HEALTHCARE REGULATORY ROUND-UP

Healthcare Headlines:
Impact of Latest Developments

January 26, 2022

Introductions

Martie Ross
mross@pyapc.com

Kathy Reep
kreep@pyapc.com

PYA

pyapc.com
800.270.9629

ATLANTA | KANSAS CITY | KNOXVILLE | NASHVILLE | TAMPA

Agenda

1. Health care staff vaccination interim final rule
2. COVID-19 public health emergency and related regulatory flexibilities
3. Provider Relief Fund update
4. Recent Supreme Court hearings
5. Co-location/shared space
6. Organ procurement costs
7. Graduate medical education
8. MedPAC recommendations for 2023 payment updates

1. Health Care Staff Vaccination Interim Final Rule

- Applies to all provider types subject to Conditions of Participation, Conditions for Coverage, or Requirements for Participation
  - **Does not apply** to physician offices, EMS providers, assisted living facilities, home & community-based services
- Enforcement status
  - Rule published November 5; first shot compliance required by December 6
  - In late November/early December, lower federal courts issued preliminary injunctions effectively staying enforcement in 25 states
  - On December 28, CMS published State Survey guidance applicable in 25 states in which no preliminary injunction was in effect (+ D.C. and territories)
  - On January 13, U.S. Supreme Court stayed preliminary injunctions (except Texas)
  - On January 14, CMS published State Survey guidance applicable to remaining states (except Texas)
  - On January 18, federal court dismissed Texas lawsuit challenging mandate

Implementing Regulations

- Example - for PPS hospitals, amends 42 CFR 482.42 - Infection Prevention and Control and Antibiotic Stewardship Programs
  - New subsection (g) - COVID–19 Vaccination of hospital staff
  - Develop and implement specific P&Ps to ensure ***all staff*** fully vaccinated
- Similar regulatory provisions for other provider types
- No additional data reporting requirements

‘All Staff’

Includes -

- Facility employees
- Licensed practitioners (medical staff)
- Students, trainees, volunteers
- Individuals who provide care, treatment, or other services for facility and/or its patients, under contract or by other arrangement

Does not include –

- Staff who exclusively provide telehealth services outside hospital setting who have no direct contact with patients and other staff
- Staff who provide hospital support services performed exclusively outside hospital setting who have no direct contact with patients and other staff
- Vendors, volunteers, or professionals who infrequently provide ad hoc, non-health care services or services that are performed exclusively offsite and not at or adjacent to any site of patient care

Required Policies & Procedures (Nos. 1 and 2)

1. Process to ensure all staff have received initial dose prior to providing any services for hospital and/or its patients and thereafter are fully vaccinated unless exempt/temporary delay
   - Fully vaccinated = 2 weeks after completion of primary vaccination series (including all required doses of a multi-dose vaccine)
   - No alternative to vaccination (e.g., routine testing, antibodies)
2. Process to ensure implementation of additional precautions for all staff not fully vaccinated (in process of becoming fully vaccinated or granted exemption)
   - E.g., source control (masking), testing, distancing, modified job duties

Required Policies and Procedures (No. 3)

3. Process for tracking and securely documenting vaccination status of all staff (including receipt of booster doses)
   - Documentation
     - Providers “have the flexibility to use the appropriate tracking tools of their choice”
     - Examples of acceptable forms of proof of vaccination
       - CDC COVID–19 vaccination record card (or legible photo)
       - Documentation of vaccination from health care provider or EHR
       - State immunization information system record
   - Include process for documenting temporary delays in vaccination due to CDC-recommended clinical precautions and considerations (e.g., individuals who received monoclonal antibodies)

Required Policies and Procedures (No. 4)

4. Process by which staff may request exemption based on ADA disability, medical condition, or sincerely held religious belief
   - Include process for tracking and securely documenting information provided by those requesting and receiving exemptions; use templates created by Safer Federal Workforce Task Force
   - For each medical exemption, must have signed and dated recommendation from state-licensed practitioner acting within scope of practice that lists recognized clinical reasons vaccination is contraindicated
   - For religious belief exemption, not required to validate sincerity of belief (Bristol Myers lawsuit)

Compliance Deadlines - Group 1

Deadline	Phase 1 Deadline	Phase 2 Deadline
California		
Colorado		
Connecticut		
Delaware		
District of Columbia		
Florida		
Hawaii		
Illinois		
Maine		
Maryland		
Massachusetts		
Michigan		
Minnesota	January 27, 2022	February 28, 2022
Nevada		
New Jersey		
New Mexico		
New York		
North Carolina		
Oregon		
Pennsylvania		
Rhode Island		
Tennessee		
Vermont		
Virginia		
Washington		
Wisconsin		

Phase 1 –

- All required P&Ps implemented
- All staff have received 1st dose (or exemption/temporary delay)

Phase 2 –

- All staff have received 2nd dose
- No ‘booster’ deadline (yet…)

Compliance Deadlines - Group 2

Deadline	Phase 1 Deadline	Phase 2 Deadline
Alabama Alaska Arizona Arkansas Georgia Idaho Indiana Iowa Kansas Kentucky Louisiana Mississippi Missouri Montana Nebraska New Hampshire North Dakota Ohio Oklahoma South Carolina South Dakota Utah West Virginia Wyoming	February 14, 2022	March 15, 2022
Texas	February 22, 2022	March 21, 2022

Phase 1 –

- All required P&Ps implemented
- All staff have received 1st dose (or exemption/temporary delay)

Phase 2 –

- All staff have received 2nd dose
- No ‘booster’ deadline (yet…)

Enforcement

- CMS will NOT use new COVID-19 Vaccination Coverage among Health Care Personnel quality measure to monitor compliance
- State surveyors to conduct on-site compliance reviews as part of re-certification surveys and complaint surveys; accreditation organizations also will assess for compliance
  - Review of P&Ps; number of resident and staff COVID-19 cases over last 4 weeks; list of all staff and their vaccination status; interviews and observations
  - Will not investigate/validate basis for exemptions

Enforcement, Con't

- Nursing facilities, home health agencies, and hospices subject to civil money penalties; other providers subject to termination
  1. Immediate Jeopardy
     - Serious scope of non-compliance, failure to address deficiencies, close interaction with patients of unvaccinated staff.
     - Termination within 23 days following citation if not immediately addressed
  2. Condition-Level Citation
     - Substantial non-compliance that must be addressed to avoid termination
  3. Standard-level Citation
     - Minor non-compliance; continued operation subject to facility's agreement to CMS-approved plan of correction
- "CMS's goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance."

Less than 100% Vaccination/Exception Rate

- Beginning January 27 (or February 14) - Facility above 80% and has plan to achieve 100% within 60 days not subject to additional enforcement action; otherwise, facts and circumstances determine type of enforcement action (if any)
- Beginning February 28 (or March 15) - Facility above 90% and has plan to achieve 100% within 30 days not subject to additional enforcement action; otherwise, facts and circumstances determine type of enforcement action (if any)
- Beginning March 30 (or April 14) – Facts and circumstances determine type of enforcement action (if any)

2. PHE/Regulatory Flexibilities

- PHE declaration renewed January 16; next renewal due April 16
- Regulatory flexibilities end with termination of PHE - review and track changes to internal policies and practices; establish process to complete unwind
  1. Expanded capacity
  2. Burden relief
  3. Provider enrollment relief
  4. Stark Law waivers
  5. HIPAA enforcement discretion
  6. Patient inducement enforcement discretion
  7. DEA waivers
  8. Expanded telehealth coverage
- Medicaid continuous coverage requirement ends with termination of PHE, with states required to complete re-determination within 12 months
  - Impact of disenrollment?

Provider Relief Fund

- Latest Distributions
  - Rural Providers – 44,000 providers received $7.5 billion
  - Phase 4
    - Batch 1 (December 2021) – 69,000 providers received $8.7 billion
    - Batch 2 (January 2022) – 7,700 providers received $2 billion
- Additional distributions?
- Enforcement actions to date
  - False certification of eligibility
  - Mis-use of funds for personal purposes
- OIG Work Plan – audit of General Distribution applications and payments
- PRF Audit Contracts (from ProPublica COVID-19 contract listings)
  - KPMG (program integrity support) - $3 million
  - Kearney & Company (PRF audit support) - $1.6 million
  - Creative Solutions Consulting (audit and financial review services) - $729K

3. Provider Relief Fund

- Reporting Schedule

	Payment Received Period (Payments Exceeding $10,000 in Aggregate Received)	Reporting Time Period
Period 1	April 10, 2020 to June 30, 2020	July 1, 2021 to September 30, 2021
Period 2	July 1, 2020 to December 31, 2020	January 1, 2022 to March 31, 2022
Period 3	January 1, 2021 to June 30, 2021	July 1, 2022 to September 30, 2022
Period 4	July 1, 2021 to December 31, 2021	January 1, 2023 to March 31, 2023

- Providers must return excess funds no later than 30 days following end of applicable reporting period
- HRSA will pursue enforcement action – including repayment and debt collection - against providers retaining unreported funds

4. Recent Supreme Court Hearings

- 340B hospital payment rate
  - Focus on reduction in rates to 340B hospitals at ASP-22.5%
    - Other drugs paid at ASP+6%
  - Issue of non-340B hospitals that received higher payments resulting from savings derived from 340B reduction

Recent Supreme Court Hearings

- Disproportionate share payments
  - Dispute involves treatment of dual eligible exhausted days (no payment from Medicare)
  - Rule promulgated in 2005 did not meet notice and comment rulemaking requirements under the Administrative Procedures Act
    - Also argued 1996 decision barred CMS from implementing 2005 change
  - Supreme Court determination will provide universally applicable interpretation of “entitled to Medicare”
  - Reaction of justices: “indecipherable”; “exhausted by the dispute”

5. Co-Location/Shared Space

- Refer to QSO-19-13-Hospital: Revised 11/12/21
  - Guidance for Hospital Co-location with Other Hospitals or Healthcare Facilities *(Revised)*
- Requires all co-located hospitals to demonstrate independent compliance with the hospital CoPs
- Identification of mutual spaces
- Guidance does not address co-location with physician practices

6. Organ Procurement Costs

- Changes addressed in FY2022 IPPS NPRM
  - Determining Medicare's share of organ acquisition costs
    - Proposed requiring that organs be transplanted into Medicare patients
    - Also proposed requiring donor community hospitals and transplant hospitals to bill OPOs the lesser of customary charges reduced to costs, or negotiated rates (following Medicare reasonable cost principles)
- Final rule issued December 17
  - Did not finalize original proposal to limit
  - Did finalize policies related to reasonable cost principles

7. Graduate Medical Education

- Health Equity in GME
  - Promoting Rural Hospital GME Funding Opportunity
    - Allows increases in FTE caps for accredited rural training track
- Distribution of additional 1,000 new residency slots (2023)
  - Limited to no more than 200 slots per year (limit 5 per year per hospital, not to exceed 25 in total)
  - Hospitals must –
    - Be training residents in excess of their FTE cap and
    - Show they have applied for or received approval to either establish a new program or expand existing program

Graduate Medical Education

- New residency slots
  - Four eligibility categories -
    - Hospitals located in rural areas
    - Hospitals training in excess of their caps
    - Hospitals located in states with new medical schools or new branches of existing schools
    - Hospital training programs with residents rotating at least 50% of their time at sites located in primary care or mental health professional shortage areas

8. MedPAC 2023 Payment Update Recommendations

- Hospital services
  - Inpatient – 2.5% increase
  - Outpatient – 2.0% increase
- Skilled nursing, home health, inpatient rehab – 5% decrease
- Ambulatory surgical centers, hospice – no update
- Physician, other health care professionals, long-term care hospitals – follow current law

Our Next Health Care Regulatory Round-Up:

Hospital at Home: Past, Present, and Future

February 9, 2022

How can we HELP?

A national healthcare advisory services firm providing consulting, audit, and tax services