Centers for Medicare & Medicaid Services
COVID-19 Fourth Interim Final Rule with Comment (IRF-4)
National Stakeholder Call
October 30, 2020
12:30 p.m. ET

Operator: This is Conference #: 1069572.

Alina Czekai: Good afternoon and thank you for joining our CMS COVID-19 call to discuss the agency's Fourth Interim Final Rule with Comment, also known as the IFC-4.

On today's call, we'll be joined by a number of our subject matter experts to answer your questions related to IFC-4. And we also encourage you to join our Office Hours, which will take place next Tuesday, November 3rd at 5 p.m. Eastern.

It's now my pleasure to introduce CMS Administrator Seema Verma. Administrator, over to you.

Seema Verma: Thank you, Alina. Thank you all for joining today's call on CMS' comprehensive strategy on vaccine coverage and therapeutics.

This week, we announced our Fourth Interim Final Rule during the COVID public health emergency as well as the set of toolkits for providers, states, and insurers. The toolkits provide critical, understandable information on vaccine coverage and administrations, Medicare reimbursement, and how to enroll in Medicare to administer the vaccine.

Together, these announcements represent a crucial plank in the Trump administration's comprehensive strategy to ensure broad vaccine access and coverage for all Americans and to guarantee that seniors are prioritized for new COVID treatments and therapeutics.

Let me start with the rule. This is our fourth COVID-related regulation. The three prior ones, as many of you know, have relaxed regulations to accelerate telehealth revolution, allowed hospitals to expand their capacity, and boosted

our healthcare workforce. They've also placed new requirements on nursing homes, increased testing capacity, and provided flexibility to providers on the frontlines.

The rule in turn fulfils two of President Trump's highest priorities; guaranteeing that Americans have access to a COVID-19 vaccine at no cost when one becomes available and ensuring that potentially lifesaving therapeutics are available to seniors who need them.

Under normal circumstances, rules like these take about a year, so four in just over six months represents its really historic output for CMS and I'm grateful to the dedicated staff that have worked so hard to churn these rules out in record time.

The day a vaccine is approved by the FDA will be a great day in the history of our nation and the entire world. It will be a turning point in our war against this virus and mark the beginning of the end of the pandemic that has claimed too many precious lives and upended virtually everything.

With work on a vaccine progressing at a pace worth of the name, Operation Warp Speed, that may – that day may not be too far.

As you know, there are several vaccines in phase three trials. Production and distribution plans are well underway and CMS is doing its part by laying the essential groundwork for coverage and payment when a vaccine does arrive. So, it will be widely available and accessible to seniors and every American.

First, the rule establishes that any COVID-19 vaccine receiving Food and Drug Administration's emergency use authorization or standard approval will be covered by Medicare Part B as a preventative vaccine at no cost to Medicare beneficiaries.

This clarifies the regulation that Congress's intent in the CARES Act was to cover any vaccine authorized for use by the FDA regardless of its path. While the federal government is paying for the vaccine, insurers including Medicare, Medicaid, and private plans must cover the cost of administering it.

The rule removes any existing ambiguity around Medicare's coverage of the COVID-19 vaccine and allows us to focus on the paramount goal of ensuring that all of Medicare's 62 million beneficiaries including those enrolled in the Medicare Advantage Plan can receive the vaccine at the provider of their choice, again, at no cost.

Second, the rule requires that most private insurance plans including individual health plans and employer plans to provide both in-network and out-of-network coverage for the vaccine at no cost for their members. And this is going to represent about 200 million Americans.

In addition, providers who receive free COVID-19 vaccines from the federal government will be prohibited from charging consumers any additional cost for the administration of the vaccine beyond what their insurance covers. So, no surprise billing or balance billing for vaccines. That's going to be strictly prohibited.

To round out coverage across all of CMS' programs, the 68 million beneficiaries on Medicaid and the children's health insurance programs will also be covered for their COVID-19 vaccine cost free.

Additionally, for anyone without insurance, the government has worked to ensure that the vaccine's administration is free and will be using the Provider Relief Fund to cover these costs.

Third, the rule prepares for a new generation of COVID-19 treatments that may be approved or authorized by the FDA. The president has made clear that Medicare beneficiaries deserve timely access to therapeutics that have been proven to be safe and effective in treating those with COVID-19. Our job at Medicare is to make sure that as these medications enter the market, they can be immediately accessed by seniors who need them.

To that end, we are announcing changes to improve Medicare payment to hospitals for emerging COVID-19 therapeutics for both the inpatient and outpatient settings. This will eliminate financial disincentives that hospitals may face for furnishing potentially lifesaving treatment to American seniors.

Under our current rule, Medicare payments are fixed for services and treatments provided in the hospital inpatient settings. COVID-19 treatments have been handled under that traditional hospital payment or fixed reimbursement.

Traditionally, when a hospital's cost or a particular patient exceeds Medicare payment, the hospital can qualify for additional outlier payments but only after their costs exceed a threshold of about $30,000.

But under our rule, Medicare will pay an additional 65 percent of the cost for innovative COVID therapies authorized or approved by the FDA provided in the inpatient hospital settings when treatment costs exceed the Medicare payment up to that $30,000 threshold. And of course, if a hospital still exceeds the threshold, they can still qualify for an outlier payment.

So, in short, we are bridging the gap between the standard payment and the outlier payment. And the policy is modeled on how we traditionally handle payments for new technology, but this policy is unprecedented.

Unlike our current policy for new technology add-on payments that require a year-long application process, new COVID-19 therapeutics will automatically qualify for additional payment during the public health emergency after they've been approved by the FDA.

Now, for patients that received a COVID treatment in a hospital outpatient department such as an observation stay or emergency department visit, the rule will ensure that Medicare pay separately for the COVID-19 drug rather than having the drug cost bundled into the traditional hospital outpatient payment. And we're also putting out information on how administration for new infusion therapies designed for the outpatient setting could be billed in the event that one is approved or authorized by the FDA.

These efforts build on other financing methods that we've provided to hospitals to take care of patients with COVID-19 such as the 20 percent increase for COVID inpatient hospitalizations and Medicare as well as funding through the Provider Relief Fund.

By building the payment infrastructure ahead of time for both the future vaccine and future therapeutics, CMS is making sure that providers, both public and private, are uninhibited by the typical bureaucratic hurdles when vaccines and treatments are approved by the FDA.

The rule also delivers on another one of President Trump's priorities and that's price transparency. As many of you know, we released a large price transparency rule just yesterday that's going to require insurance companies to post all of their prices and is also going to require that they provide a personalized estimate for their members.

But this price transparency effort is around our test for COVID-19 and it's going to require that providers make the cash price of COVID-19 diagnostic test readily available to patients and that goes into effect right away.

Providers must already clearly post their cash price for COVID-19 test on their website. But if they don't have their own website, the rule requires to make the cash price available in writing within two business days and through signage. The rule is going to give CMS discretion to take additional enforcement action to ensure compliance with these transparency requirements. Providers that are noncompliant may be subject to civil monetary penalties up to $300 per day.

As I mentioned, we also released a new slew of toolkits on the vaccine to a range of stakeholders including providers, private insurers, and state Medicaid programs. The provider toolkit makes it clear that we're eager to securely enroll as many providers as possible in our program including those nontraditional ones in order to make the eventual vaccine as widely and conveniently available as possible.

The simple step-by-step process for provider enrolment is laid out in the toolkit and our hotline processes – process will validate requests within 24 hours. So, many novel immunization sites such as pharmacies and schools and other nontraditional or non-Medicare providers can host, enroll providers for vaccine administration.

The toolkits also provide current and perspective providers whether in Medicare or Medicare Advantage or Medicaid or private insurance with guidance on how to bill, handle new vaccine codes, and interact seamlessly with whatever payer under which they are operating. And we're working closely with the AMA to release specific billing codes for each vaccine.

In addition, these toolkits delineate exactly how much Medicare will pay for each dose in the vaccine series; $17 for the first one and $28 for the second. Now these rates are higher than usual for vaccines because they factor in the additional required reporting to the CDC and Operation Warp Speed as well as patient outreach and counseling to make sure that beneficiaries are receiving both the first and second round of the vaccines.

And we're hopeful that this information can be a tool for state Medicaid programs and private payers to simplify administrative burden and complexity for providers. So, hopefully, it will be a model for reimbursement for administering the vaccine.

Also, Medicare will also pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in Medicare Advantage. So, our MA plans will not be responsible for reimbursing providers who administer it.

Finally, CMS continues to support our state Medicaid program. To date, we've approved over 580 COVID-related waivers because states need flexibility to manage their programs during this pandemic. And that's why we're providing them with clear guidance on the requirements to maintain eligibility for enrolled beneficiaries, make changes to beneficiary coverage and cost sharing while continuing to receive the temporary increase in federal funding provided through the Families First Coronavirus Response Act.

The other piece of this is that there is a state Medicaid program toolkit which sort of goes over everything that they you need to know about vaccine administration. During the public health emergency, all of the vaccines are covered for all populations with no cost sharing. But after the public health emergency, states will have to review their coverage. And if they want to

make changes, we've laid out some of the required SPAs or waivers that they might need.

The COVID-19 pandemic has taken a dire toll on our country just as it has on countries around the world. And thankfully, the policies contained in this rule will provide clarity on coverage and take unprecedented and timely action to protect the Americans especially seniors and Medicaid beneficiaries. And they represent a definitive framework that will allow a vaccine combined with new therapeutics to bring the pandemic to a close.

Thank you. And with that, I'd be happy to answer your questions. And we're also joined by the CMS staff that can help answer any questions that you might have. Thank you.

Alina, do you want to open up the line?

Alina Czekai: Sounds great. Operator, can you please give instructions for questions? Thank you.

Operator: Thank you. At this time, I would like to inform everyone in order to ask a question, please press star one on your telephone keypad. Again, that is star one to ask a question.

We have your first question from a participant ending – phone number ending in 3354. Your line is open.

Male: Hi. Thank you. Thank you very much for this call and this presentation. I just had a quick question about the effective date of this interim final rule. When I was reading it, I saw that the effective date was the date that it was listed in the public – or I'm sorry – in the federal register. And I just wanted to double check that. It hadn't yet been posted there or if you can give any clarity on the effective date that would be great.

CMS - Jeff Wu: Hi, this is – this is Jeff Wu. I can take that question. Yes, so it has not posted yet. When it – when it posts with the federal register, that indeed will be the day. As folks probably know, it usually just takes a couple of days with federal register process and post. So, I think we anticipate that will happen

imminently and you're correct, as soon as that posting occurs, the rule is effective.

Male: Great. Thank you very much.

Operator: Again, if you would like to ask a question, please press star one on your telephone keypad. Again, that is star one to ask a question.

We have your next question from the participant's phone number ending in 1554. Your line is open.

Female: Hi, thanks for taking my call. You mentioned the pharmaceutical itself for the vaccine product and also the administration fee or the cost of administrating. Can you go – discuss a little bit about the coverage of the vaccine itself, the product versus the coverage of the administration of the product?

CMS - Seema Verma: So I'm going to take that question, so the cost of the actual vaccine is going to be covered by the federal government. We're already in contract with the manufacturers; production has already started. We're expecting about 100 million doses by the end of the year and 700 million by the beginning of the next quarter of next year. So, the announcement that we were making in the Medicare program was about the cost of administration of the vaccine.

So, in Medicare, we're covering that cost. Obviously, that's going to be covered in Medicaid and the rule also covered for private insurance companies, so they need to cover the cost of administering it. And if anybody is uninsured, the federal government will use the Provider Relief Funds to cover the administration cost.

Female: Thank you.

Operator: We have your next question from Kala Shankle. Your line is open.

Kala Shankle: Hi, thanks. This is Kala Shankle from the National Association of Chain Drug Stores. I have a question about the streamline process for enrolling new mass immunizers. Thank you for the expedited 24-hour process in the IFR

but the IFR does say that Medicare will be providing these enrollments, any new enrolled mass immunizers' information to state Medicaid programs.

And I was curious what is the significance of that for state Medicaid programs? Is that meant to – I guess just could you explain your thinking a little bit on that for the significance to state Medicaid programs to have that information on new mass immunizers?

CMS - (Sabine): Hi, this is (Sabine). I can take that question. So, what we're doing is that if a provider wants to be enrolled also in the Medicaid program, we're trying to make it easier by sharing any data that we have in Medicare with the state, so that they can process your enrollment that much quicker.

Kala Shankle: And I have a follow-up question to that. Have you heard from states that this information maybe sufficient enough for pharmacists or pharmacy to streamline their enrollment processing to the Medicaid program? Is there an understanding that if you're enrolled in Medicare that it might be sufficient at the state level as well?

CMS - (Sabine): I think it's going to depend on the state to state basis but they will leverage what they can. They most likely will reach out to the provider to get any additional information that they need or additional screening that they would have to do but they are able to leverage Medicare data to process the enrollment on their end.

Kala Shankle: OK. Thank you.

CMS - (Sabine): Sure.

Operator: We have your next question from the phone number ending in 0844. Your line is open.

(Dale Gibson): Hi, yes, this is Dale Gibson. I wanted to ask the question about Critical Access Hospitals. You were talking about how much cost is going to arise. Critical Access Hospitals are paid on a per diem based on cost from previous years. You know, with the COVID-19, their cost is going to be up during the timeframe when their per diem was established on probably lesser cost. Is

there any provision for Critical Access Hospitals or are they just going to have to make that up on the next cost report?

CMS - Female: Hi. I'm actually not sure we have the right folks to respond to that in detail on this call. We can – we can check with our colleagues and try and answer it on the Tuesday Office Hours Call.

(Dale Gibson): All right, thank you.

Operator: We have your next question from the participant's phone number ending in 3861. Your line is open.

(David): Thank you. This is David with the American Dental Association. Do you know if additional providers will end up being included for mass immunizers, for example dentists? And will all providers that do become mass immunizers have to participate in Medicare or enrolling Medicare in order to do this?

CMS - Seema Verma: I'm sorry, can you repeat the question again?

(David): Will CMS end up expanding the types of providers to include dentists or other types of providers that already aren't included as mass immunizers and will every provider …

CMS – Liz Richter: Yes, I think that the – the toolkit sort of address this issue. We are trying to expand the number of mass immunizers and so, sort of spell out the qualifications but I think suffice to say that we are looking at having nontraditional providers with this which is why we're really building on the structure of the mass immunizer program. So, we can follow up with you but I think it's – I think it's pretty wide. I mean we're trying to encourage as many people to come in to the program as possible.

(David): OK, so even if they do extend further, everyone still have to enroll into Medicare?

CMS – Liz Richter: Yes, correct. Now that's only to be able to provide the immunization to Medicare beneficiaries. And as they indicated earlier on the call, we're going to be sending all of the enrolled providers all the information that we have,

we'll share it with the state Medicaid programs but it will be up to the state Medicaid programs about whether they want to accept that or not.

And then in terms of other insurance companies, if you're not in – if you obviously don't have a contract with that insurance company, you'd be considered an out-of-network provider. And I think the point we're making with the rule is that there's still no balance billing or anything like that, so you'd have to accept whatever that insurance company is reimbursing for the administration of the vaccine.

(David): Thank you.

Operator: We have your next question from Brenda Shwilky. Your line is open.

(Brenda Shwilky): Thank you so much. Good job pronouncing my last name. Hi, my name is Brenda Shwilky. I just have a couple of quick questions and this should be very easy. First, the effective date is not going to be retroactive to the beginning of March, correct?

CMS – Jeff Wu: Correct.

(Brenda Shwilky): OK. Next, is – so any Medicare or Med Advantage, excuse me, any Med Advantage patient needs to be billed to Medicare fee for service when they provide the immunizations?

CMS - Seema Verma: Correct.

(Brenda Shwilky): OK. Final question, do you require an order and what if we go out in the mobile van, are you going to require supervision of the mass, when we try to go out and reach the homeless population?

CMS - Seema Verma: Liz, you want to answer that?

CMS - Liz Richter: Well, so for Medicare, we don't think that you need an order. We're still tightening that up but I believe that is being (inaudible).

(Brenda Shwilky): OK.

CMS - Liz Richter: Obviously, depending on what insurance coverage the patient has, there maybe a different answer.

(Brenda Shwilky): Sure. I totally get it. But the homeless population that 99 percent are uninsured, to be clear, we can bill them to the – I'm assuming to – how are we going to bill those people that don't have insurance at all? Yes, I get that we're getting it paid out of a different bucket but …

CMS - Seema Verma: Yes, so they're going to put out some more information from HHS because they handle the Provider Relief Fund but they'll put that information probably pretty similar to what we've done today with providing for people that are uninsured and they're COVID-related cost? So (inaudible) …

(Brenda Shwilky): Awesome.

Seema Verma: … have same (thing) at all.

(Brenda Shwilky): OK, awesome. Thank you so very much.

Operator: We have your next question from the participant's phone number ending in 0114. Your line is open.

(Nicholas Offer): Hello, yes, this is Nicholas Offer calling from Florida. And this maybe addressed in the toolkit but I wanted to know what do states have to do in relation to the public health emergency and the increased FMAP or is there anything that we can do?

CMS - Seema Verma: Calder, do you want to take that and also explain the changes in IFC4?

CMS – Calder Lynch: Sure. So, there are a number of requirements for states that are accepting an enhanced FMAP, one of which is maintaining a maintenance of that for enrollment for individuals who are enrolled at the beginning of the public health emergency.

We made some modifications to that requirement in IFC4 and this rule that we're talking about today that would give state a little bit more flexibility to move individuals between categories of eligibility as long as they maintained

similar benefits as well as to make adjustments in the cost sharing requirements and benefit requirements within existing statutory limits.

So, how those are going to apply are going to vary a little bit from state to state and so our team and the Medicaid office is available to states to help walk through that. And we also will – they're going to be discussing that on a weekly all-state calls as well.

(Nicholas Offer): Thank you.

Operator: Again, if you would like to ask a question, please press star one on your telephone keypad. Again, that is star one to ask a question.

We have your next question from the phone number ending in 5941. Your line is open.

Male: Yes, thank you and thank you for all of your thoughts into this and everything that's been laid out here. Is additional information coming on how Medicaid providers will be billing and what codes they will use as well?

CMS – Calder Lynch: Sorry, this is Calder again. You know, we'll have to kind of be watchful of the individual state and Medicaid agencies if they release information that are specific to their programs but we released a toolkit for states to kind of make those assessments.

And then there's also just general information available on our website now for providers at large where we'll have information about billing and coding that will apply more broadly but certainly they will be some need to kind of monitor it on a state by state basis for expenses that occurred there. So, we encourage you to go reach back up to your state Medicaid programs.

Male: So for the public health emergency period where it's all provided, if the state receiving the 6.2 FMAP, will they use the same Medicare code or would that vary by state?

CMS - (Calder Lynch): I think we expect that states and other payers involved – we're encouraging (inaudible) payers to look to Medicare as a model and follow the

same – the same protocols but we just released this information to states as well, so they need some time to digest that but that's certainly our expectation.

Male: And then is there additional information forthcoming on the volume of vaccines that will go to states or did – because it says the toolkit that the federal government will be purchasing, are there a certain number that will be available for Medicaid and by state Medicaid program?

CMS - (Calder Lynch): I think that's probably something that we don't have the right people on this call to address because that's managed out of different part of HHS. But, we would refer you back to the HHS and Operation Warp Speed folks as well as just the state public folks that are coordinating on that front.

Male: Thank you.

Alina Czekai: Great, thank you. And thanks everyone for joining our call today. As I mentioned, we do have our CMS COVID-19 Office Hours this upcoming Tuesday, November 3rd at 5:00 p.m. Eastern and we hope that you'll join us there. In the meantime, have a great rest of your day and enjoy your weekend. Take care.

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