NHPCO COVID-19 Update – 11/18/20

NHPCO has created this update for hospice and palliative care providers to share recent news and helpful links. Please note, these Updates are published when there is helpful news to share.

"What lies behind us, and what lies ahead of us, are tiny matters compared to what lies within us." — Ralph Waldo Emerson

Policy Update

CLIA Certificate Information for Hospice Providers

Given the variety of simple COVID-19 testing systems, hospices may want to offer testing services directly, rather than contracting with an outside clinical laboratory. For hospices who are considering offering testing for employees, a CLIA Certificate is required. There may also be state clinical lab license requirements as well. NHPCO has prepared a COVID-19 Member Alert, "COVID-19 Testing by Hospice Providers" (11/17/20) available on the member-only COVID-19 resource page. This member Alert provides the details of obtaining a CLIA Certificate, determining testing reporting requirements and other issues hospice providers should consider. *(Log into the NHPCO website and then access the link to download the PDF of the Alert.)*

Weekly Update on the Provider Relief Fund Program

This week, HHS focused efforts on validating Phase 3 General Distribution applicants with states following last week's application deadline. HHS remains committed to distributing payments as quickly as possible to providers confronting this pandemic. As of the week of November 8, HHS has made the following total payments under the General and Targeted Distributions of the PRF program: $106,431,598,358 in payments to 548,550 provider TINs.

- Of these payments, 380,548 providers (unique TINs) have attested to the Terms and Conditions for $97,086,509,470 in payments. A listing of PRF distributions to providers that have accepted the Terms and Conditions is available on the CDC website.

As of November 11, HHS has made COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured payments to 25,420 providers including:

- Testing claims: $774,299,738
- Treatment claims: $1,153,891,616

A listing of health care entities that have agreed to the Terms and Conditions and received claims reimbursement can be found on the CDC website.

FDA Authorizes First COVID-19 Test for Self-Testing at Home

On November 17, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test for self-testing at home and that provides rapid results. The Lucira COVID-19 All-In-One Test Kit is a molecular (real-time loop mediated amplification reaction) single use test that is intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. Read the FDA press release.

Provider Update

Healthcare Facilities That Have Implemented COVID-19 Electronic Case Reporting

Electronic case reporting (eCR) is the automated, real-time exchange of case report information between electronic health records and public health agencies. In partnership with the Association of Public Health Laboratories (APHL) and the Council of State and Territorial Epidemiologists (CSTE), CDC has been rapidly onboarding healthcare facilities to eCR during the COVID-19 pandemic. As of November 12, 2020, more than 6,100 facilities are sending COVID-19 initial electronic case reports to public health using eCR.

PPE Notes

- **Increasing Domestic Production Capacity**: On November 13, DOD in partnership with HHS awarded a $6.18 million contract to Medline Industries, Inc. to increase domestic production capacity of surgical masks. This industrial base expansion effort will allow Medline to increase production capacity in Lithia Springs, Georgia by 36 million surgical masks per month by May 2021.
- How to Protect Yourself (ANA Free Webinar): This new webinar represents a critical and necessary update to this earlier webinar. Since that time, our knowledge of COVID-19 and the importance of strong PPE protection has continued to grow, so ANA is providing all nurses access to this free PPE webinar that emphasizes the most current information. This 60-minute on-demand webinar is FREE for all nurses.

Resources

Avoid Fraudulent Flu and COVID-19 Products

Today, the FDA issued a new Consumer Update urging consumers to avoid fraudulent flu products and offering tips on how to spot them. These unproven products, sold online and in stores, have not been evaluated by the FDA for safety and effectiveness. Know that there are no legally marketed over-the-counter (non-prescription) drugs to prevent, mitigate, treat, or cure the flu. But there are legal over-the-counter (OTC) drugs to reduce fever and to relieve muscle aches, congestion, and other symptoms typically associated with the flu. The agency has been and will continue to take action against bad actors, as evidenced by warning letters sent to companies offering for sale medical products with fraudulent claims to prevent, mitigate, treat, or cure COVID-19.

Coronavirus Treatment Acceleration Program

On November 10, the FDA updated the dashboard on the Coronavirus Treatment Acceleration Program (CTAP) webpage. As of October 31, more than 560 drug development programs were in planning stages, over 370 trials had been reviewed by FDA, 5 COVID-19 treatments were currently authorized for emergency use, and 1 treatment was approved by FDA for use in COVID-19.

Distribution of Misbranded and Unapproved COVID-19 Products

At FDA's request, the Dept. of Justice filed a civil complaint in the U.S. District Court for the District of New Jersey against Natural Solutions Foundation and two individuals associated with the entity, seeking to permanently enjoin them from distributing Dr. Rima Recommends™ Nano Silver 10PPM in interstate commerce as a prevention or treatment for COVID-19 and other diseases. The complaint alleges that Natural Solutions Foundation and the individual defendants, Dr. Rima Laibow and Ralph Fucetola, violated the Federal Food, Drug, and Cosmetic Act by unlawfully distributing a misbranded and unapproved new drug.

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