

Centers for Medicare & Medicaid Services
Organ Procurement Organization Public Information Session
Wednesday, October 12, 2022
1pm-2pmET

Recording:

https://cms.zoomgov.com/rec/share/Qmx8CZQjeweUwqYEpYzZSq1TIA_GBPJgiWM5yopO44cMQFch8ByRIh1ZMc9oD2_0.aSO8M5Bglk7uhcpg

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Jean Moody-Williams: Thank you all for joining the call today. Before we get started, I want to share a few housekeeping items. This session is being recorded and it will be posted on the CMS transcript and podcast page and at least the first part of it will be. Not necessarily the Q&A. All participants will be muted throughout the call and closed captioning is available via the link at the close captioned window. Today's call is closed to the press. We have a full agenda for you today and we are eager to hear from you. In the event that we are not able to get to all of the comments today, there is an opportunity for you to submit written feedback and that email address is going to be provided in the chat QSOG_OPO@cms.hhs.gov if you would like to have written comments, and with that, I will turn over to Dr. Lee Fleisher who is the director of the Center for Clinical Standards and Quality and he will get us started.

Lee Fleisher: I will be very quick and I will speak at the end but it is a pleasure to be joined today by Jonathan Blum. I will let Jon open today's meeting.

Jon Blum: We are really happy to be here today to talk about how we see the program going forward. CMS finalized new regulations during 2020 to hold OPO to a higher standard focusing on quality and improvement and more equitable results for organ transplants. We at CMS have a huge commitment to hold true to those rules and also to share data and talk about best practices. One of the principles we have at CMS that we don't want to surprise organizations and we want to make sure they understand where they sit with data results, have an opportunity to correct it, to improve. And as we move forward to fulfill these new regulations, we want to make sure that we are being open and communicative to share results and to take any questions. Our goal is for organizations to be at the highest tier and it is not a good result for CMS and our partners and beneficiaries to have OPO in tier 3 categories. CMS will move forward to compete those regions where we have performance issues but before we get to that, we want to make sure that we are being as clear as possible and as transparent as possible and to have conversations like this where we can say, here is the data that we see and tell us whether we are right based on the standards. Then have an opportunity to talk through the best pathways to ensure our organizations are at the highest possible tiers. That's the spirit of today's conversation. We intend to have more reform in an attempt to engage directly with organizations that are at tier three status. The goal that we have is better outcomes and more equitable outcomes and a true conversation for how we work together to see the best possible pathways for improvement. I want to thank everyone for joining us and this is the first of several conversations that we will have going forward and I think the CMS team and I thank our HRSA colleagues and I thank you for coming to this conversation in the spirit of what is best for CMS beneficiaries and all patients and to promote better health care outcomes for the whole country. Let's go back to Lee who will guide us through today's program.

Lee Fleisher: I really want to echo your personal commitment to monitoring and connecting with your OPO leadership. I also want to echo one of your comments thanking the CMS and HRSA teams as one of the key things you will see for those who are here today is that the joint commitment for CMS and HRSA to work together to improve the overall transplant ecosystem. Our goal is for every OPO to meet minimum health and safety standards that must be met by providers and suppliers participating in Medicare and Medicaid programs. There are high expectations from CMS and stakeholders in Organ Procurement and transportation and, most importantly, the true North, our patients deserve the best opportunity to receive a high-quality transplant. We know that tackling the challenges of the transplant ecosystem is larger than the work CMS regulates. I am joined by colleagues to start this dialogue and we will be data driven, encouraging the sharing of the bright spots we see from the data. While you will hear from the federal team for the first half of this call, we will spend the second half listening to you. We encourage all of you to share your best practices that you're implementing. Tell us how you are using programs to drive improvement, including ensuring more equitable transplant ecosystem and share with us the anticipated challenges and barriers and as Jon noted, we always like to hear from all the stakeholders. With that, I will turn it over to Chris to speak next.

Chris McLaughlin: I am Chris McLaughlin. I am a senior advisor within the health system Bureau at HRSA. Our oversight of the system is really driven by three prongs. The first is statutory framework that was provided by the national organ transplant act which established the Organ Procurement transportation network. We have an OPTN (Organ Procurement and Transportation Network) final rule regulation which outlines expectations for the OPTN and SRTR (Scientific Registry of Transplant Recipients) and the authorities those organizations have. HRSA maintains contracts with both the OPTN and SRTR. We work very closely with CMS and have been for quite some time and in all aspects of oversight of the system and policymaking to performance monitoring and adverse event reporting and within the last year set up a new agency wide collaborative group that is known as the organ transplantation affinity group to formalize the relationship and make that relationship effective. I will hand over the presentation to Jean Williams.

Jean Moody-Williams: I appreciate all the comments that have been made and I think everyone knows that CMS is involved with Organ Procurement in a number of different ways, first through our payment mechanisms and our conditions and requirements of participation, survey and oversight and the quality measures of recording and our innovation models that continue to work to improve kidney health and there are other areas as well. The team will speak to you shortly about the current and future state of our oversight through survey requirements. Most of this call is dedicated to looking at the certification process and how we prepare over the next several years for that cycle. We are happy to hear about other areas outside of this call. I wanted to spend a minute to tell you about the charge that we have from the secretary as well as the administrators of both HRSA and CMS to work in a formal way to align efforts to make improvements in the organ transportation system. Both HRSA and CMS formed an affinity group about a year ago to find joint opportunities. I spoke about this at the SRTR consensus conference. We are taking a complete systems approach with a view of all of the parties involved from beginning to end and you encouraged us to do this, not to just look at one segment but to look at the system as a whole. This is what our charge has been. We

have come up with an action plan that we are sharing with our sister agencies now outside of CMS to get their input. We will come to the public and we will make it public and get your thoughts and ideas. There are no surprises in the action plan and it aligns well with the recent release of the NASEM report. We will be giving you more information about this because we recognize like anything of importance that we do as a country, there is no one agency or Association or one connection that can do it alone. We shall work together to achieve joint goals and I know this can be achieved on behalf of those we serve. We will get more information to you but we want to turn back to the survey and certification cycle and I will turn to my colleagues. Roxane will give a brief five minutes of the current cycle of the survey process which most of you have received your reports and Annette is going to talk about the future cycle. It is not future anymore because it began last month, in August, but where we go from here. Then, we will stop talking and listen to you. We sent out questions ahead of time and I will tell you when we will queue it up. Anyone who wants to speak on those questions or other items will be able to do so at that time- after we hear from Roxanne and Annette.

Roxanne Rocco: I will provide a brief summary of the 2022 recertification cycle. CMS performs unannounced recertification surveys for OPO at least every four years. The purpose of the survey process is to determine whether the OPO meets all applicable statutory and regulatory requirements. Certification, compliance with Federal requirements is accomplished through observation, interviews, document and record reviews. OPO agreements are renewed following determination of full compliance with participatory requirements. CMS concluded the 2022 recertification survey process this past July. All 57 OPO were re-certified. We noted that 35 of 57 or roughly 61% of OPO survey has standard level deficiencies cited. No condition-level deficiencies were identified during the recertification period.

We identified that 24 of the 35 OPOs with deficiencies cited this year had deficiencies cited in 2018 during the last recertification cycle. As you can see from the slides, the three most frequent standard level deficiency fell under the following two conditions for coverage: administration, governing body and evaluation and management of potential donors and organ placement recovery. Z085, Administration governing body requires an OPO to have an advisory board and that means the authority and membership requirements. Z 094 requires bylaws for each of his board that address potential conflicts of interest, length of terms and criteria for selecting and removing members. Z191, donation after cardiac death, requires OPO's to have criteria and follow the criteria for declaration of death and time period that must elapse prior to organ recovery. Key takeaways, CMS is monitoring trends in citations and performance, and we will continue to do so as we move closer toward 2026 recertification cycle. We will continue to address complaints timely and initiate surveys as often as necessary to ensure compliance with requirements. As Jean mentioned, there is going to be more ongoing collaboration with our partners and QIOs, working together to monitor trends. I will now turn it over to my colleague, Annette Snyder, who will provide an overview on the performance measures.

Annette Snyder: We have just completed a 2020 cycle and beginning August 1, we have entered into the 2026 cycle which comprises the years of 2023 through 2026. August 1st actually kicks off this cycle and begins the full implementation of the final rule of new measures that we will talk about. There are now two measures, formally, we have three and the two measures are in effect as of August 1 are donation rate and transplantation rate. What has changed is that

the donation rates is now using it as the denominator, deaths identified by the multiple cause of death file from the CDC. That is a file published annually and it is published 12 months after the close of the data year. We receive the death support given year 12 months after the file closes. The transportation rate is the number of organs transplanted divided by the number of organs prepared by the OPO. While we don't have the third measure on pancreatic and islet cells for research, those are still included in these calculations as part of the transplant rate. Based on the scores on these two measures, OPOs are placed into one of three tiers. The top-tier and they are relative to each other rankings of the 57 OPOs. The top 25% are in tier one and below the top 25% but above median is tier two and falling below the median places the OPO at tier three. This recertification cycle which will come due in 2026, other tier one OPOs will be recertified for four years given that they are also compliant with the remaining conditions for certification. Tier two OPOs have to compete to retain their DSA and they are eligible to compete to other eligible DSAs. Tier three OPOs are automatically decertified. They can't compete for a DSA but they may appeal. To compete, an OPO must be recognized as an OPO certified by CMS and they must be performing at a tier one or tier two based on the outcome measures of 486.318 and they must be compliant with the other conditions of coverage. As we proceed, as noted, we began the 2026 survey cycle August 1 and in the interim years of 2023 through 2026, OPOs will receive an annual report based on their scores on the two outcome measures. *{Note updated slide for this section including with public posting}* The transplantation rates and being placed in a tier of each year. It is an expectation and we have language in the rule that OPOs will incorporate the knowledge from these reports in their QAPI activities. QAPI has always been part of our regulations and we have specifically stated that it is expected that outcome reports will be reflected in that work. The next survey cycle will begin in January 2026 and continue through July 31, 2026. Thank you very much.