



Tuesday, May 5, 2020

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## **HHS Delays Enforcement of Interoperability Rules**

On April 21, the Office of the National Coordinator for Health IT (ONC), Centers for Medicare & Medicaid Services (CMS), and HHS Office of Inspector General (OIG) announced enforcement of major parts of ONC's landmark healthcare technology interoperability rule will be delayed in response to the COVID-19 public health emergency. **Read below.**

## **HHS Urges Federal Appeals Court to Reinstate Site Neutral Payments**

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## **CMS to Move Forward with Survey of 340B Hospitals' Drug Acquisition Costs**

On April 23, the federal Office of Information and Regulatory Affairs (OIRA) released its final approval for the Centers for Medicare & Medicaid Services (CMS) to move forward with a survey on drug acquisition costs for hospitals in the 340B drug discount program. **Read below.**

## **FULL STORIES**

### **Senate Returns to D.C.; Next COVID Relief Bill Still To Be Determined**

The Senate returned to Washington, D.C. on May 4, but the House remains out of session. Nevertheless, House Democrats have begun work on another large COVID relief bill expected to prioritize support to state and local governments whose budgets have been hit hard by the crisis. House Republicans, on the other hand, have suggested they want to make sure the previous relief bills are implemented correctly before moving on to another bill. In the Senate, Majority Leader Mitch McConnell (R-KY) has said that further aid for state and local governments should be paired with liability protections for businesses that re-open during the pandemic.

### **CMS Announces Second Round of Regulatory Relief, Changes to the Advance & Accelerated Payments Program and Provider Relief Fund**

On April 30, CMS issued a second interim final rule to help the American healthcare system respond effectively to the spread of COVID-19. The rule includes changes to further expand telehealth, improve COVID-19 diagnostic testing, increase hospital capacity, and decrease administrative burden. In response to provider feedback that they are frequently conducting audio-only telephone services to patients as a replacement for care that would otherwise be reported as an in-person visit or telehealth visit, effective March 1, 2020, CMS is increasing payments for telephone visits and waiving the video requirement for certain telephone E/M services. As part of CMS' "hospitals without walls" initiative, it will also allow excepted provider-based hospital outpatient departments (PBDs) that relocate off-campus to continue being paid under the hospital outpatient prospective payment system during the public health emergency, but noted that if hospitals choose to permanently relocate these PBDs off-campus, they would be considered new off-campus PBDs and be paid under the physician fee schedule following the end of the public health emergency.

On April 26, CMS announced that the Advance Payment Program will be suspended for Part B providers and that it is currently reevaluating all pending applications under the Accelerated Payment Program. The agency reported that more than \$100 billion has been disbursed to providers and suppliers through the advanced & accelerated payment program and directed providers still in need of assistance to the HHS Provider Relief Fund.

To date, a total of \$175 billion has been appropriated for the HHS fund, \$100 billion from the CARES Act and \$75 billion from the recently enacted Paycheck Protection Program and Health Care Enhancement Act. Unlike the advanced and accelerated payments, these funds do not have to be paid back to CMS.

The Provider Relief Fund will be allocated in the following manner:

- \$50 billion in a general allocation to providers to address healthcare-related expenses or lost revenue attributable to the COVID-19 pandemic and to ensure uninsured Americans can get treatment for COVID-19.
  - \$30 billion was immediately distributed to eligible providers between April 10 and April 17 based on their 2019 Medicare fee-for-service reimbursements. An additional \$20 billion is currently being allocated to eligible providers for a total distribution reflecting their 2018 patient revenues.
- \$10 billion to targeted hospitals located in COVID-19 hot spots.
- \$10 billion to rural health clinics and hospitals.
- \$400 million to the Indian Health Service.

HHS has announced it will allocate the remaining \$29.6 billion to reimburse providers for treating uninsured patients with COVID-19, targeted funding for skilled nursing facilities, dentists, and providers that solely take Medicaid, though details for exactly how this funding will be distributed are still being determined. It also has yet to indicate how it will distribute the additional \$75 billion from the Paycheck Protection Program and Health Care Enhancement Act.

To view the CMS press release on the second interim final rule, [CLICK HERE](#).

To view the CMS press release announcing the suspension of the Advance & Accelerated Payment Program, [CLICK HERE](#).

To view HHS' webpage with the latest information about the Provider Relief Fund, [CLICK HERE](#).

## Members of Congress Urge Leadership to Prioritize DIR Fee Reform in Next Pandemic Relief Package

On April 27, a bipartisan group of 114 members of Congress urged Congressional leadership to include a provision in the next pandemic relief package that would reform the process by which insurers collect Direct and Indirect Remuneration (DIR) fees from pharmacies.

“Ensuring the viability of our nation’s pharmacies has never been more important. As negotiations on the next aid package move forward, we respectfully request that you remove the barriers that threaten pharmacy financial stability and a pharmacy’s ability to support patients,” the lawmakers write. “This can be achieved by enacting much needed pharmacy DIR clawback reform. Pharmacies report that DIR clawback fees continue to be assessed against them right now, even during this period of intense strain. CMS states that DIR fees grew by 45,000 percent between 2010 and 2017, and now, during this financial crisis in which pharmacies are already struggling, DIR fees threaten to cause more pharmacies to close their doors.”

In recent years, pharmacies have argued that Direct and Indirect Remuneration (DIR) fees, most of which are collected from pharmacies after the medication is dispensed, have not only become a serious burden for pharmacies but are being used to boost Pharmacy Benefit Manager (PBM) revenue. A March report from *Drug Channels* found that pharmacies paid a record \$9.1 billion in DIR fees to Part D plans last year and that pharmacy fees accounted for 18 percent of all Medicare Part D rebates.

To read the Congressional Letter, [CLICK HERE](#).

## Joe Grogan To Depart White House Domestic Policy Council

On April 30, the White House announced that Domestic Policy Council Director Joe Grogan will be departing on May 24. As one of the administration’s most senior policy advisors, Grogan was The White House point person on a number of healthcare policy issues including the administration’s efforts to address high drug prices and implement site neutral payment policies in Medicare. He also played a role in the administration’s decision to rescind a proposed rule that would require Medicare Part D prescription drug rebates be passed on to consumers.

Prior to joining The White House staff, Grogan was the top healthcare official the Office of Management and Budget, and before that a lobbyist for the Gilead Sciences.

## HHS Delays Enforcement of Interoperability Rules

On April 21, the Office of the National Coordinator for Health IT (ONC), the Centers for Medicare & Medicaid Services (CMS), and the HHS Office of Inspector General (OIG) announced enforcement of major parts of ONC's landmark healthcare technology interoperability rule will be delayed in response to the COVID-19 public health emergency. The announcement gives providers an additional six months to comply with the new regulations, which were finalized in March.

According to the announcement, ONC's enforcement of the rule's information blocking and certification policy provisions won't go into effect until November 2. On CMS' part, the implementation timeline for providers to share admission, discharge, and transfer notifications as a condition of participation will be extended an additional six months to spring 2021. Further, the requirement that Medicare Advantage carriers, Medicaid fee-for-service programs, Medicaid managed care plans, CHIP fee-for-service programs and CHIP managed care entities provide patients access to their claims and encounter information, including cost, through a third-party app of their choosing will go into effect January 1, 2021 but won't be enforced until July 1, 2021.

Further, the electronic health record (EHR) provider Epic, which emerged earlier this year as one of the rule's fiercest critics, has now voiced support for the new regulations. In a statement provided to several media outlets, Epic said the final rules addressed many of its initial concerns about increasing third party developer access to patient health information and include greater flexibility for healthcare organizations to educate patients on how these developers will use their data.

To read a joint statement from ONC and CMS announcing the delay in enforcement, [CLICK HERE](#).

To view a timetable of the new compliance dates and timelines, [CLICK HERE](#).

To view a fact sheet from CMS on the delay, [CLICK HERE](#).

## HHS Urges Federal Appeals Court to Reinstate Site Neutral Payments

On April 17, the U.S. Department of Health and Human Services (HHS) urged the U.S. Court of Appeals for the District of Columbia Circuit to reinstate HHS' site-neutral payment policy for physician office visits. During oral arguments, Department of Justice attorney Alisa Klein, who is representing the federal government in the case, told the court that Congress empowered HHS to reduce service volume and it was this authority that the agency invoked when it finalized the site neutral payment rule in order to address the payment disparities between visits at independent physician offices and hospital outpatient departments (HOPDs).

The case centers around HHS' authority to issue payment adjustments. In bringing the suit against the government, hospital groups have argued that Congress did not authorize HHS to make targeted payment adjustments that aren't budget-neutral, as the site neutral payment rule suggests. Late in 2019, U.S. District Judge Rosemary Collyer ruled that Congress did not give HHS the ability to change reimbursement rates to lower utilization and that the law required payment changes to be budget neutral. HHS has appealed that decision.

To read more about the latest developments in the case, *American Hospital Association v. Azar*, No. 19-5352, [CLICK HERE](#) and [HERE](#).

To read the American Hospital Association's press release on the oral arguments, [CLICK HERE](#).

## CMS to Move Forward with Survey of 340B Hospitals' Drug Acquisition Costs

On April 23, the federal Office of Information and Regulatory Affairs (OIRA) released its final approval for the Centers for Medicare & Medicaid Services (CMS) to move forward with a survey on drug acquisition costs for hospitals in the 340B drug discount program. The survey is in response to a court decision in December 2018 that ruled CMS didn't have the authority to change 340B payment rates because it hadn't collected the necessary data to set the rates based on acquisition costs. The final approval to move forward with the survey came after several months of public comment, including opposition from hospital groups.

The 340B survey is now available on the CMS website and will remain open for submission until May 15. All hospitals that participate in the 340B program, excluding critical access hospitals, are required to submit survey responses to CMS.

To read the OIRA's conclusion, [CLICK HERE](#).

To read more about the survey and see the survey documents, [CLICK HERE](#).