All-State Medicaid and CHIP Call
November 9, 2021

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Agenda

• COVID-19 Pediatric Vaccine Confidence
• Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule with Comment
• Open Mic Q and A
Research Summary for Pediatric Vaccines

1. Parents are cautious, but beginning to make up their minds
   • 34% of parents with children 5-11 report that they intend to get their child vaccinated as soon as the vaccine is available. This rate has increased somewhat in the last 3 months but is less than half the vaccine confidence rate of adults.
   • Nearly half of vaccinated parents are hesitant to get their 5–11 year-old vaccinated.
   • These numbers are similar to the confidence rates before the vaccine was made available to adults in early 2021, and to confidence rates for parents of 12–17 year-olds before the vaccine was available to them.

2. There is a large movable audience that can be persuaded with pro-vaccine messaging
   • 32% of parents of 5-11 year-olds are persuadable. Just 1 in 4 report that they would definitely not get their child vaccinated – a rate that has remained steady over time.
   • Short and long-term vaccine side effects are the top concern for more than 90% of parents.

3. Most parents anticipate getting their children vaccinated at doctors’ offices, but many are open to other channels
   • 60% of parents would prefer to get their child vaccinated at a doctor’s office, followed by pharmacy (22%), health clinic (16%), community vaccination site (11%) and school (10%). There is general openness to a wide variety of sites, but they are not top-of-mind for parents and will require significant publicity.
Guidelines for Messaging Pediatric Vaccines

1. Highlight the benefits of the vaccine, while acknowledging concerns
   - As parents weigh the pros and cons of getting their child vaccinated, our most important argument is that \textit{when it comes to their child's safety, COVID-19 poses a far greater threat than the vaccine.}
   - Unlike previous campaigns, we must proactively address some vaccine safety concerns, but we should do so while also highlighting the benefits of the vaccine and the risks of COVID-19. The HHS team can provide additional guidance on this front.
   - Parents have a high standard for their children – it’s important to show empathy; we know this is a complex decision and are at the ready to answer any questions.

2. Expanding the pool of trusted messengers
   - Many parents most trust their own child’s doctor for advice on the vaccine, but we cannot rely solely on these providers. We must encourage providers at all the places children access healthcare (pediatric offices, CHCs, CBOs, schools) to provide pro-vaccine messaging.
   - For broader outreach, we want to replicate the kinds of conversations that a parent might have with their doctor – this means fresh faces, non-governmental doctors, and pediatricians.

3. More persuasion than mobilization, but both will be critical
   - Because a large portion of parents are movable, our priority with the 5-11 vaccine rollout is persuasion (not mobilization).
   - As always, it will be important to publicize that the vaccine is available at no cost, regardless of citizenship or insurance status, at tens of thousands of locations across the country.
Target Audiences for Pediatric Vaccine Outreach

1. Parents who are vaccinated, but hesitant about getting their children vaccinated
   - Nearly half of vaccinated parents are hesitant to get their 5–11 year-old vaccinated.
   - The audience for whom we can have the biggest impact is vaccinated parents. Unvaccinated parents and parents who are skeptical of other childhood vaccines are – at this time – relatively unlikely to get their child vaccinated.
   - Mothers, parents without college degrees, Latino parents, and lower income parents are most likely to be part of the movable audience.

2. Parents without easy access to medical services
   - Much like the initial vaccine rollout, we will need to pay special attention to parents and children who do not regularly see a medical provider, who may not have a good source to get vaccine questions answered, and who we are unlikely to reach through earned media efforts.
   - Lower income parents, those without college degrees, and Black and Latino parents all report the highest rates of concern about vaccine access, vaccine safety, and COVID risk.

Note: we are targeting parents, not children ages 5-11
The COVID-19 vaccine is the best way to keep your child safe.

- The long-term effects of a pediatric COVID case can be serious and last months; the most common side-effect of the COVID vaccine, which provides lasting protection, is a sore arm. The best way to protect your child against COVID-19, including the Delta variant, is to get them vaccinated.

- Like other pediatric vaccines, the COVID-19 vaccine thoroughly tested on children before being recommended.

- If you have questions, talk to a pediatrician, school nurse, or another trusted healthcare provider about your child and the COVID-19 vaccine.
Thank You
Agenda

• Opening Remarks
• Overview of the Interim Final Rule and Guidance
  • Eligibility
  • Basic Requirements
  • Enforcement
  • Interactions with other Regulations and Requirements
  • Action to Take
• Questions and Answers
Eligibility – Who is included?

Requirements apply to **facilities** regulated under the Medicare Conditions of Participation (CoPs)

**This Includes:**
- Ambulatory Surgery Centers
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Long Term Care Facilities
- Programs for All-Inclusive Care for the Elderly Organizations (PACE)
- Psychiatric Residential Treatment Facilities
- Rural Health Clinics/Federally Qualified Health Centers

**So What?** – If you are one of the above providers or suppliers, this regulation applies to you and you must abide by the requirements
Eligibility – Who is excluded?

The following provider and supplier types are not included in this requirement:

- Religious Nonmedical Health Care Institutions (RNHCIs)
- Organ Procurement Organizations
- Portably X-Ray Suppliers

Additionally, the requirements do not apply to the following:

- Assisted Living Facilities
- Group Homes
- Home and Community-based Services
- Physician’s Offices

**Key Fact to Remember**: This regulation and the requirements within only apply to providers and suppliers regulated under the CMS Conditions of Participation (CoPs)
Requirements – What must my facility do?

There are three basic requirements that facilities must complete:

1. You must have a process or plan for vaccinating all eligible staff

2. You must have a process or plan for providing exemptions and accommodations for those who are exempt

3. You must have a process or plan for tracking and documenting staff vaccinations
Requirements – When must my facility do it?

• You must have your process or plan in place for vaccinating staff, providing exemptions and accommodations, and tracking and documenting staff vaccinations within 30-days (by December 6, 2021)

• Additionally, your process or plan for vaccinating staff must ensure that all eligible staff receive:
  • 1st Dose or One-Dose Vaccine by December 6, 2021
  • Received all shots for full vaccination by January 4, 2022
Requirements – Who in my facility must be vaccinated?

• The vaccination requirements **apply to all eligible staff**, both current and new, working at a facility regardless of clinical responsibility or patient contact, including:
  • Facility Employees
  • Licensed Practitioners
  • Students
  • Trainees
  • Volunteers
  • Contracted Staff

• The vaccination requirements also apply to staff who perform duties offsite (e.g. home health, home infusion therapy, etc.) and to individuals who enter into a CMS regulated facility
  • Example: A physician with privileges in a hospital who is admitting and/or treating patients onsite

• This requirement **does not** apply to full time telework staff
Requirements – How does CMS define fully vaccinated?

• CMS considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19
  
  • **Important Note**: Staff who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination

• Completion of a primary vaccination series for COVID-19 means:
  
  • Staff received a single-dose vaccine
    • Janssen (Johnson & Johnson) COVID-19 Vaccine
  
  • Staff received all required doses of a multi-dose vaccine
    • Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine)
    • Moderna COVID-19 Vaccine
  
  • Staff received vaccines listed by the World Health Organization (WHO) for emergency use (in accordance with CDC guidelines)

• **Are boosters included?** – No, however CMS strongly encourages facilities and staff to review the CDC’s *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* for additional detail on additional doses
Requirements – How do exemptions work?

CMS requires facilities to allow for the following exemptions to staff in accordance with federal law:

- Recognized medical conditions for which vaccines are contraindicated
- Religious beliefs, observances, or practices

**Basics for Medical Exemptions:**
- Facilities must develop a process for permitting staff to request a medical exemption
- Facilities must ensure all documentation is signed and dated by a licensed practitioner
- Documentation must contain all information specifying why the COVID-19 vaccines are clinically contraindicated for the staff member
- Documentation must include a statement by the authenticating practitioner recommending the staff member be exempted

**Basics for Religious Exemptions:**
- Facilities must develop a process for permitting staff to request a religious exemption
- Facilities must ensure all requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of the facility’s policies and procedures
Requirements – How do accommodations work?

• CMS requires facilities to develop a process for implementing additional precautions for any staff who are not vaccinated

• Potential accommodations for exempted staff could include, but are not limited to:
  • Testing
  • Physical Distancing
  • Source Control

• In all cases – facilities must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals
Requirements – Anything else my facility should know?

• Vaccination is the only option – this regulation does not include a testing option for unvaccinated staff
  • Facilities are encouraged to voluntarily institute testing alongside other infection prevention measures such as physical distance and source control

• There are no new data reporting requirements within this regulation
  • Facilities, specifically hospitals and nursing homes, are still expected to continue complying with the facility-specific data reporting requirements set forth in emergency regulations issued by CMS in May 2020, August 2020, and May 2021, respectively
Enforcement – How will CMS check for compliance?

• CMS works directly with the State Survey Agencies to regularly review compliance with Medicare/Medicaid regulations across multiple health care settings

• CMS expects State Survey Agencies to conduct onsite compliance reviews for the requirements in two ways:
  • Recertification Surveys
  • Complaint Surveys

• Surveyors will check to determine if a facility has met the three basic requirements:
  1. Having a process or plan for vaccinating all eligible staff
  2. Having a process or plan for providing exemptions and accommodations for those who are exempt
  3. Having a process or plan for tracking and documenting staff vaccinations

• Accrediting Organizations will also assess for compliance
Enforcement – What if my facility is out of compliance?

Surveyors will cite facilities based on the level or severity of the noncompliance.

**So what?** – Facilities that are out of compliance will be cited and provided an opportunity to return to compliance.

**If not?** – CMS may use enforcement remedies, such as civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure.
Interactions with Other Regulations and Requirements

**Bottom Line Up Front:** *If* your facility participates in the Medicare and Medicaid programs and is regulated under the CMS Conditions of Participation, Conditions for Coverage, or Requirements, *then* the CMS Omnibus COVID-19 Health Care Staff Vaccination Regulation takes priority and your facility is expected to abide by the requirements.

Other Considerations:

- *If* facilities are not certified under the Medicare and Medicaid programs and therefore not regulated by the CoPs, *then* the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or OSHA COVID-19 Healthcare Emergency Temporary Standard apply.

- *If* none of the above regulations apply, *then* employers are subject to the OSHA Employer Emergency Temporary Standard (for facilities with greater than 100 employees).

- Lastly, this regulation pre-empts any state law under the Supremacy Clause of the United States Constitution.
Actions to Take

• DO review the Omnibus COVID-19 Health Care Staff Vaccination Regulation and the specific sections applicable to your facility

• DO review the Frequently Asked Questions document specific to this regulation on the CMS Emergencies Page

• DO begin developing your process or plan for vaccinating staff, providing exemptions and accommodations, and documenting and tracking staff vaccinations

• DO note the two milestone dates by which compliance is expected
  • 30-days → December 6, 2021
  • 60-days → January 4, 2022