties, but we will continue on with another alternative speaker,

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02:25:49.690 --> 02:25:54.680

Zehra Hussain: and next on our list is either Mark Gamble or Beth,

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02:25:55.110 --> 02:25:58.109

Zehra Hussain: If either of you would like to present at this time.

658

02:26:12.530 --> 02:26:14.389

Hearing none, we will

659

02:26:14.400 --> 02:26:20.260

Zehra Hussain: go ahead and move on to the next alternate presenter from united wound healing.

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02:26:20.820 --> 02:26:23.149

Zehra Hussain: If you wish to speak, please do so.

661

02:26:36.770 --> 02:26:40.399

Zehra Hussain: Um, I'm going to.

662

02:26:47.300 --> 02:26:49.910

Martha R Kelso: Can you hear me? Yes, we can hear you.

663

02:26:50.530 --> 02:26:58.770

Martha R Kelso: Okay, Thank you for taking me off me. I appreciate that. Let me go ahead and share my slideshow, and then we'll get ready to start. Thank you,

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02:27:00.710 --> 02:27:02.389

Martha R Kelso: and my slide show is up.

665

02:27:02.400 --> 02:27:03.920

Zehra Hussain: Yes, you are good, too.

666

02:27:04.600 --> 02:27:19.059

Martha R Kelso: Thank you so much. I want to start by saying that I believe our my company is uniquely positioned because we do touch so many states, so many Macs, and then also a lot of different sites of care.

667

02:27:19.070 --> 02:27:35.699

Martha R Kelso: I'm not going to read this slide, but I did put it up, so that, you understand I have worked with numerous Federal and State agencies across the board, doing different items in the twenty years that I've been serving advanced windcare as a healthcare professional.

668

02:27:35.710 --> 02:28:02.899

Martha R Kelso: Additionally, we touched numerous types of care across the healthcare continuum across all of these beds, and so far I've heard a lot of HpV comments and a lot of physician office comments, and although those are also near and dear to my heart, I don't want the less the rest of the industry left out. We do touch patients and associate living. We touch them in long-term care, residential care rehab facilities, long-term acute care hospitals

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02:28:02.910 --> 02:28:12.699

Martha R Kelso: so we run the gamut. And oftentimes we're seeing these patients same patient, same wound, different care settings, which means different reimbursement,

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02:28:12.710 --> 02:28:27.169

Martha R Kelso: different reimbursement methodologies, which becomes extremely confusing. And oftentimes these people get lost across the care setting, because it is so confusing to figure out how reimbursement works in those care settings.

671

02:28:27.630 --> 02:28:46.680

Martha R Kelso: So I want to start with. We've just got access to the usage within the last four to five years in the post-acute care space. So non-position offers non hotd, and this is one of those tools that we desperately need in our toolkit, and have needed it on long. But we just got access.

672

02:28:46.740 --> 02:28:54.489

Martha R Kelso: I think we deal with the most complicated and chronically-solved wounds in those acute in those prosecute care settings

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02:28:54.550 --> 02:29:11.440

Martha R Kelso: the more tools we have in our toolkit the greater the chance we have of preventing amputation sets of hospitalizations, and ultimately increasing the quality of life of some of these nation's retired core and underserved in those care settings

674

02:29:11.500 --> 02:29:25.700

Martha R Kelso: commonly in the prosecute care sector. We deal with the most co-morted medical conditions, the most poly pharmacy, and the most cognitively impaired, whether it's from psychosis depression, dementia, alzheimer's, et cetera.

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02:29:25.710 --> 02:29:38.680

Martha R Kelso: And so me speaking to you today, I understand the importance and the weight that this carries for that population. We treat thousands of patients, thousands of wounds a week.

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02:29:39.360 --> 02:29:55.049

Martha R Kelso: We know that persecute care. We have transportation issues oftentimes to and from advanced lum centers, or they are not designed and set up to care for somebody that's cognitively impaired. That may need babies; that while they're there in the clinic or the ambulance transport that's tied up.

677

02:29:55.060 --> 02:30:08.429

Martha R Kelso: We know that we deal with developmentally disabled age-related and physical impairments. So getting access to advanced healing wound modalities is challenging and difficult when we are limited by payers.

678

02:30:09.060 --> 02:30:26.860

Martha R Kelso: I want to show you, Mrs. Jones, and she is a very uncommon patient presentation. The reason, I say, that is because she's a young Medicare insurance. She's in her thirtys, and she has multiple comorbid conditions, including intellectual disabilities. She is cognitively impaired from birth. She

679

02:30:26.870 --> 02:30:41.669

also has epilepsy and hydrocephalus she's. On over thirteen medications. And she has a large stalled post-operative wound that fails multiple interventions. This wing has been present for a minimum of four years before it landed at my company.

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02:30:41.880 --> 02:30:52.719

Martha R Kelso: Square centimeters was one hundred and seventy five square centimeters on presentation to my

company. So Medicare does absolutely need to consider the impact to larger rooms.

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02:30:53.020 --> 02:30:57.980

Martha R Kelso: This is not an uncommon weing for F to see in the post-acute care setting.

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02:30:58.240 --> 02:31:08.630

Martha R Kelso: So if it's if she's inpatient, and in a Drg That's one story that we have tons of patients in the outpatient care setting that have larger wounds,

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02:31:08.640 --> 02:31:23.040

and I heard a lot of discussion about diabetic healthcare and venus ulcers. We are using ctps to treat pressure ulcers in post-acute care because it's allowed by Medicaid in most of the States that we service

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02:31:23.060 --> 02:31:30.379

so we can use it for chronically stalled wounds. We can use it for pressure ulcers, and we have had really good results

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02:31:30.460 --> 02:31:36.650

Martha R Kelso: getting these wings to heal or go down into smaller wounds to increase their quality of life.

686

02:31:36.750 --> 02:31:59.179

Martha R Kelso: We know that the hospital outpatient package reimbursement system is insufficient. We know that the perspective payment system is kind of when some loosome, but the package payment Ah, method, reimbursement is not going to work. That asp plus six percent is consistent if we use it across all care settings and across all methodology.

687

02:31:59.340 --> 02:32:07.709

Martha R Kelso: So I want to show you Ms. Jones, after seven applications of a well-studied presental thin substitute, we got this way down to a dime,

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02:32:07.720 --> 02:32:36.450

Martha R Kelso: was willing to come back out to the dining room and be social for a change. She was willing to eat again. We did lose her to follow up here, because she does charge to another facility, and I am in the process of mining my database, because we have hundreds of prosecute care wounds that we have treated, and I want to present that evidence to Medicare. So you can see the difference that we have created by using Cpt. That database is important, and Cms should

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02:32:36.460 --> 02:32:40.049

consider it before making their final determination.

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02:32:40.480 --> 02:32:43.589

Martha R Kelso: Thank you very much for giving me time to present today.

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02:32:47.130 --> 02:32:49.559

Zehra Hussain: Thank you, Martha, for your presentation,

692

02:32:50.450 --> 02:33:06.570

Zehra Hussain: and now we will continue to move on to our alternate presenters, and, as mentioned before, Um, if you do not wish to speak. You do not have to. When I call upon your name, feel free to unmute, and if you choose to not do so, then I will just move on to the next alternate present.

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02:33:07.710 --> 02:33:14.450

Zehra Hussain: So the next alternate presenter on the list was residential home for the developmentally disabled.

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02:33:14.520 --> 02:33:17.450

Zehra Hussain: If you wish to speak, please unmute yourself.

695

02:33:22.910 --> 02:33:30.089

DeVonne Parks: The moderator has to unmute them, but I need to know their name not really the company.

696

02:33:30.100 --> 02:33:33.440

Kris Corwin: Uh they're not. They're not on. I don't see

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02:33:33.540 --> 02:33:34.720

Kris Corwin: her anger

698

02:33:39.950 --> 02:33:40.980

at that.

699

02:33:41.150 --> 02:33:47.599

Zehra Hussain: I know you have, James. Did you happen to see the next speaker from Bcps Florida?

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02:33:48.690 --> 02:33:50.940

Kris Corwin: Uh checking? Now bear with me.

701

02:33:59.980 --> 02:34:01.560

Kris Corwin: I do not.

702

02:34:05.030 --> 02:34:06.650

Next speaker

703

02:34:06.740 --> 02:34:08.289

of a line from

704

02:34:08.300 --> 02:34:10.109

Zehra Hussain: Halifax Medical Center?

705
02:34:27.490 --> 02:34:28.539
No.

706
02:34:30.820 --> 02:34:31.589
And then I do

707
02:34:31.600 --> 02:34:36.660
Zehra Hussain: believe the next speaker is on as a panelist saw the Nasser.

708
02:34:50.260 --> 02:34:56.810
Zehra Hussain: We will move on to the next speaker from Steve Clark. Dpm.

709
02:35:09.990 --> 02:35:11.899
Don't think I see the modest of it,

710
02:35:11.910 --> 02:35:13.109
the either

711
02:35:18.470 --> 02:35:19.869
Kris Corwin: neither name

712
02:35:20.730 --> 02:35:23.090
and then the last alternate

713
02:35:23.100 --> 02:35:32.960
Zehra Hussain: center that indicated they were interested in responding. Um, it's from and called Corp and Office Bearer of Society for bio materials.

714
02:35:34.290 --> 02:36:02.299
Subramanian Gunasekaran: Yeah, my long name is suburban. I'm gonna safer um. I have been in the industry for thirty-eight years, and uh and especially my training. And the uh uh background is in the area of uh tissue. And with respect to the uh, the Bio material science, That's why I know when I have been in the society to buy a materials uh more than thirty-five years now, and as an active participant, and also as an

715
02:36:02.310 --> 02:36:31.350
Subramanian Gunasekaran: um. With respect to uh the uh questions uh which are subject to the Town Hall meeting. Um ask in substitute the first question I would like to address. First of all, I I would like to go along with most of the speakers. They all were uh discouraging the bundle of payment which I think you know everyone should be uh experiencing the the difficulties, using the payment, so that it's one of the

716
02:36:31.360 --> 02:36:43.560

Subramanian Gunasekaran: important aspects which Cms. Should be considering for having a fat and appropriate payment system. And in continuation of that I would also like to have

717

02:36:43.570 --> 02:36:52.289

Subramanian Gunasekaran: the methodology that is being used. The relative value Update Committee's decision that is heard by the

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02:36:52.330 --> 02:36:59.019

Subramanian Gunasekaran: for designing the valuation. I'm. Talking about the commercial valuation of the product.

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02:36:59.030 --> 02:37:21.139

Subramanian Gunasekaran: I think there is a small glitch. I I really respect all the doctors of the physicians, all the the providers of the medical care. But, however, there's a small background that has to be filled up by the people who I refer to as the basic biological scientist on biochemical science.

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02:37:21.150 --> 02:37:44.089

Subramanian Gunasekaran: Why, it is very important, in my opinion. I don't know how many of you are over hearing the the Roman being spread out in the recent months and the maybe a couple of years after the Ah, the suburb of one of the paper scientific papers in Nature, which very clearly,

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02:37:44.100 --> 02:38:01.990

Subramanian Gunasekaran: which is a molecule present in A. In some of the constructs of the skin substitute. They have to be considered as or syogens, and because once they are degraded. It is very well documented scientifically. So why Don't um Medicare, or I mean Cms.

722

02:38:02.000 --> 02:38:08.160

Subramanian Gunasekaran: Has some influence of the basic Science people in that committee

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02:38:08.270 --> 02:38:27.039

Subramanian Gunasekaran: which I'm. Trying to promote through our society the societies of biomaterials to have a consortium, or one of the speakers also suggesting that we have to have a proper ah team of people to to decide the best product available for the own, their applications from the from the

724

02:38:27.050 --> 02:38:29.699

Subramanian Gunasekaran: the composition of the product per se.

725

02:38:29.710 --> 02:38:58.540

Subramanian Gunasekaran: And with this Ah find I would like to add one more thing. I had been working with the Fba Um through the Society for Biomedicals. As As a matter of fact. And also these are the people who are representing the high level. Ah, directorial positions, official positions. They tissue the generative technology. I ask them. Basically How come this information or not properly related to? Ah, the Cms.

726

02:38:58.570 --> 02:39:21.889

Subramanian Gunasekaran: Why? Because lately I don't know why. What is the influence Cms is getting for approving,

I would say not. Dozens of these. Ah! The Adiatric membrane products have been approved by Cms. And it is very surprising to me how come the Fb. Is not taking this part, because they are the people who are designing the safety and advocacy of a product

727

02:39:21.900 --> 02:39:35.459

Subramanian Gunasekaran: from the Safety perspective. I I don't know When I asked them. They told me, Una, there is no proper conduit between Fda and Cms, same as decides. Things are, so I think this is a major major

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02:39:35.530 --> 02:39:53.180

Subramanian Gunasekaran: to be done in order to answer your question, to have a fair, appropriate, and consistent valuation of it on the key, and I I want to skip the go to the second question that once again I would say, Um, the

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02:39:53.190 --> 02:39:59.690

Subramanian Gunasekaran: the ar you see, committee would be the the

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02:39:59.700 --> 02:40:12.720

Subramanian Gunasekaran: yeah. I think over that I would say that I have been in the industry, as I told for decades, and I have seen when a product was called as a dressing,

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02:40:12.820 --> 02:40:31.560

Subramanian Gunasekaran: and then, in order to have the the bursting material, has a biological, degradable um sense. Then it would be, you know it was called at the time.

732

02:40:31.570 --> 02:41:00.780

Subramanian Gunasekaran: Um! The skin substitute. And now it is going by going again. I a change, don't you manage a product? I think that is unnecessary, in my opinion, and that has to be ah ah! Considered I I think with this I don't know. Ah, I have time to answer the other questions, but with this I I close my um comments, and I wish all the best for this. Ah! The Town Hall meeting,

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02:41:00.790 --> 02:41:15.279

Subramanian Gunasekaran: to make the proper decision to move forward with the positive note with the intention of improving our health care system. Thank you. Thank you, and you are at time, but we appreciate your remarks.

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02:41:15.440 --> 02:41:16.740

Thank you.

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02:41:18.160 --> 02:41:27.319

Zehra Hussain: So, because we have gone through the alternate presenters list, we will no longer be having any presentations at this time,

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02:41:27.410 --> 02:41:48.670

Zehra Hussain: and just wanted to thank everyone for their time. We really on behalf of Cms. We really do appreciate these recommendations and your comments, especially as we approach the upcoming rulemaking cycle. So we would like to thank everyone for their time for taking the time to really think out these thoughtful comments and

recommendations,

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02:41:48.680 --> 02:42:07.419

Zehra Hussain: and just some closing remarks. I just want to reiterate that if you were interested in providing a response, and you were not able to present during today's Town Hall, you can submit your responses or presentations to Medicare Physician fee schedule at Cms. Dot

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02:42:07.430 --> 02:42:10.310

Zehra Hussain: and I will put this in the chat

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02:42:10.660 --> 02:42:20.869

Zehra Hussain: and to address a lot of the questions we've been receiving today about the recording and transcript. These will be available, and we will make it publicly available,

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02:42:20.880 --> 02:42:33.550

Zehra Hussain: and we do plan on posting this on the Pfs website. However, when we do so, we will make sure to outreach to participants, and that way you all have access to the recordings and the transfers.

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02:42:33.690 --> 02:42:45.150

Zehra Hussain: And if you also have any other written comments, you would like to submit to the physician fee schedule. Please do so also. At this email before February tenth, two thousand and twenty-three.

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02:42:45.450 --> 02:42:55.170

Zehra Hussain: This ends today's Town Hall session, and again on behalf of everyone here at see me at Cms. Thank you all for your participation today in the skin substitutes Town Hall.