Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare, Centers for Medicare & Medicaid Services

Answers to Questions for the Record
Subcommittee on Health
House Committee on Energy and Commerce
What's the Prognosis?: Examining Medicare Proposals to Improve Patient Access to Care & Minimize Red Tape for Doctors

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U.S. House Committee on Energy & Commerce, Subcommittee on Health
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Thursday, October 19, 2023
Questions for the Record

The Honorable Earl L. "Buddy" Carter

1) Dr. Seshamani - What can CMS do to improve the availability of specialty-developed APMs, and how will the agency make sure that other models, like ACOs, provide relevant, meaningful engagement opportunities for specialists?

2) Dr. Seshamani - Considering the low participation of surgical specialties in alternate payment models and the goal of moving everyone to an APM by 2030 – how is CMS working to ensure greater APM participation across all medical specialties?

Answer (1-2):
We appreciated Congress' work to extend incentive payments for clinicians who are qualifying participants in advanced alternative payment models through 2025, which we believe has helped serve as an incentive to clinicians of all types, including specialists. CMS is further driving quality care and advancing value by linking clinician payment to performance on certain metrics. As you know, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program, which consists of two participation tracks: Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). Through MIPS, CMS is authorized to implement positive, neutral, or negative payment adjustments based on a clinician or group's performance in four categories: Quality, Cost, Improvement Activities, and Promoting Interoperability. In the Advanced APM track, clinicians participating sufficiently in certain advanced alternative payment models, such as the Medicare Shared Savings Program and certain Innovation Center Models, receive lump sum APM Incentive Payments.

CMS is working within the statutory framework provided by Congress to cohesively advance these programs (traditional MIPS, Shared Savings Program and Advanced APMs) through the alignment of metrics, reduced burden, and a transition to the use of interoperable data and data systems, as well as layered incentives where feasible. In addition, CMS has aligned primary care metrics across these programs, and is leveraging the new MIPS Value Pathways (MVPs). MVPs are sets of measures and activities related to a given specialty or episode of care that may allow for a more meaningful assessment of clinicians' performance. An MVP is designed with a given specialty and medical conditions in mind and groups measures and activities to ensure a more coherent assessment of the quality of care that a specialist may provide. MVPs are developed with extensive input from stakeholders and specialty groups. CMS also proposed changes to align the Quality Payment Program with the Universal Foundation, to drive change more effectively. This Universal Foundation of quality measures will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross- comparisons across programs, and help identify measurement gaps.

The Center for Medicare and Medicaid Innovation (Innovation Center) published the Strategy to Support Person-centered, Value-based Specialty Care in November 2022, including the goals of supporting specialists to further embed in primary-care focused models and creating incentives within population-based models to encourage specialty care integration. In July 2023, the Innovation Center issued a Request for Information that sought input from the public regarding the design of an episode-based payment model, including how best to integrate specialty care.

3) Dr. Seshamani - when Congress first passed a law to create Medicare's home infusion benefit, the Congressional Budget Office estimated that Medicare would produce significant savings for taxpayers and patients by transitioning millions of infusions from institutional facilities to the home setting. However, as we've seen in the data released by your agency, that transition simply hasn't happened. Given the potential benefits for both cost savings and patient quality of life, will your agency commit to working with Congress to address the challenges that have limited the availability of home infusion services?

Answer:
CMS believes that people should be able to receive care in the most appropriate setting for their needs. The Medicare home infusion therapy benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment (DME) benefit), remote monitoring, and monitoring services for the provision of home infusion drugs, furnished by a qualified home infusion therapy supplier in the individual's home. The home infusion therapy services are covered for the safe and effective administration of certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is an item of DME. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the DME benefit. CMS would be happy to work with you on this issue.

The Honorable John Joyce

Dr. Seshamani – Recently, CMS had to intercede and ensure that on October 1, three Medicare Administrative Contractors did not implement new Local Coverage Determinations (LCDs) that would have cut off Medicare patient access in Pennsylvania and 14 other states to more than 100 products within the "skin substitutes" category, including some products that are leaders in the marketplace and that have for several decades substantially helped diabetic patients with chronic wounds. One stakeholder concern was that some restrictions only appeared in the final LCD and offered no opportunity for public comment.

I am grateful that CMS Headquarters convinced its contractors to withdraw the LCDs and to restart the rulemaking process. It seems quite inefficient for these contractors to go down a problematic pathway and to start to cause providers to change their ordering habits just to pull back at the last minute.

1) Do you believe that your regional contractors are taking sufficient care when they develop new LCDs and that they are engaging in sufficient stakeholder discussions before finalizing their new regulations?

2) Are you confident that the three contractors will avoid taking the same approach as they revisit this LCD issue in the coming months?

Answer (1-2):
Under the Medicare statute, Medicare Administrative Contractors (MACs) are authorized to develop LCDs in the absence of national policy or if the LCDs do not conflict with a national policy. The MACs develop LCDs in accordance with chapter 13 of the Program Integrity Manual (Internet-Only Manual Publication Number 100-08), which lays out an open and transparent process the MACs must follow. The process requires the MACs to have a summary and analysis of the evidence section within their LCDs, a bibliography of the evidence reviewed, and a Response to Comments article.

As you noted, on September 28, 2023, it was announced that the Skin Substitute Grafts/Cellular and/or Tissue Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCDs and referenced articles will be retired and will not go into effect on October 1, 2023. Therefore, current coverage will not change, and the existing LCDs will remain in effect. The MACs intend to publish new proposed LCDs in the future. All proposed LCDs will follow the LCD standard process, which includes a public comment period and a public Open Meeting.

The Honorable Dan Crenshaw

1) Dr. Seshamani, the CMS Innovation Center found that only six of the more than 50 models it tested in its first decade produced statistically meaningful financial savings. Is there a systemic or programmatic reason for this? Do you see promise in direct contracting for Medicare and the models that currently take this approach? Will that help with savings?

Answer:
One of CMS' top priorities is to drive innovation to tackle our health system challenges. The CMS Innovation Center is critical to achieving this vision, as we work to drive high-quality, affordable, person-centered care for beneficiaries. In 2021, the Innovation Center launched a new strategy that builds on the lessons learned over the last decade. The first ten years of testing and learning have laid a strong foundation for the Innovation Center to lead the way towards broad and equitable health system transformation. Each model we have tested has yielded important policy and operational insights, helping to address continued challenges with health costs and quality of care.

In this second decade, we are focused on using everything we have learned so far to test new models to drive higher-quality, more efficient care to improve outcomes for patients and reduce disparities. We believe changing care delivery in ways that improve quality and reduce costs will improve outcomes in the long run and those changes might spread to other parts of the system in ways we're not yet detecting.

We have systematically reviewed a decades' worth of evaluation reports for common threads and themes across models that resulted in changes and posted these "synthesis" reports on our website.

Our newly-announced models are aligned with our strategy and our intent to drive improvement by decreasing expenditures and improving quality. For example, the Making Care Primary Model, an advanced primary care model, the States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model, a model to collaborate with states to curb health care cost growth, and the current ACO Realizing Equity, Access, and Community Health (ACO REACH) Model are all focused changes in care delivery that can improve quality or reduce costs. We anticipate our current and future models will have a substantial positive impact on beneficiaries' care experience and clinical outcomes while generating savings.

The Honorable Diana Harshbarger

Dr. Seshamani: In its final 2024 IPPS rule, the Centers for Medicare & Medicaid Services (CMS) recently restored program integrity protections for Physician-Owned Hospitals, emphasizing that it is important for the Agency to continue: "protecting the Medicare program and its beneficiaries, as well as Medicaid beneficiaries, uninsured patients, and other underserved populations, from harms such as overutilization, patient steering, cherry-picking, and lemon-dropping."

1) In your view, would the discussion draft legislation before the subcommittee in effect reverse your recent actions and how would this impact quality of care in rural communities?

Answer:
As part of the Fiscal Year 2024 IPPS final rule CMS reinstated the program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity as they apply to high Medicaid facilities. CMS believes that not applying the program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity to high Medicaid facilities poses a significant risk of program or patient abuse. Additionally, CMS believes that treating all hospitals the same under the expansion exception process by applying the program integrity restrictions to both applicable hospitals and high Medicaid facilities will promote consistency among decisions to approve or deny expansion exception requests. CMS considers the factors outlined in § 411.363(i)(2) when deciding to approve or deny an expansion exception request, which, in addition to program integrity, also include quality of care concerns related to the hospital, the specialty of the hospital, and the needs of the hospital and its surrounding community. I am not able to comment on specific legislation, but CMS is happy to provide technical assistance.

2) Dr. Seshamani: A central goal of MACRA was to move us away from a fee-for-service health care model to a system of value-based payment through the use of alternative payment models. Unfortunately, many specialty physicians wishing to move beyond fee-for-service will find that not a single physician-focused alternative payment model is available because none of the models approved by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) have been tested as proposed. While numerous proposals have been recommended for testing or implementation by the PTAC, CMMI has not moved forward with any of them. Dr. Seshamani, how can Congress move the needle to make sure value-based care models for specialty medicine are put into practice?

Answer:
One of CMS' top priorities is to drive innovation to tackle our health system challenges. The CMS Innovation Center is critical to achieving this vision, as we work to drive high-quality, affordable, person-centered care for beneficiaries. In 2021, the Innovation Center launched a new strategy that builds on the lessons learned over the last decade. The first ten years of testing and learning have laid a strong foundation for the Innovation Center to lead the way towards broad and equitable health system transformation. Each model we have tested has yielded important policy and operational insights, helping to address continued challenges with health costs and quality of care.

In this second decade, we are focused on using everything we have learned so far to test new models to drive higher-quality, more efficient care to improve outcomes for patients and reduce disparities. We believe changing care delivery in ways that improve quality and reduce costs will improve outcomes in the long run and those changes might spread to other parts of the system in ways we're not yet detecting.

We have systematically reviewed a decades' worth of evaluation reports for common threads and themes across models that resulted in changes and posted these "synthesis" reports on our website.

The Innovation Center's vision for broad health system transformation is ambitious and requires collaboration with and actions by a wide range of stakeholders. When designing new payment and service delivery models, the Innovation Center actively seeks input from a broad array of stakeholders across the country. The Innovation Center sees the PTAC as an important partner in our efforts to move towards value-based care and is committed to taking under serious consideration all proposals submitted by the PTAC. The Innovation Center has responded to all recommendations from the PTAC. Additionally, we have incorporated components of PTAC proposals into a number of our models. For example, during the pandemic, the Innovation Center used the PTAC's expertise and its efforts as a convener of practitioners to give guidance to the Innovation Center on key themes for model testing, including care coordination and specialty integration. The Innovation Center intends to carefully review any future PTAC proposals and work closely with the PTAC to obtain their input on key concepts and evidence generation for future models.

The Honorable Mariannette Miller-Meeks

1) Dr. Seshamani, while I understand that you likely cannot answer fully today, I am concerned that a lot of our joint efforts towards value-based care may have had an unintended effect of consolidation in the physician community. Can you assure me that CMS is working to ensure that the dollars allocated by Congress for APM bonuses, which result from the quality work of physicians, are going actually benefiting those doctors who are participating in these models, rather than to the entities such as hospitals or insurers that either employ them or contract with them in those models?

Answer:
We appreciated Congress' work to extend incentive payments for clinicians who are qualifying participants in advanced alternative payment models through 2025.

We note that CMS shares your concern about health care provider consolidation, which is why CMS has taken steps to address consolidation, such as releasing ownership information on health care providers and promulgating regulations designed to enhance healthcare price transparency to drive competition through its Hospital Price Transparency and Transparency in Coverage initiatives.

CMS is further driving quality care and advancing value by linking clinician payment to performance on certain metrics. As you know, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program, which consists of two participation tracks: Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). Through MIPS, CMS is authorized to implement positive, neutral, or negative payment adjustments based on a clinician or group's performance in four categories: Quality, Cost, Improvement Activities, and Promoting Interoperability. In the Advanced APM track, clinicians participating sufficiently in certain alternative payment models receive lump sum APM incentive payments. Per Medicare regulations, CMS makes APM incentive payments to the Tax Identification Number (TIN) associated with clinician's Part B claims. *See* 42 C.F.R. § 414.1450. These TINs can be for individual clinicians or for entities, such as group practices or hospitals. The nature of physician compensation from entities with which they contract is ultimately a private matter outside the scope of CMS's authority.

2) Dr. Seshamani, over 66 million Medicare beneficiaries receive services under the DMEPOS benefit. The benefit allows patients to receive medically needed treatments such as oxygen, wheelchairs, and medical supplies in the comforts of their homes, keeping them out of expensive in-patient settings such as hospitals and nursing facilities. Due to the implementation of the DMEPOS competitive bidding program, which applied pricing derived from highly populated competitive bidding areas to all areas of the country, there has been a significant decrease in payment rates which caused a significant number of DMEPOS location closures. Just this last year, about 11% of DMEPOS locations closed, furthering diminishing beneficiary access to DMEPOS suppliers. The loss ultimately leads to far less patient access and choice. The bid program was put on hold in 2018 due to a need to update the bidding process and it was put on hold again in 2020 due to no additional savings. In all, the bid program has been on hold for the last 5 years, resulting in DMEPOS payments continuing to be based on rates from the flawed bidding program. My legislation. H.R.5555, which I am proud to be leading with Congressman Tonko, would provide much needed rate relief in former bid areas and non-rural areas, which will help protect patient access to cost-effective home-based care. Will CMS commit to working with me on this important issue?

Answer:
The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). The CARES Act increased the payment rates to a 75/25 blend for durable medical equipment (DME) and enteral nutrients, supplies, and equipment furnished in areas other than rural and non-contiguous non-CBAs through the duration of the

COVID-19 Public Health Emergency (PHE) period. CMS will continue to monitor payments in all non-CBAs, as well as health outcomes, assignment rates, and other information. CMS is happy to work with you on this issue moving forward.

The Honorable Debbie Dingell

As we focus on improving patient access to care, I want to talk about how we're working to expand access to health care beyond a traditional doctor's office or hospital setting. The fact is—patients don't want to have to travel to a doctor's office when they don't have to. And this is especially true for patients with cancer, heart failure, autoimmune disease, and other conditions who may need routine treatments over the course of an extended period. However, despite Congress' intent, the Centers for Medicare and Medicaid Services have improperly implemented the benefit for Medicare Part B home infusion drugs by requiring a nurse to be physically present in the patient's home in order for providers to be reimbursed. As a result, provider participation in this important benefit has dropped, and beneficiaries have experienced reduced access to home infusion.

1) Dr. Seshamani, how does access to home-based care — and specifically, home infusion — fit into the agency's approach to expanding patient access to medical care for Medicare beneficiaries? When you look at the commercial market, private insurance plans are recognizing that access to home infusion services is vital to maintaining quality of life for patients with transportation challenges, mobility issues, and those living in rural settings who are unable to easily access traditional health care centers.

2) Dr. Seshamani, data released by your agency in both the 2022 and 2023 Home Infusion Therapy Monitoring Reports suggest that Medicare is lagging significantly behind the commercial market in promoting access to home infusion services. Can you commit to working with Congress to address these gaps in access which appear to be unique to the Medicare program?

3) Dr. Seshamani, can you briefly elaborate on any current models of care that help high needs and home-bound populations receive the personalized care services they need?

Answer (1-3):
CMS believes that people should be able to receive care in the most appropriate setting for their needs. The Medicare home infusion therapy benefit covers the professional services, including nursing services, furnished in accordance with the plan of care, patient training and education (not otherwise covered under the durable medical equipment (DME) benefit), remote monitoring, and monitoring services for the provision of home infusion drugs, furnished by a qualified home infusion therapy supplier in the individual's home. The home infusion therapy services are covered for the safe and effective administration of certain drugs and biologicals administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual, through a pump that is an item of DME. The infusion pump and supplies (including home infusion drugs) will continue to be covered under the DME benefit. The home infusion therapy services benefit provides a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the

infusion therapy services furnished in the patient's home by a qualified home infusion therapy supplier.

Through the Innovation Center, CMS is testing a variety of innovative payment and service delivery initiatives aimed at finding ways to deliver better, more equitable care at lower costs. As the nation's largest payer for health care, CMS plays a key role in incentivizing high-quality care and smarter spending across the industry. The vision of the Innovation Center's work is a health system that achieves equitable outcomes through high-quality, affordable, and person-centered care. Over the last several years, providers and suppliers participating in Innovation Center models have made important progress in transforming our nation's health care system into one that works better for everyone and rewards value over volume. Several of the Innovation Center's models focus on the care of high need and homebound populations. For example, the recently announced Guiding an Improved Dementia Experience (GUIDE) model focuses on dementia care management and aims to improve quality of life for people living with dementia, reduce strain on their unpaid caregivers, and enable people living with dementia to remain in their homes and communities. The Enhancing Oncology model also includes Medicare payment for post-discharge home visits and care management home visits with the goal of putting the patient at the center for a care team that provides equitable, high value, evidence based care.

The Honorable Annie Kuster

1) I understand that the Medicare Clinical Laboratory Fee Schedule covers testing for critical conditions such as diabetes, heart disease, cancer, and infections. Do you think continued access to clinical lab tests is important for ensuring doctors have the information they need to provide care? Additionally, what would happen to payment for these laboratory services, under the fee schedule, if Congress does not pass the Saving Access to Laboratory Services Act?

Answer:
We share your goal of ensuring access to clinical laboratory services for Medicare beneficiaries. CMS follows the statute with respect to the Clinical Laboratory Fee Schedule (CLFS). Consistent with the law, for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. We estimate 14.8 percent (191) of tests on the CLFS may be subject to the full 15 percent phase-in reduction in CY 2024.

2) Pharmacists have played an important role in delivering vaccines and medications, particularly in underserved and rural areas, throughout the COVID-19 pandemic. The Equitable Community Access to Pharmacist Services Act would create a Medicare reimbursement pathway for pharmacists in states that already allow them to deliver such services. Do you agree that advancing such legislation fits well within the goal of improving patient access to care for Medicare patients?

Answer:
CMS agrees that pharmacists play a critical role in the health care delivery system, especially in rural and underserved areas. Under current law, pharmacists do not have provider status under

Medicare Part B. However, pharmacists can act as auxiliary personnel to provide services incident to the professional services of a Medicare-enrolled physician or nonphysician practitioner who supervises and bills for the services if payment for the services is not made under the Medicare Part D benefit. This includes providing services incident to the services of the Medicare billing physician or non-physician practitioner and in accordance with the pharmacist's state scope of practice and applicable state law. CMS also permits an entity or individual who wishes to furnish certain Part B preventive vaccinations -- but may not otherwise qualify as a Medicare provider -- to enroll as a "Mass Immunizer." While I am not able to comment on specific legislation, CMS is happy to provide technical assistance on this bill.

The Honorable Nanette Diaz Barragán

1) Dr. Seshamani, year after year, we are hearing growing concerns that the Medicare program is consistently implementing policies that result in cuts to reimbursement under Medicare's physician fee schedule for equipment intensive therapies, such as radiation therapy for the treatment of cancer. We understand that nearly two-thirds of all new cancer cases are diagnosed in the Medicare population. What are the steps, if any, that CMS can take to ensure there is adequate reimbursement for radiation oncology treatments to protect patient access to radiation therapy in all communities across the United States, including low-income communities?

2) Dr. Seshamani, we are hearing concerns that Medicare's hospital programs for innovative technologies—the transitional pass-through program in the hospital outpatient setting and the new technology add-on payment (NTAP) program in the hospital inpatient setting—have failed to embrace new technologies used to treat cancer patients with radiation therapy. What steps can CMS take to protect Medicare beneficiaries who require access to transformative innovations in radiation therapy under the Medicare program?

Answer (1-2):
We are committed to promoting higher quality cancer care and improving outcomes for Medicare beneficiaries while reducing costs. As part of that effort, the Biden Administration has taken a number of efforts to improve the care of Medicare cancer patients, most notably with the President's cancer agenda and the Cancer Moonshot.

Medicare payment policy is set by Congress, and CMS works within the confines of the law to establish payment polices for physicians and other health care professionals. As part of the CY 2022 Medicare Physician Fee Schedule final rule, CMS finalized a proposal to update the clinical labor rates for CY 2022. Clinical labor rates were last updated in CY 2002. There had been considerable stakeholder interest in updating the clinical labor rates, and when we solicited comment on this topic in past rules, such as in the CY 2019 PFS final rule (83 FR 59480), stakeholders supported the idea. In particular, a number of interested parties suggested that certain wage rates were inadequate because they did not reflect current labor rate information. Therefore, we updated the clinical labor pricing for CY 2022, in conjunction with the final year of the most recent supply and equipment pricing update. We believe it is important to update the clinical labor pricing to maintain relativity with the recent supply and equipment pricing updates. The final policy updates the payment rates through the addition of a four-year transition period

as requested by public commenters. We believe the four-year transition to incorporate new pricing data will help provide payment stability and maintain beneficiary access to care.

Additionally, as part of the CY 2024 Medicare Physician Fee Schedule final rule, CMS finalized coding and payment changes to better account for resources involved in furnishing patient-centered care involving a multidisciplinary team of clinical staff and other auxiliary personnel. These finalized services are aligned with the HHS Social Determinants of Health Action Plan and help implement the Biden-Harris Cancer Moonshot goal of every American with cancer having access to covered patient navigation services. Specifically, we finalized a policy to pay separately for Community Health Integration, Social Determinants of Health Risk Assessment, and Principal Illness Navigation services to account for resources when clinicians involve certain types of health care support staff such as community health workers, care navigators, and peer support specialists in furnishing medically necessary care. Community Health Integration and Principal Illness Navigation services involve a person-centered assessment to better understand the patient's life story, care coordination, contextualizing health education, building patient self-advocacy skills, health system navigation, facilitating behavioral change, providing social and emotional support, and facilitating access to community-based social services to address unmet social determinations of health (SDOH) needs.

The Hospital Outpatient Prospective Payment System (OPPS) pass-through and Inpatient Prospective Payment System (IPPS) NTAP collectively incentivize hospitals to quickly adopt and promote beneficiary access to innovative technologies through additional payments. Sections 1886(d)(5)(K) and (L) of the Act establish the process of identifying and ensuring adequate payment for certain new medical services and technologies under the IPPS. The OPPS transitional pass-through provisions are established under section 1833(t)(6) of the Act. The intent of the OPPS transitional device pass-through payment is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the overall procedure payment rate (66 FR 55861). A criterion for both NTAP and OPPS pass-through is that the device will substantially improve, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the CY 2020 and FY 2021 annual rulemaking processes for the OPPS and IPPS, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation, under which these devices are not evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining NTAP or pass-through eligibility but do need to meet the other requirements.

Additionally, regulations at § 412.87 outline eligibility criteria for an alternative pathway for additional payments for certain innovative antimicrobial products. This pathway is available to: a new medical product designated by FDA as a Qualified Infectious Disease Product (QIDP) that has received marketing authorization for the indication covered by the QIDP designation; or for discharges occurring on or after October 1, 2021, a new medical product that is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway.