Summary of Key Regulatory Communications Re: COVID-19 April 3, 2020

4/02/20

- 1. CMS and the Centers for Disease Control and Prevention (CDC) issued new recommendations to State and local governments and long-term care facilities/nursing homes to help mitigate the spread of COVID-19 in such facilities.
- 2. COVID-19 creates significant challenges and safety concerns regarding data collection for the Healthcare Effectiveness Data and Information Set (HEDIS) measures and the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. As a result of these challenges, on Monday March 30, 2020, CMS announced it was eliminating the requirement for Medicare health plans to submit HEDIS 2020 data covering the 2019 measurement year. CMS also eliminated the requirement to submit 2020 CAHPS survey data for Medicare health and drug plans. CMS confirms that the elimination of these requirements for the same reporting years applies to Medicare-Medicaid Plans (MMPs).
- 3. CMS issued a reminder to Medicare Advantage Organizations and Cost-Based Contractors regarding certain flexibilities for notice delivery to beneficiaries receiving institutional care. If a beneficiary is being treated with suspected or confirmed COVID-19 and receiving institutional care, CMS encourages the provider community to be diligent and safe while issuing required beneficiary notices. CMS issued a reminder of existing notice delivery instructions, which provide flexibilities for delivering notices to beneficiaries in isolation.

3/30/20

- CMS issued guidance for Medicare Advantage and Part D Plans regarding COVID-19. The
 guidance covered flexibility to waive cost sharing and provide expanded telehealth benefits, Part D
 Sponsors' ability to relax "refill-too-soon" and maximum day supply edits, home and mail delivery
 of Part D drugs, 2021 Star Ratings data collection changes, 2022 Star Ratings calculations, and
 MA and Part D appeals and organization determination guidance.
- 2. CMS announced that, effective immediately, it will reprioritize its scheduled program audits for Medicare Advantage Organizations, Part D Sponsors, Medicare-Medicaid Plans, and PACE organizations by:
 - a. Temporarily shifting from conducting routine audits to prioritizing investigation of: (i) instances of noncompliance where the health and/or safety of beneficiaries are at serious risk; and (ii) complaints alleging infection control concerns, including COVID-19 or other respiratory illnesses.
 - b. Suspending RADV audit activities related to payment year 2015. CMS will not initiate any additional contract-level RADV audits until after the public health emergency has ended. Organizations should immediately suspend soliciting RADV-related medical records from providers.

The suspension of these activities is time limited. CMS will announce when normal audit activities resume after the public health emergency ends.

CMS issued an array of temporary regulatory waivers and new rules to provide maximum flexibility
to respond to the COVID-19 pandemic. These temporary changes apply immediately across the
entire U.S. healthcare system for the duration of the emergency declaration and empower local

hospitals and healthcare systems to:

- a. Increase Hospital Capacity: A variety of temporary changes to increase hospital capacity including, among other things, permitting ambulatory surgery centers to contract with local healthcare systems to provide hospital services or enroll and bill as hospitals during the emergency declaration, permitting hospitals to transfer patients to non-hospital buildings and spaces for patient care and quarantine while still receiving hospital payments, and announcing that Medicare will now pay hospitals, labs, and other entities under certain circumstances to perform tests for COVID-19 on people at home and in other community-based settings outside the hospital.
- b. Rapidly Expand the Healthcare Workforce: Allows hospitals and healthcare systems options to increase their workforce capacity by removing barriers for physicians, nurses, and other clinicians to be hired from the local community as well as those licensed from other states without violating Medicare rules; issues waivers so that hospitals can use other practitioners, such as physician assistants and nurse practitioners, to perform services such as order tests and medications that may have previously required a physician's order where this is permitted under state law; waives requirements that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician; allows healthcare providers (clinicians, hospitals and other institutional providers, and suppliers) to enroll in Medicare temporarily to provide care during the public health emergency.
- c. <u>Put Patients Over Paperwork:</u> Medicare will now cover respiratory-related devices and equipment for any medical reason determined by clinicians whereas previously Medicare only covered them under certain circumstances; hospitals are not required to have written policies on processes and visitation of patients who are in COVID-19 isolation and have more time to provide patients a copy of their medical record; CMS is providing temporary relief from many audit and reporting requirements.
- d. Further Promote Telehealth in Medicare: CMS will now allow for more than 80 additional services to be furnished via telehealth. During the public health emergencies, individuals can use interactive apps with audio and video capabilities to visit with their clinician for an even broader range of services. Providers also can evaluate beneficiaries who have audio phones only. Providers can bill for telehealth visits at the same rate as in-person visits. Telehealth visits include emergency department visits, initial nursing facility and discharge visits, home visits, and therapy services, which must be provided by a clinician that is allowed to provide telehealth. CMS is allowing physicians to supervise their clinical staff using virtual technologies when appropriate, instead of requiring in-person presence. New as well as established patients now may have a telehealth visit with their provider; clinicians can provide remote patient monitoring services to patients with acute and chronic conditions, and can be provided for patients with only one disease (e.g., remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry).

3/29/20

CMS sent a <u>letter to the nation's hospitals on behalf of Vice President Pence</u> requesting they report
data to in connection with their efforts to fight COVID-19. Specifically, the Trump Administration is
requesting that hospitals report COVID-19 testing data to HHS, in addition to daily reporting
regarding bed capacity and supplies to the CDC National Healthcare Safety Network (NHSN)
COVID-19 Patient Impact and Hospital Capacity Module.

3/28/20

CMS announced an expansion of its accelerated and advance payment program for Medicare
participating health care providers and suppliers, to ensure they have the resources needed to
combat COVID-19. This program expansion, which includes changes from the recently enacted

Coronavirus Aid, Relief, and Economic Security (CARES) Act, is one way that CMS is working to lessen the financial hardships of providers facing extraordinary challenges related to the COVID-19 pandemic. The payments can be requested by hospitals, doctors, durable medical equipment suppliers and other Medicare Part A and Part B providers and suppliers.

3/27/20

- 1. CMS announced it is delaying the start of the 2019 Part C and D Reporting Requirements data validation scheduled to begin on Wednesday April 1, 2020. The 2020 Data Validation web-based training is not yet available on the Medicare Learning Network system and it must be completed by reviewers prior to starting any data validation activities. CMS will provide more information once the training is available and also will provide notice if it modifies the data validation schedule this year.
- CMS approved an additional five state Medicaid waiver requests under Section 1135 of the Social Security Act, bringing the total number of approved Section 1135 waivers for states to 34. On 3/27, CMS approved Section 1135 waivers for: Connecticut, Delaware, Minnesota, Pennsylvania and Wyoming. All Section 1135 waivers granted by CMS may be found here.
- 3. CMS released an electronic toolkit regarding telehealth and telemedicine for Long Term Care Nursing Home facilities.
- 4. CMS released a memo and fact sheet supplement to provide additional guidance to health care providers participating in quality reporting programs. Among other things, CMS extended the 2019 Merit-based Incentive Payment System (MIPS) data submission deadline from March 31 by 30 days to April 30, 2020 to provide relief to clinicians responding to COVID-19. In addition, the MIPS automatic extreme and uncontrollable circumstances policy will apply to MIPS eligible clinicians who do not submit their MIPS data by the April 30, 2020 deadline.

3/26/20

- 1. CMS issued a summary of several recent actions it has taken in response to COVID-19:
 - a. Granted additional Section 1135 State Medicaid waivers
 - b. Granted additional Appendix K Amendments to existing Home and Community Based Services (HCBS) Waivers
 - c. Released FAQs regarding the implementation of provisions under the Families First Coronavirus Response Act (Public Law 116-127) that provide states with enhanced federal Medicaid funding during the COVID-19 pandemic
 - d. Released <u>FAQs on Medicare Provider Enrollment Relief related to COVID-19</u> including the toll-free hotlines available to Medicare Administrative Contractors (MACs)
 - e. Released guidance on <u>Payment and Grace Period Flexibilities for Issuers Offering Coverage on the Federally-facilitated Exchanges and State-based Exchanges on the Federal Platform.</u>
 - f. Released Telehealth FAQs for Private Health Insurance issuers;
 - g. Released Prescription Drug FAQs for Individual and Small Group health insurance issuers

3/25/20

1. CMS approved more state Medicaid waiver requests under Section 1135 of the Social Security Act,

bringing the total number of approved Section 1135 state waivers to 23.

3/23/20

- CMS released <u>FAQs on Medicare Provider Enrollment Relief</u> related to COVID-19, including the toll-free hotlines available to provide expedited enrollment and answer questions about COVID-19 enrollment requirements.
- 2. CMS approved an additional 11 state Medicaid waiver requests under Section 1135 of the Social Security Act, bringing the total number of approved Section 1135 waivers for states to 13. These Section 1135 waivers are effective March 1, 2020 and will end upon termination of the public health emergency, including any extensions.
- 3. CMS announced the preliminary results of a recent inspection of the Life Care Center nursing home in Kirkland, Washington the epicenter of the 2019 Novel Coronavirus (COVID-19) outbreak in that state. CMS released an accompanying fact sheet. CMS also announced that only the following types of facility inspections will be conducted over the next few weeks: complaint inspections, targeted infection control inspections, and self-assessments.

3/22/20

- CMS announced it is granting exceptions from reporting requirements and extensions for clinicians and providers participating in Medicare quality reporting programs with respect to upcoming measure reporting and data submission for those programs. In addition, no data reflecting services provided January 1, 2020 through June 30, 2020 will be used in CMS's calculations for the Medicare quality reporting and value-based purchasing programs.
- 2. CMS released four checklists to make it easier for states to receive the federal waivers and implement flexibilities in their Medicaid and CHIP programs.

3/20/20

- CMS encourages Part D sponsors to work with their FDRs to identify means of ensuring that medication is delivered to patients without requiring face-to-face contact, which could result in transmission of the coronavirus. HHS does not require and will not audit for patient signatures as proof of delivery for any medications, including for controlled substances.
- 2. CMS announced it will hold a call on Tuesday, March 24 at 4PM ET for PACE organizations and state officials on issues related to COVID-19.
- 3. CMS released two comprehensive toolkits on telehealth that are specific to general practitioners as well as providers treating patients with End-Stage Renal Disease (ESRD):
 - a. Telehealth toolkit for general practitioners
 - b. Telehealth toolkit for End-Stage Renal Disease providers

3/19/20

1. CMS approved a 1135 Medicaid waiver request for the state of Washington and provided a link where all Section 1135 Medicaid waiver approval letters will be posted as they are issued.

3/18/20

- 1. CMS posted several of its stakeholder calls regarding COVID-19.
- 2. CMS announced its recommendation that <u>all elective surgeries</u>, <u>non-essential medical</u>, <u>surgical</u>, <u>and dental exams and procedures be delayed</u> during the COVID-19 outbreak.

3. CMS issued FAQs for catastrophic health plans to clarify coverage for the diagnosis and treatment of COVID-19.

3/17/20

- 1. CMS approved Florida's Section 1135 Medicaid waiver request in response to the COVID-19 national emergency.
- 2. CMS announced <u>expanded Medicare telehealth coverage</u> and said it will temporarily pay clinicians to provide telehealth services for beneficiaries residing across the entire country. CMS also published <u>related telehealth FAQs</u>.
- 3. CMS issued COVID-19 guidance to PACE organizations.

3/14/20

- 1. President Trump declared a national emergency due to COVID-19. CMS issued a <u>fact sheet</u> outlining several actions it was taking.
- 2. CMS announced <u>new measures it is taking to significantly restrict visitors and nonessential personnel</u> as well as restrict communal activities inside nursing homes.

3/13/20

 In response to President Trump's declaration of a national emergency, CMS provided a Medicaid and CHIP <u>Disaster Response Toolkit</u>, announced it would temporarily suspend non-emergency survey inspections, activated blanket waivers of certain Medicare, Medicaid and CHIP requirements, and published FAQs to ensure individuals, issuers and states have information on <u>Essential Health Benefits (EHB) coverage</u> for COVID-19.

3/11/20

1. The IRS advised that health plans that otherwise qualify as high deductible health plans (HDHPs) will not lose that status merely because they cover the cost of testing for or treatment of COVID-19 before plan deductibles have been met.

3/10/20

- 1. CMS issued guidance to help Medicare Advantage and Part D Plans respond to COVID-19, outlining the flexibilities plans have to waive certain cost-sharing, PA, prescription refill limits, restrictions on home or mail delivery of prescription drugs, and restrictions on telehealth.
- 2. CMS issued protective mask guidance for healthcare workers treating patients with COVID-19.
- 3. CMS issued guidance for home health providers and guidance for dialysis facilities dealing with COVID-19.

3/09/20

- 1. CMS issued guidance to hospitals with EDs on patient screening, treatment and transfer requirements regarding COVID-19 patients.
- 2. CMS issued a <u>press release highlighting the telehealth benefits</u> in the agency's Medicare program for use by patients and providers.
- 3. CMS delivered <u>guidance</u> on the screening, treatment and transfer procedures healthcare workers must follow when interacting with patients to prevent the spread of COVID-19 in a hospice setting.

CMS issued guidance for hospice providers and nursing homes.

4. CMS published its website for the most current information regarding the COVID-19 emergency.

3/06/20

1. CMS issued a <u>FAQ for providers</u> regarding Medicare payment for lab tests and other services related to COVID-19.

3/05/20

- CMS issued a <u>second code</u> for certain COVID-19 laboratory tests, in addition to the following three fact sheets about coverage and benefits for medical services related to COVID-19 for CMS programs:
 - a. Medicare Fact Sheet
 - b. CHIP Fact Sheet
 - c. Individual and Small Group Fact Sheet

3/04/20

- 1. CMS suspended non-emergency inspections across the country.
- 2. CMS issued an FAQ for providers with guidance for infection control and prevention concerning COVID-19 for patient triage, placement and hospital discharge.
- 3. CMS issued guidance for infection control and prevention of COVID-19 in nursing homes.

2/13/20

1. CMS issued new code for COVID-19 lab test.

2/06/20

- 1. CMS issued a memo to help the nation's healthcare facilities take critical steps to prepare for COVID-19.
- 2. CMS issued a <u>notification</u> to Surveyors of the Authorization for Emergency Use of the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Assay and Guidance for use in CDC Qualified Laboratories.