### POLICY

## MEDICARE'S REGULATORY RESPONSE TO THE COVID-19 CRISIS

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In early 2020, the rapidly spreading novel coronavirus and its associated deadly disease, COVID-19, drastically altered the health care delivery system in the United States. In March 2020, the President declared a national emergency. This declaration, coupled with the nationwide public health emergency declaration from the Secretary of Health and Human Services in January, triggered new flexibilities for the Centers for Medicare & Medicaid Services (CMS) to address the pandemic in the Medicare program. In the subsequent weeks, CMS issued numerous Public Health Emergency (PHE)-related rules, waivers and guidance.

As of this writing, Congress has passed four bills relating to the COVID-19 crisis.¹ While there are some Medicare coverage provision changes in the four bills, most of the Medicare-related changes have been issued by CMS through regulation and sub-regulatory guidance.² This article focuses on CMS's regulatory response to the crisis, highlighting a few of the most important changes: expansion of telehealth services; waivers of statutory and regulatory requirements for nursing facilities; and coverage for COVID-19 testing.

The Center for Medicare Advocacy has compiled, and continues to update, a comprehensive catalogue of the wide-ranging changes in the Medicare program during the pandemic, available at https://medicareadvocacy.org/covid-19-anadvocates-guide-to-medicare-changes/.

While most of the Medicare-related changes are retroactive to March 1, 2020, and will last until the Public Health Emergency related to the COV-ID-19 crisis is lifted,<sup>3</sup> this article examines changes, including those that are likely to be extended.

#### **TELEHEALTH SERVICES**

Early data suggests that COVID-19 is particularly harmful for older adults.<sup>4</sup> As a result, much of CMS's regulatory flexibility has been aimed at practical ways to remove barriers to urgent and necessary health care, while minimizing potential exposure of older adults to the virus. Therefore, one of the chief Medicare policy changes re-

sponding to the pandemic is the broad expansion of coverable telehealth services.

During the health emergency, CMS is permitting Medicare beneficiaries to receive coverage for a wider range of health care services without having to travel to a facility. CMS accomplished this by waiving a number of requirements in order to expand the list of providers who can offer telehealth services during the emergency. This has been accomplished by permitting routine visits, preventive health screenings for cancer and other illnesses to be included in telehealth, and by providing payment parity for telehealth. More than 80 additional services are covered by Medicare when furnished via telehealth, including emergency department visits, initial nursing facility and discharge visits, and home visits.

During the pandemic, telehealth has been critical in limiting disruptions in care while protecting beneficiaries from the spread of the deadly virus. CMS has signaled that it intends to make many of the Medicare telehealth changes permanent after the conclusion of the current crisis. There is also widespread support in Congress for expanding telehealth benefits. 10

Given the likelihood of continued telehealth expansion, future policy proposals should stress that telehealth cannot replace face-to-face visits; rather, telehealth should be considered an important complementary tool to in-person services. One concern with increasing reliance on tele-

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health as a substitute for personalized in-person services is that it could exacerbate existing health disparities, many of which were starkly exposed by the pandemic. Early COVID-19 research and data suggest a correlation between low incomes, communities of color and risks of illness and severity of illness.<sup>11</sup>

Many underserved beneficiaries do not have reliable broadband and have limited, if any, access to digital literacy training and remote technologies. Access to reliable internet must be factored

into telehealth policy.<sup>12</sup> Additionally, difficulty hearing well enough to use a telephone, even with hearing aids, along with difficulty seeing well, difficulty speaking, and limited English proficiency are all factors that could jeopardize health outcomes when care is only provided virtually.<sup>13</sup>

Any expansion of telehealth must ensure privacy and data security for personal health in-

formation. HIPAA privacy protections, which have largely been suspended for telehealth interactions between patient and provider during the pandemic,<sup>14</sup> must apply to such interactions. Personal health data must also be kept secure.<sup>15</sup>

Additionally, expanding telehealth must not be used as a means to further weaken Medicare Advantage network adequacy requirements. CMS has already begun this process by allowing Medicare Advantage plans to meet weaker network standards if they provide certain services via telehealth.16 This essentially allows plans to "count" certain telehealth availabilities toward the standard of how many providers are within the time and distance required for a large percentage of their enrollees. Unfortunately, the end result of weakened network requirements is that beneficiaries may end up having to pay more for out-of-network providers when they cannot find an accessible provider in their plan's network of providers.

#### **SKILLED NURSING FACILITIES**

During the public health emergency, CMS has approved a waiver that expands Medicare coverage

of skilled nursing facilities (SNF). For individuals affected by COVID-19, CMS has waived the requirement that a patient must first have spent at least three consecutive days as an inpatient in an acute-care hospital in order for Medicare Part A to pay for a patient's subsequent stay in a skilled nursing facility.<sup>17</sup>

While CMS cannot make this waiver permanent without legislation, CMS does have the authority and discretion under the Medicare statute to count all time in the hospital — including time

HIPAA privacy protections, which have largely been suspended for telehealth interactions between patient and provider during the pandemic, must apply to such interactions. Personal health data must also be kept secure.

spent in "observation status" — toward the three-day stay requirement.<sup>18</sup> A large coalition of consumer and patient advocates, along with health care providers, support CMS exercising this authority to allow greater access to skilled nursing facility coverage beyond the pandemic.<sup>19</sup>

Despite the broadening access to SNF benefits resulting from the CMS waiver, many other CMS waivers have limited beneficiary protections for nursing home residents during this pandemic. CMS suspended certain reporting requirements, residents' rights, nurse aide training rules and many oversight activities that are designed to protect nursing home residents.<sup>20</sup> In addition, in the absence of federal leadership, nursing facilities have been in competition with each other for tests and personal protective equipment.<sup>21</sup> These factors, as well as low staffing levels in many facilities, and infection control issues, have led to massive outbreaks in facilities.

The COVID-19 pandemic has resulted in a staggeringly large number of deaths in nursing facilities. As of September 2020, over 80,000 deaths from COVID-19 occurred in long-term care facilities, which include nursing care facili-

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ties, amounting to over 41% of COVID-19 deaths in the United States.<sup>22</sup> In order to address these issues, CMS must fully reinstitute Requirements of Participation<sup>23</sup> as well as survey and enforcement activities that have been waived during the pandemic. CMS must also require nursing facilities to be transparent about COVID-19 infection and staffing levels in the nation's nursing facilities retroactive to January 2020. A coordinated federal response for personal protective equipment and expanded testing for staff and residents is also essential.

#### **COVERAGE FOR COVID-19 TESTING**

CMS guidance ensures broad coverage for CO-VID-19 testing. Testing is covered with no costsharing in both traditional Medicare and Medicare Advantage plans. During the current pandemic, CMS also waived the requirement that there be a doctor's or other provider's written order, allowing tests to be covered when ordered by a broad range of health care professionals.<sup>24</sup> In keeping with CMS's objective to minimize person-to-person contact during the pandemic, Medicare is authorized to pay laboratory technicians to travel to a beneficiary's home to collect a specimen for COVID-19 testing, eliminating the need for the beneficiary to travel to a health care facility for a test.25 Medicare Part B also will cover beneficiary cost-sharing for provider visits during which a COVID-19 diagnostic test is administered or ordered.26

Medicare Advantage plans must provide coverage for COVID-19 diagnostic testing, including the associated cost of the visit, in order to receive testing at no cost to the beneficiary.<sup>27</sup> CMS also temporarily relaxed rules so that Medicare Advantage plans can expand benefits, add additional benefits and institute more generous costsharing.<sup>28</sup> This allows plans to waive or reduce enrollee cost-sharing for COVID-19 treatment and address issues or medical needs raised by the outbreak, such as covering meal delivery or medical transportation services.<sup>29</sup> Additionally, if a COVID-19 vaccine is developed, it will be covered under Part B with no cost-sharing.<sup>30</sup>

CMS should extend the broad coverage of testing for COVID-19 in order to keep the virus under control, even if the public health emergency declaration is ended.

#### CONCLUSION

CMS responded to the catastrophic and rapidly spreading COVID-19 pandemic with various waivers to regulations in the Medicare program. The pandemic waivers limited disruptions in care and provided expanded benefits in some cases, but also suspended some crucial beneficiary protections. Some waivers, such as expansions in telehealth, are likely to continue after the pandemic.

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#### NOTES

1. On March 6, 2020, the President signed into law the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, H.R. 6074, 116th Cong. (2020) (sometimes referred to as COVID Bill #1); On March 18, 2020, the President signed into law the Families First Coronavirus Response Act, H.R. 6201, 116th Cong. (2020) (COVID Bill #2); On March 27, 2020, the President signed into law the Coronavirus Aid, Relief, and Economic Security (CARES) Act, H.R. 748, 116th Cong. (2020) (COVID Bill #3); On April 24, 2020, the President signed into law the Paycheck Protection Program and Health Care Enhancement Act, H.R. 266, 116th Cong. (2020) (referred to as an interim emergency funding package).

2. See CMS' webpages devoted to the COVID crisis: https://www.cms.gov/About-CMS/Agency-Information/ Emergency/EPRO/Current-Emergencies/Current-Emergencies-page and https://www.cms.gov/outreach-education/partner-resources/coronavirus-covid-19-partner-toolkit. CMS' list of their ongoing waivers: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf. On April 6, 2020, CMS published an Interim Final Rule (hereinafter referred to as the IFR), at 85 F.R. 19230 (April 6, 2020), https://www.govinfo.gov/content/pkg/FR-2020-04-06/ pdf/2020-06990.pdf. On May 8, 2020, CMS published another Interim Final Rule (hereinafter referred to IFR 2) at 85 F.R. 27550 (May 8, 2020), https://www.govinfo. gov/content/pkg/FR-2020-05-08/pdf/2020-09608.pdf. 3. CMS, "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers," https://www.cms. gov/files/document/summary-covid-19-emergencydeclaration-waivers.pdf.

4. CDC, "COVID-19 Guidance for Older Adults," https://www.cdc.gov/aging/covid19-guidance.html.

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5. CMS, "Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19" (updated April 29, 2020), https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf. Previously, covered telehealth only included services provided by doctors, nurse practitioners, clinical psychologists and licensed clinical social workers. CMS has waived a number of requirements to include "all those that are eligible to bill Medicare for their professional services. As a result, a broader range of practitioners, such as physical therapists, occupational therapists, and speech language pathologists can use telehealth to provide many Medicare services."

6. CMS, "Physicians and Other Clinicians."
7. CMS, "President Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak," https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak.

8. See, for example, CMS memo "Medicare Telemedicine Health Care Provider Fact Sheet," March 17, 2020, https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet. Please note that telehealth services are distinguished from brief communications or "virtual check-ins," which are short patient-initiated communications with a health care practitioner, and e-visits, which are non-face-to-face patient-initiated communications through an online patient portal.

9. Casey Ross, "'I Can't Imagine Going Back': Medicare Leader Calls for Expanded Telehealth Access after Covid-19," *Stat*, June 9, 2020, https://www.statnews.com/2020/06/09/seema-verma-telehealth-access-covid19/.
10. Mohana Ravindranath, "Senators Push for Permanent Telehealth Changes," *Politico*, June 15, 2020, https://www.politico.com/newsletters/morning-ehealth/2020/06/15/senators-push-for-permanent-telehealth-changes-788506.

11. See, for example, Center for Medicare Advocacy Weekly Alert, "Research: Low-Income and Communities of Color at Increased Risk From COVID-19," May 21, 2020, and citations therein, https://medicareadvocacy.org/research-low-income-and-communities-of-color-at-increased-increased-risk-from-covid-19/ and Ways & Means Committee, Chairman Richard Neal, "The Disproportionate Impact of COVID-19 on Communities of Color," https://waysandmeans.house.gov/legislation/hearings/disproportionate-impact-covid-19-communities-color-0.

12. July 2020 Congressional Report, "Left Out: Barriers to Health Equity for Rural and Underserved Communities Report of the Committee on Ways and Means Majority U.S. House of Representatives," https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/WMD%20Health%20Equity%20 Report\_07.2020\_FINAL.pdf; see also *The New York Times*, "Is Telemedicine Here to Stay?" Aug. 3, 2020, https://www.nytimes.com/2020/08/03/health/covid-telemedicine-congress.html?smid=tw-nythealth&smtyp=cur

13. Judy George, "Telehealth Boom Misses Older Adults," MedPage Today, Aug. 4, 2020, https:// www.medpagetoday.com/practicemanagement/ telehealth/87901?xid=nl\_mpt\_DHE\_2020-08-05&eun=g1439001d0r&utm source=Sailthru&utm medium=email&utm\_campaign=Daily%20Headlines%20Top%20Cat%20HeC%20%202020-08-05&utm\_term=NL\_Daily\_DHE\_dual-gmail-definition. 14. HHS Office of Civil Rights, "OCR Issues Bulletin on Civil Rights Laws and HIPAA Flexibilities That Apply During the COVID-19 Emergency," March 28, 2020, https:// www.hhs.gov/about/news/2020/03/28/ocr-issuesbulletin-on-civil-rights-laws-and-hipaa-flexibilities-thatapply-during-the-covid-19-emergency.html. 15. Nicol Turner Lee, Jack Karsten and Jordan Roberts, "Removing Regulatory Barriers to Telehealth Before and After COVID-19," The Brookings Institution and The John Locke Foundation, May 6, 2020, https://www.brookings. edu/research/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/. 16. 85 F.R. 33796 (June 2, 2020), Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program, https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-

the-medicare-advantage-program.

17. Requirement at 42 U.S.C. §1395x(i); waiver, https://www.cms.gov/files/document/covid19-emergency-declaration-health-care-providers-fact-sheet.pdf; see also https://www.cms.gov/files/document/se20011.pdf.

18. See generally, Center for Medicare Advocacy, "Out-patient Observation Status," https://medicareadvocacy.org/medicare-info/observation-status/; "Observation Status Deprives Medicare Beneficiaries of Their Skilled Nursing Facility Benefit. Period.," https://medicare advocacy.org/observation-status-deprives-medicare-beneficiaries-of-their-skilled-nursing-facility-benefit-

contract-year-2021-policy-and-technical-changes-to-

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period/. Also, a federal district court recently found that certain beneficiaries have the right to appeal their coverage as "observation status" hospital patients to Medicare. Alexander v. Azar, \_\_\_ F. Supp. 3d \_\_\_, 2020 WL 1430089 (D. Conn. 2020), appeal filed (2d Cir. May 22, 2020) (No. 20-1642). For more information see https://medicareadvocacy.org/litigation/active-cases/.

19. Center for Medicare Advocacy, "Observation Stays Fact Sheet," https://www.medicareadvocacy.org/wp-content/uploads/2017/09/Observation-Coalition-Fact-Sheet,pdf.

20. More information is available at https://medicaread-vocacy.org/cmas-toby-edelman-testifies-at-congressional-hearing-on-covid-in-nursing-homes/.

21. Danielle Brown, "Providers Appeal to VP to Investigate PPE Distribution 'Failures'; Senate Subcommittee Holds Hearing on Pandemic's Impact on Nursing Homes," McKnight's Long-Term Care News, June 12, 2020, https://www.mcknights.com/news/providersappeal-to-vp-to-investigate-ppe-distributions-failuressenate-subcommittee-holds-hearing-on-pandemicsimpact-on-nursing-homes/; See also Neville M. Bilimoria, "More Equipment and Less Liability for COVID-19, Please!," McKnight's Long-Term Care News, April 4, 2020, https://www.mcknights.com/blogs/guestcolumns/more-equipment-and-less-liability-for-covid-19-please/; see also Jordan Rau, "Nursing Homes Run Short of COVID-19 Protective Gear as Federal Response Falters," NPR, June 11, 2020, https://www.npr.org/ sections/health-shots/2020/06/11/875335588/ nursing-homes-run-short-of-covid-19-protectivegear-as-federal-response-falters.

22. Kaiser Family Foundation, "State Data and Policy Actions to Address Coronavirus," September 24, 2020, https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/. This number could be higher, as CMS only required nursing facilities to report COVID-19 deaths and problems since May 8, not since the beginning of the pandemic: IFR 2, Page 27601-02.

23. 42 C.F.R § 483.11-483.95

24. IFR 2, Page 27555.

25. IFR, Page 19258.

26. Note: this does not mean that all COVID-related treatment is covered without cost sharing. According to CMS, "cost-sharing does not apply for COVID-19 testing-related services, which are medical visits that: are furnished between March 18, 2020 and the end of the Public Health Emergency (PHE); that result in an order for or administration of a COVID-19 test; are related to furnishing or administering such a test or to the evaluation of an individual for purposes of determining the need for such a test; and are in any of [certain] categories of HCPCS evaluation and management codes."

27. CMS Memo, April 21, 2020, https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plansponsors-42120.pdf.

28. "CMS Memo, April 21, 2020."

29. "CMS Memo, April 21, 2020"

30. Section 3713 of Coronavirus Aid, Relief, and Economic Security (CARES) Act, H.R. 748, 116th Cong. (2020), https://www.congress.gov/bill/116th-congress/house-bill/748/text.

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