

Reimbursement & Policy

CMS to recoup advance Medicare payments

CMS has begun recouping Accelerated and Advance Payments (AAPs) sent to hospitals as part of the CARES Act. Recoupment began on March 30 or on the one-year anniversary of the first payment received by the hospital or provider.

For documentation, hospital and providers should note that the recoupments are noted as adjustments in the Provider-Level Balance (PLB) section of the remittance advice. For the first 11 months, recoupment amounts will not exceed 25% of the Medicare payment. For balances after that point, recoupment will not exceed 50% of the Medicare payment. The interest rate for the AAPs will be 4%. For additional details please see the [CMS memo](#).

FDA authorizes additional doses and OTC home tests

Late last week, the FDA took actions that expanded the amount of Moderna vaccine doses per vial and increased the number of tests asymptomatic individuals can utilize at home.

For the Moderna vaccine, manufacturers can now add up to 15 doses per vial, up from the 10-dose vials that were being shipped. Vaccinators may also be able to extract an additional dose in the vials provided they have certain syringes and needles. For more information, please review the [updated provider fact sheet](#).

Last week, the FDA also [expanded the testing options](#) for asymptomatic people. These tests were previously authorized for those with symptoms. This change will allow for expanded use by schools, businesses and other locations in screening their populations.

Of the tests, three are available without a prescription (OTC) and can be done at home – although one does require a telehealth proctor. The other two tests are authorized for point of care settings.

Resources & Equipment

Of vaccines and variants

The development and roll-out of three highly efficacious vaccines against severe COVID-19 is the result of monumental scientific, clinical, and public health achievements. To many, it also signifies that the end of the pandemic is in reach, and that a return to normalcy is near.

As of today, IDHW reports that 311,731, or nearly a quarter of Idaho's eligible population is fully vaccinated against COVID-19. Concurrent with these massive achievements, however, is the somewhat disquieting development of a very small proportion of fully vaccinated individuals testing positive for SARS-CoV-2 – also known as "breakthrough" cases. As of today, Idaho has reported 97 such cases, or 0.03% of the fully vaccinated population.

That the majority of these 97 cases were asymptomatic or had mild symptoms speaks to the efficacy of the available vaccines in preventing severe COVID-19, but understanding why we are detecting breakthrough cases is of paramount importance to local, national, and international public health professionals. Breakthrough cases that are associated with viral mutations could indicate that current vaccines are less efficacious against certain strains of SARS-CoV-2.

To these ends, IDHW is prioritizing whole genome sequencing (WGS) of viral samples from breakthrough cases and samples that demonstrate S-gene target failure upon molecular testing. To date, WGS identified that three breakthrough cases were caused by one of the variants first identified in California, which are not associated with decreased vaccine efficacy; there is no indication that breakthrough cases are linked to vaccine resistant SARS-CoV-2 variants in Idaho. However, increased incidence rates of COVID-19 in Eastern Idaho align with the identification of more virulent and transmissible B.1.1.7 (the UK variant) and B.1.427/B.1.429 (the California variants) in the region.

Viral mutations are common and typically result in no appreciable impact on the host population. When these mutations do result in changes to viral transmissibility or virulence, however, a variant of concern (VOC) is born. As these mutations relate to vaccines, viral mutations can also impact vaccine efficacy. Of the currently circulating VOCs, only B.1.351 (the South Africa Variant) has been shown to be partially resistant to vaccine-induced neutralizing antibodies from the Pfizer, Moderna and Novavax vaccines.^{1,2} Others, e.g. B.1.1.7 (the UK Variant), still demonstrate susceptibility to current vaccine formulations, while vaccine efficacy is unknown for other VOCs first identified in Brazil and New York.

As of April 5, IDHW reports that 478 virus samples have returned results from WGS, of which 96 tested positive for a VOC or variant of interest* (VOI). The majority of these were either the UK variant or one of the California variants. The South Africa variant (B.1.351) was also identified in two of the samples, prompting concern for decreased vaccine efficacy.

Despite the small number, these breakthrough cases serve as a reminder that vaccines – including the mRNA vaccines that predominate in Idaho – are not 100% effective at stopping SARS-CoV-2 transmission; until herd immunity is reached, even those who are vaccinated should continue to mask and physical distance per public health recommendations.

¹ Moore JP. Approaches for Optimal Use of Different COVID-19 Vaccines: Issues of Viral Variants and Vaccine Efficacy. JAMA 2021.

² Garcia-Beltran WF, Lam EC, St Denis K, et al. Circulating SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity. medRxiv 2021

* **Variant of Interest** is "a variant with specific genetic markers that have been associated with changes to receptor binding, reduced neutralization by antibodies generated against previous infection or vaccination, reduced efficacy of treatments, potential diagnostic impact, or predicted increase in transmissibility or disease severity." A Variant of Concern is "a variant for which there is evidence of an increase in transmissibility, more severe disease (increased hospitalizations or deaths), significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures."

The pandemic's impact on US mortality

From 2015 through 2019, year-over-year increases in the number of deaths in the United States has averaged 1.2%; but in 2020, the percent increase in the number of deaths relative to 2019 was an astounding 17.7% - increasing from 2,854,838 in 2019 to 3,358,814 in 2020.¹ Death rates, which are adjusted to account for yearly differences in underlying population distribution, also increased 15.9%.

These statistics show that most of the excess deaths are directly attributable to COVID-19 (345,323 of 503,976) – i.e. that the underlying cause of death listed on the death certificate was U07.1.* However, deaths attributable to other causes also increased; the number of deaths attributable to heart disease and stroke increased by 4.8% and 6.0%, respectively. There were also increases in the number of deaths attributable to unintentional injury (11.1%), Alzheimer disease (9.8%), and diabetes (15.4%). All of these increases are likely consequences of the pandemic related to delays or disruptions in care, or sequelae of SARS-CoV-2 itself.²⁻⁴

Mortality patterns in 2020 also differed in terms of seasonality relative to prior years. Typically, deaths in the United States are highest in the winter months; in 2020, however, mortality patterns reflected the three COVID-19 waves that occurred in the United States, with marked increases in deaths in April, July and December.

Although the data presented here are provisional, it is clear that COVID-19 has had a massive impact on life and death in the United States – and will continue to do so. Even as vaccines become more available and the end of the pandemic seems near, over 100,000 people in the U.S. have died from COVID-19 in 2021, a sobering reminder of the need to continue to follow public health guidelines until we reach herd immunity.

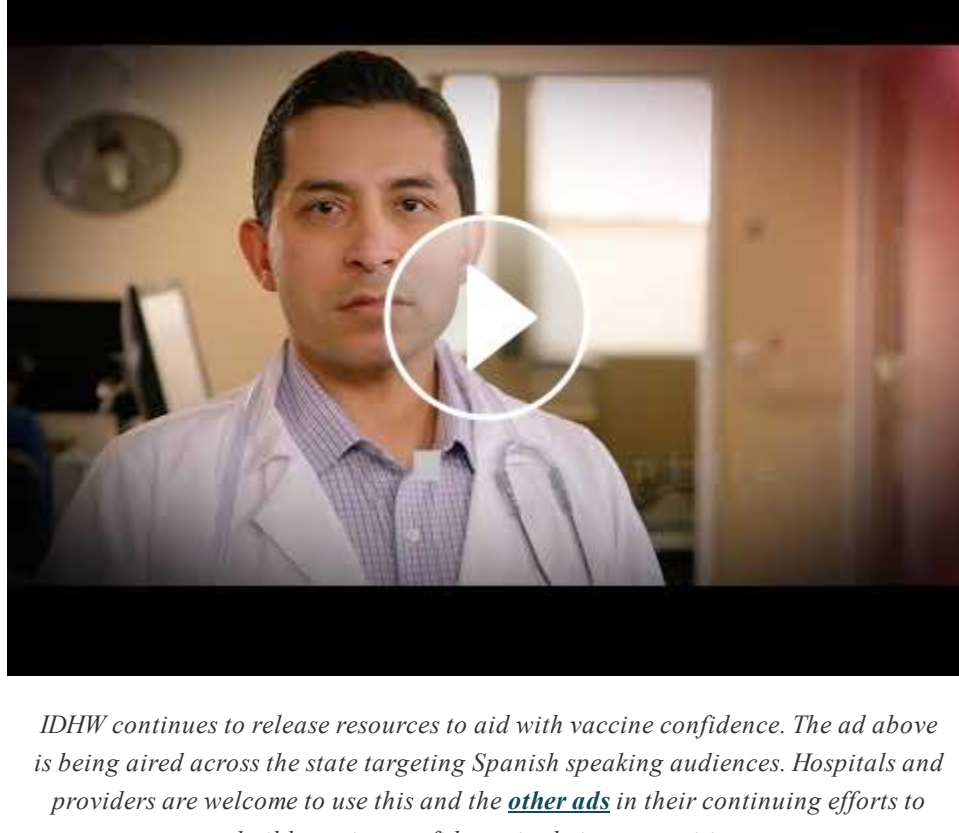
¹ Ahmad FB, Anderson RN. The Leading Causes of Death in the US for 2020. JAMA 2021.

² Katsanos AH, Palaioimou L, Zand R, et al. The Impact of SARS-CoV-2 on Stroke Epidemiology and Care: A Meta-Analysis. Ann Neurol 2021;89:380-8.

³ Koutsoukis A, Delmas C, Roubille F, et al. Acute Coronary Syndrome in the Era of SARS-CoV-2 Infection: A Registry of the French Group of Acute Cardiac Care. CJC Open 2021;3:311-7.

⁴ Lanza GA, De Vita A, Ravenna SE, et al. Electrocardiographic findings at presentation and clinical outcome in patients with SARS-CoV-2 infection. Europace 2021;23:123-9.

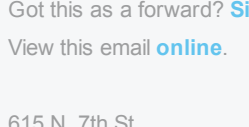
* Underlying cause of death is the precipitating event that initiates a chain of events resulting in the death of an individual.



IDHW continues to release resources to aid with vaccine confidence. The ad above is being aired across the state targeting Spanish speaking audiences. Hospitals and providers are welcome to use this and the [other ads](#) in their continuing efforts to build vaccine confidence in their communities.

[Click to get our COVID-19 Updates](#)

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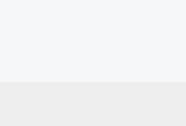
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