

June 18, 2021: National Advocacy Update

HHS provides greater flexibility for provider relief funds

On June 11, 2021, the U.S. Department of Health and Human Services (HHS) revised the Health Resources and Services Administration (HRSA) Provider Relief Fund (PRF) reporting requirements, allowing more time for providers to use the funds received and extending greater flexibility in provider reporting on the use of those funds. The latest revision (PDF) applies to PRF General and Targeted Distributions. The revised reporting requirements do not apply to rural health clinics COVID-19 testing programs, HRSA COVID-19 uninsured program claims or the HRSA COVID-19 coverage assistance fund.

Providers in receipt of PRF payments exceeding \$10,000 in aggregate during a payment period are required to report on the use of their funds during a revised reporting time period. The first key change relates to the time to use the PRF payments. Providers now have 12 months from the end of the payment period to use the funds received. The second important revision relates to reporting. Under the revised guidance, reporting on the funds used is now due during a 90-day period following the end of the revised deadline. Previously, providers had only 30 days to report on the period's funds. Reporting is limited only to the open period; providers may not report on payments received until the reporting time period is open, even if the funds have already been expended.

Period 1

- Payment received period: April 10–June 30, 2020
- Deadline to use funds: June 30, 2021
- Reporting time period: July 1–Sept. 30, 2021

Period 2

- Payment received period: July 1–Dec. 31, 2020
- Deadline to use funds: Dec. 31, 2021
- Reporting time period: Jan. 1–March 31, 2022

Period 3

- | Payment received period: Jan. 1–June 30, 2021
- | Deadline to use funds: June 30, 2022
- | Reporting time period: July 1–Sept. 30, 2022

Period 4

- | Payment received period: July 1–Dec. 31, 2021
- | Deadline to use funds: Dec. 31, 2022
- | Reporting time period: Jan. 1–March 31, 2023

Detailed information on reporting requirements based on how the funds were used is described in the latest guidance. The reporting requirements are applicable to all past and future PRF payments. Entities receiving more than a total of \$750,000 in federal funds (including PRF payments and other federal financial assistance) during their fiscal year are subject to single audit requirements.

HRSA recently provided an opportunity to address questions and promised written materials to further illustrate the revised standards.

CMS increases payment for COVID-19 vaccinations administered in the home

The Centers for Medicare & Medicaid Services (CMS) will provide an additional payment for COVID-19 vaccinations administered at home to certain Medicare beneficiaries. Effective June 8, 2021, providers who deliver the COVID-19 vaccination to hard-to-reach Medicare beneficiaries at home will receive an additional \$35 per dose for COVID-19 administration. This additional amount brings the payment for a one-dose vaccination up to approximately \$75 (previously about \$40); a two-dose vaccination would result in payment of approximately \$150 (previously around \$80). The payments are geographically adjusted. The additional code is M0201.

With this extra payment, CMS intends to facilitate vaccination for those Medicare patients who have a condition that makes them more susceptible to contracting COVID-19, who experience a considerable amount of effort when they rarely leave the house, or who face barriers or challenges to getting vaccinated outside of the home (such as transportation, caregiving responsibilities, communication or disability) by allowing for this additional payment. When billing, the provider must document the patient's clinical status or the barriers which prohibit the Medicare beneficiary receiving the COVID-19 vaccination outside of the home.

The new payment addition allows for a number of settings to qualify for the "in the home" setting. This includes a private residence, a temporary source of lodging (e.g., a hotel, a motel, campground, a homeless shelter), an assisted living facility, a group home, an apartment and a Medicare patient's home that has been considered "provider-based to a hospital" during the COVID-19 public health emergency. CMS notes that a physician's office, a clinic, an outpatient hospital, an inpatient hospital or skilled nursing facility would not qualify as "in the home" and would not be eligible for the additional payment.

CMS has provided an information sheet (PDF) and has provided more information on its website on the additional payment.

OSHA issues COVID-19 health care emergency temporary standard for employers

On June 11, the Occupational Safety and Health Administration (OSHA) announced issuance of a COVID-19 health care emergency temporary standard (ETS). The ETS lays out requirements to help protect workers in health care settings. The requirements included in the ETS are effective immediately upon publication in the Federal Register. Employers will have 14 days to comply.

Under the requirements in the ETS, employers must:

- | Mandate health care worker use of masks (respirators for those performing aerosolizing procedures).
- | Mandate physical distancing.
- | Provide physical barriers when physical distancing is not possible.
- | Prepare a COVID-19 plan.
- | Screen and manage patients entering health care facilities to reduce risk of transmission.
- | Have in place policies for employee health screening and medical management of possible/confirmed COVID-19 infections among employees.
- | Ensure appropriate record-keeping of all employee instances of COVID-19 infections.

The ETS provides exemptions for fully vaccinated employees from the masking, distancing and physical barrier requirements so long as there is not reasonable expectation that those employees should come in to contact with a COVID-19 positive individual. OSHA will use enforcement discretion where employers are making good faith efforts to comply with the requirements of the ETS. OSHA will consider updating the ETS once it determines that grave danger to employees from COVID-19 no longer exists.

Significant shortage of sodium citrate blood specimen tubes used in coagulation testing; FDA issues guidance for conservation

The AMA would like to alert physicians that the United States is currently experiencing a significant interruption in the supply of sodium citrate blood specimen (light blue top) tubes. These tubes, also known as “blue top tubes,” are used for coagulation testing. Increased demand due to COVID-19, along with vendor manufacturing challenges, has led to nationwide supply constraints that are expected to persist for the remainder of the year.

The U.S. Food and Drug Administration last week issued guidance to laboratories and health care providers outlining strategies for conservation of the blue top tubes. Physicians should expect that hospitals and health systems will be implementing conservation strategies that may limit availability of coagulation testing until the shortage can be rectified.

CMS examines how best to address reporting of health disparities in post-acute care quality programs

In recognition of persistent health disparities and the Biden administration commitment to closing health equity gaps, CMS recently put out a request for information (RFI), “Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs,” within the 2022 Inpatient Rehabilitation Facility Prospective Payment System proposed rule. The RFI focused on how best to make reporting of health disparities based on social risk factors, race and ethnicity more comprehensive and actionable for providers within CMS post-acute care quality programs.

Consistent with the priority it places on promoting health equity, the AMA submitted comments (PDF) emphasizing that as CMS begins to consider addressing health inequities and the potential development of a quality measure for use in an accountability program, CMS must consider potential

unintended consequences and provide supportive education to ensure that a measure, tool or quality reporting program component does not exacerbate inequities and ensure that institutions are appropriately educated on best practices for data collection and/or program implementation.

In addition, the AMA noted the need for quality measures to account for risk factors such as lack of access to food, housing and/or transportation that affect patients' ability to adhere to treatment plans, as well as the need to disaggregate race and ethnicity data. More specifically, the comments highlighted the need to potentially change how we currently collect data, such as asking about ancestry or cultural affiliation given race is a social construct and as our society diversifies over time it clouds how these variables are defined. Given the Biden administration recognition of persistent health disparities and the need to address health equity, AMA suspects CMS will release additional RFIs on health equity within upcoming rules, which the AMA will continue to monitor and offer feedback.

AMA supports bill to improve maternal and infant health

The AMA recently sent a letter (PDF) of support for S. 1675, the "Maternal Health Quality Improvement Act," which would provide grants to identify, develop and disseminate best practices to improve maternal health care quality and outcomes. Additionally, provisions within the Maternal Health Quality Improvement Act would encourage collaboration with state maternal mortality review committees to identify issues and reduce preventable maternal mortality and severe maternal morbidity, promote perinatal quality collaborative activities and implement integrated health care services for pregnant and postpartum women.

In the letter, AMA Executive Vice President and CEO James L. Madara, MD, stated that, "As the country shifts our focus from battling the COVID-19 pandemic in U.S. hospitals to encouraging people to get the COVID-19 vaccines, we need to remember pregnant individuals in our policy discussions. This legislation would allow HHS to consider the importance of increasing awareness and knowledge of the safety and effectiveness of vaccines to prevent disease in pregnant and postpartum women and infants and emphasize the need to improve vaccination rates in communities and populations with low rates of vaccination."

The AMA is committed to working with a variety of stakeholders to tackle the issues surrounding maternal mortality and morbidity. The AMA looks forward to working with members of Congress to achieve passage of the Maternal Health Quality Improvement Act to improve maternal health in this country.

“Safe Step Act” would allow exemptions from medication step-therapy protocols

This week the AMA sent letters of support for H.R. 2163 (PDF)/S. 464 (PDF), the “Safe Step Act,” which allows for exceptions from medication step-therapy protocols. Medication step-therapy protocols, and more broadly utilization management programs, can create significant barriers for patients by delaying the start or continuation of necessary medical treatment, which can negatively affect patient health outcomes. While a particular drug or therapy might generally be considered appropriate for a condition, the presence of comorbidities or patient intolerances may necessitate an alternative treatment. Furthermore, forcing patients to abandon already effective treatment and repeat a therapy that has been proven ineffective delays care and may result in negative health outcomes.

Recognizing these negative impacts, the AMA and other organizations have created the Prior Authorization and Utilization Management Reform Principles (PA Principles) (PDF), which promote commonsense concepts to improve prior authorization, step-therapy and other utilization management programs. These bills address concerns related to patient safety, negative clinical outcomes and interruptions in care caused by utilization management programs by amending the Employee Retirement Income Security Act (ERISA) to require a group health plan to provide an exception process for any medication step-therapy protocol, which aligns with our PA Principles. Importantly, the bill requires that insurers implement a clear and transparent process for a patient or physician to request an exception to a step-therapy protocol. Additionally, the bill sets response deadlines for regular and urgent exemption requests. By creating this process, the Safe Step Act helps ensure that patients have timely access to treatment and reduces administrative costs to the health care system.

HHS launches hotline to improve access to COVID-19 vaccines for people with disabilities

The U.S. Department of Health and Human Services (HHS) announced the launch of a first-of-its-kind national hotline to connect people with disabilities to information and services to improve access to COVID-19 vaccines.

The Disability Information and Access Line (DIAL) is now available to help people with disabilities find vaccination locations in their communities, assist callers with making vaccination appointments and connect callers to local services—such as accessible transportation—to overcome barriers to vaccination. The hotline also can provide information and resources to answer questions and address

concerns about the vaccines and can connect callers to information and services that promote independent living and address fundamental needs, such as food, housing and transportation.

DIAL connects callers to information about how to access the COVID-19 vaccine and related supports for people with disabilities. DIAL connects callers to vaccine sites and provides information related to barriers to vaccination by referring callers to local and national disability resources.

Learn more about the Disability Information and Access Line (DIAL). Call (888) 677-1199 from 9:00 a.m. to 8:00 p.m. Eastern or email DIAL@n4a.org.

HHS to insurers and providers: COVID-19 vaccines and testing must be free for patients

Central to the national plan to protect Americans and end the pandemic has been increasing testing and vaccinations. In light of recent reports of consumer cost concerns, it is important for health care providers to continue to cover the administration of COVID-19 vaccines free of charge to patients, and for group health plans and health insurers to provide coverage of COVID-19 vaccinations and diagnostic testing without patients shouldering any cost.

COVID-19 vaccines and their administration are free for any individual living in the United States, regardless of their insurance or immigration status. Currently, all providers administering COVID-19 vaccines are required to sign the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Provider Agreement. Among other requirements, this agreement states that providers must administer COVID-19 vaccines at no out-of-pocket cost to patients. Furthermore, to ensure no surprise billing, providers may not require that patients have additional medical services to receive their COVID-19 vaccination—nor can they charge any type of fee if COVID-19 vaccination is the sole medical service provided.

For expenses associated with administering vaccines, from staff trainings to vaccine storage, providers may not bill patients but can seek reimbursement through Medicare, Medicaid, private insurance or other applicable coverage. Most group health plans and health insurers are statutorily required to cover COVID-19 vaccines recommended by the Advisory Committee on Immunization Practices of the CDC without cost-sharing.

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