Summary of Key Regulatory Communications Re: COVID-19

Last updated: January 8, 2021

1/07/21

1. CMS released an HPMS memo explaining how it will make certain COVID-19 vaccine (COVAX) data available to plans for their enrollees. For Calendar Years 2020 and 2021, CMS will process all claims for payment for the COVAX administration for Medicare beneficiaries enrolled in Medicare Advantage Plans (including Local Coordinated Care Plans (CCPs), and Regional CCPs as well as other plan types), Prescription Drug Plans (PDPs) and Medicare-Medicaid Plans (MMPs), through the original fee-for-service Medicare program. While these plans are not responsible at this time for making payments for vaccine administration, CMS encourages these plans to help ensure their enrollees receive an initial COVAX dose when available to them, as well as any second dose per clinical recommendations. In order to assist with these efforts, CMS will allow plans to request certain COVAX data from CMS regarding their enrollees, subject to CMS approval. This memo outlines the process plans must follow to request certain data from CMS about COVAX claims for their enrollees.

12/28/20

1. CMS issued FAQs regarding COVID-19 Contract Year 2021 permissive actions for Medicare Advantage (MA) organizations, Part D Sponsors and Medicare-Medicaid plans.

10/28/20

1. CMS issued an HPMS memo announcing that Medicare payment for COVID-19 vaccinations administered during calendar years 2020 and 2021 to Medicare Advantage (MA) beneficiaries will be made through the Medicare Fee-for-Service (FFS) program. Medicare beneficiaries enrolled in MA plans will be able to access the COVID-19 vaccine, without cost sharing, at any FFS provider or supplier that participates in Medicare and is eligible to bill under Part B for vaccine administration, including those enrolled in Medicare as a mass immunizer or a physician, non-physician practitioner, hospital, clinic, or group practice. MA organizations should inform their contracted providers about this coverage policy and direct them to submit claims for administration of the COVID-19 vaccine to the CMS Medicare Administrative Contractor (MAC) for payment.

2. CMS issued the following:

    a. A set of toolkits for providers, state Medicaid and CHIP programs and insurers (including Medicare Advantage insurers) to help the health care system prepare to swiftly administer the COVID-19 vaccine once it is available.

    b. Information about the COVID-19 vaccine for individuals and entities who interact with Medicare beneficiaries.

    c. Updated COVID-19 Frequently Asked Questions on Medicare Fee-for-Service Billing to supplement FAQs previously released on 5/07/20.

    d. A fourth COVID-19 Interim Final Rule with Comment Period (IFC-4) and accompanying fact sheet. IFC-4 removes administrative barriers to eliminate potential delays to patient access to the COVID-19 vaccine. In addition, the rule:

i. Creates flexibilities for states maintaining Medicaid enrollment during the COVID 19 public health emergency (PHE);

ii. Establishes enhanced Medicare payments for new COVID-19 treatments;

iii. Takes steps to ensure price transparency for COVID-19 tests;

iv. Provides an extension of Performance Year 5 for the Comprehensive Care for Joint Replacement (CJR) model; and

v. Creates flexibilities in the public notice requirements and post-award public participation requirements for a State Innovation Waiver under Section 1332 of the Patient Protection and Affordable Care Act during the COVID-19 PHE.

10/14/20

1. CMS announced it expanded the list of telehealth services that Medicare Fee-For-Service will pay for during the COVID-19 Public Health Emergency (PHE). Medicare will begin paying eligible practitioners who furnish these newly added telehealth services effective immediately, and for the duration of the PHE. These new telehealth services include certain neurostimulator analysis and programming services, and cardiac and pulmonary rehabilitation services. The list of these newly added telehealth services is available here. With this action, Medicare will pay for 144 services performed via telehealth.

2. CMS released a new supplement to its State Medicaid & CHIP Telehealth Toolkit: Policy Considerations for States Expanding Use of Telehealth, COVID-19 Version that provides numerous new examples and insights into lessons learned from states that have implemented telehealth changes. The updated supplemental information is intended to help states strategically think through how they explain and clarify to providers and other stakeholders which policies are temporary or permanent. It also helps states identify services that can be accessed through telehealth, which providers may deliver those services, the ways providers may use in order to deliver services through telehealth, as well as the circumstances under which telehealth can be reimbursed once the PHE expires.

10/02/20

1. HHS Secretary Alex Azar officially extended the COVID-19 public health emergency for another 90 days. The public health emergency is now scheduled to expire on January 21, 2021. Several payment policies and regulatory adjustments are attached to the public health emergency, including Medicare inpatient 20% add-on payment for COVID-19 patients, increased federal Medicaid matching rates, requirements that insurers cover COVID-19 testing without cost-sharing, and waivers of telehealth restrictions.

9/15/20

1. CMS released additional frequently asked questions (FAQs) for Programs of All-inclusive Care for the Elderly (PACE) and COVID-19.

8/27/20

1. CMS issued a new interim final rule with comment period that revises regulations to strengthen

CMS' ability to enforce compliance with Medicare and Medicaid long-term care (LTC) facility requirements for reporting information related to COVID-19, establishes a new requirement for LTC facilities for COVID-19 testing of facility residents and staff, establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives, and establishes requirements for all CLIA laboratories to report COVID-19 test results to HHS during the Public Health Emergency (PHE). Additionally, this rule addresses the impact of COVID-19 on Part C and Part D quality Rating Systems.

7/23/20

1. HHS Secretary Alex Azar tweeted that he officially extended the COVID-19 public health emergency for another 90 days. The public health emergency is now scheduled to expire on October 23, 2020. Several payment policies and regulatory adjustments are attached to the public health emergency, including Medicare inpatient 20% add-on payment for COVID-19 patients, increased federal Medicaid matching rates, requirements that insurers cover COVID-19 testing without cost-sharing, and waivers of telehealth restrictions.

7/22/20

1. CMS announced several new initiatives designed to protect nursing home residents from COVID-19: (a) HHS will devote an additional $5 billion of the Provider Relief Fund authorized by the CARES Act, beyond the $4.9 billion previously committed, to Medicare-certified long term care facilities and state veterans' homes ("nursing homes"), to build nursing home skills and enhance nursing homes' response to COVID-19, including enhanced infection control; (b) CMS will begin requiring, rather than recommending, all nursing homes in states with a 5% positivity rate or greater test all nursing home staff each week; (c) federal Task Force Strike Teams were recently deployed to provide onsite technical assistance and education to nursing homes experiencing outbreaks in an effort to help reduce transmission and the risk of COVID-19 spread among residents; (d) CMS, in partnership with the CDC, is rolling out an online, self-paced, on-demand Nursing Home COVID-19 Training focused on infection control and best practices that will be available to all 15,400 nursing homes nationwide along with specialized technical assistance to nursing homes found to have infection prevention deficiencies in their most recent CMS inspection and had recent COVID-19 cases based upon their data submissions to the CDC; (e) the White House and CMS will release a list of nursing homes with an increase in cases that will be sent to states weekly as part of the weekly Governor's report to ensure states have the information needed to target their support to the highest risk nursing homes..

7/10/20

1. CMS issued an HPMS memo providing guidance to MA organizations and Part D sponsors regarding how they should account for expenditures related to the COVID-19 permissive actions and other costs in the medical loss ratio (MLR) calculation for contract years (CY) 2020 and 2021.

2. CMS announced it is deploying Quality Improvement Organizations (QIOs) across the country to provide immediate assistance to nursing homes in the hotspot areas as identified by the White House Coronavirus Task Force. In addition, CMS is implementing an enhanced survey process tailored to meet the specific concerns of hotspot areas and will coordinate federal, state and local efforts to leverage all available resources to these facilities.

6/29/20

1. HHS spokesperson Michael Caputo tweeted that HHS intends to extend the COVID-19 public health emergency that is currently set to expire on July 25. The extension would prolong the emergency designation by 90 days. Several payment policies and regulatory adjustments are attached to the public health emergency, including Medicare inpatient 20% add-on payment for COVID-19 patients, increased federal Medicaid matching rates, requirements that insurers cover COVID-19 testing without cost-sharing, and waivers of telehealth restrictions.

6/25/20

1. CMS announced plans to end the waiver of the requirement for nursing homes to submit staffing data through the Payroll-Based Journal System. Nursing homes must submit data for calendar quarter 2 by August 14, 2020.

6/23/20

1. CMS released Medicare claims data showing the total number of COVID-19 cases and hospitalizations among Medicare beneficiaries from January 1 through May 16, 2020. The data breaks down COVID-19 cases and hospitalizations for Medicare beneficiaries by state, race/ethnicity, age, gender, dual eligibility for Medicare and Medicaid, and urban/rural locations. CMS also released accompanying FAQs.

6/20/20

1. CMS posted the second set of COVID-19 nursing home data. The data will be updated weekly going forward.

6/19/20

1. The Centers for Disease Control and Prevention (CDC) recently updated COVID-19 testing guidelines for nursing homes. As noted in the MLN Matters Article SE20011, CMS has instructed the Medicare Administrative Contractors to make, starting on July 6, 2020, Medicare coverage determinations for laboratory tests to detect active SARS-CoV-2 infections in nursing home residents and patients that are consistent with the following sections of CDC guidelines titled "Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents":

    - Viral Testing of Residents for SARS-CoV-2
    - Initial Viral Testing in Response to an Outbreak
    - Recommended testing to determine resolution of infection with SARS-CoV-2
    - Public health surveillance for SARS-CoV-2

    MAOs must also comply with these general coverage guidelines and relevant sections of the CDC guidelines. Pursuant to the guidance issued by CMS on April 21, 2020, MAOs must not charge cost sharing (including deductibles, copayments, and coinsurance) or apply prior authorization or other utilization management requirements for laboratory tests for the detection of COVID-19, specified COVID-19 testing-related services, and COVID-19 vaccines and their administration.

6/09/20

1. CMS released reopening recommendations for healthcare systems, providers and facilities located in states and regions that are in Phase II of the Guidelines for Opening Up America Again. CMS also released a guide for individuals as they consider their in-person care options.

6/08/20

1. CMS announced an upcoming webinar training opportunity for health plans (including Medicare Advantage Plans, Medicare-Medicaid Plans, Medicare Advantage D-SNPs, and PACE organizations) to improve the quality and delivery of care for dually eligible individuals with Alzheimer's disease and related dementia, as well as family and friends providing care for them. The webinar is called "Navigating COVID-19: Supporting Individuals with Dementia and their Caregivers" and it is scheduled for Tuesday, June 23, 2020, from 12:00pm – 1:30 pm EDT. Register here.

6/05/20

1. HHS announced new guidance that specifies what additional data must be reported to HHS by laboratories along with COVID-19 test results, and accompanying FAQs.

6/04/20

1. CMS posted the first set of COVID-19 nursing home data, including an overview of the data, a letter to state officials and nursing home stakeholders about the data, and FAQs. The results of the completed nursing home surveys and reports are available on Nursing Home Compare. The next set of inspection data will be updated in two weeks. Going forward after that date, CMS plans to update the inspection data weekly.

6/03/20

1. In response to COVID-19, CMS announced it is providing new flexibilities and adjustments to current and future Center for Medicare and Medicaid Innovation (CMMI) models to address the emergency. CMS released a flexibilities table that outlines the models and the new changes.

6/01/20

1. CMS issued enhanced guidance, a letter to governors about reopening nursing homes, and enforcement for nursing homes with violations of longstanding infection control practices. Utilizing the CARES Act funding, states will be required to perform on-site surveys of nursing homes with previous COVID-19 outbreaks and will be required to perform on-site surveys (within three to five days of identification) of any nursing home with new COVID-19 suspected and confirmed cases.

5/29/20

1. Consistent with its previous April 22, 2020 memo, CMS reminded MA, PACE, MMP, cost-based MCO, and Part D Plans that it has suspended application of the 2% payment reduction that would otherwise apply during the sequestration suspension period, which runs from May 1, 2020

through December 31, 2020. Specifically, for June 2020, CMS will suspend the application of sequestration for the payments made for June 2020 enrollment, and for any adjustments made to payments made for May 2020 enrollments. CMS will continue to apply sequestration to payment adjustments made for months prior to the beginning of the sequestration suspension period.

5/27/20

1. In response to the COVID-19 public health emergency (PHE), state and local governments, hospitals, and others are developing alternate care sites to expand capacity and provide needed care to patients. The term alternate care site (ACS) is a broad term for any building or structure that is temporarily converted or newly erected for healthcare use. The Federal Healthcare Resiliency Task Force issued a toolkit to help state and local governments develop an ACS. CMS issued a fact sheet for state and local governments developing alternate care sites with information on how to seek payments through CMS programs – Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) – for acute inpatient and outpatient care furnished at the site.

5/22/20

1. CMS revised its previous 4/21/20 guidance for Part D and MMP sponsors, announcing it is exercising its enforcement discretion to allow Part D sponsors to fully or partially waive cost sharing (i.e., enrollee copays, deductibles, and coinsurance) for covered Part-D drugs with medically accepted indications for COVID-19, for both 2020 and 2021 (if the public health emergency is still in place at the time of the CY2021 bid submission). CMS will exercise this enforcement discretion to allow sponsors to waive cost sharing, consistent with this guidance, for any remaining portion of the 2020 plan year and up to the rest of the plan year and CY2021, so long as the public health emergency for COVID-19 declared by HHS is in effect as of the date that the plan begins the cost-sharing waivers. CMS provided guidance for how to report the waived cost-sharing amount for purposes of CY2021 bids, PDE reporting, reinsurance reconciliation, TrOOP threshold, and LICS. CMS noted that this guidance is also generally applicable to MMPs.

5/20/20

1. CMS recently provided additional blanket waivers for hospitals and ground ambulance organizations. For the duration of the COVID-19 public health emergency, these waivers modify existing physical environment waivers to allow for increased flexibilities for surge capacity and patient quarantine at hospitals, psychiatric hospitals, and critical access hospitals as a result of COVID-19; and modify the data collection period and data reporting period for ground ambulance organizations.

2. To help increase testing, CMS developed two codes that laboratories can use to bill for certain COVID-19 lab tests, including serology tests. CMS has updated its guidance to include payment details for additional CPT codes created by the American Medical Association. There is no cost-sharing for Medicare patients.

5/19/20

1. CMS issued a memo providing Medicare Advantage (MA) organizations with CY2021 Part C Bid Pricing Tool (BPT) and Plan Benefit Package (PBP) instructions related to COVID-19. Specifically, these instructions address how MA organizations may prepare their CY 2021 BPT and PBP given (1) required coverage and special requirements for MA plans related to COVID-19 or during a COVID-19 federal or state public health emergency; and (2) benefits and flexibilities that are permissive for MA plans to have in place for affected enrollees during a federal or state public health emergency.

5/18/20

1. HHS published a new Notification of Enforcement Discretion to inform the public that the Office for Civil Rights (OCR) will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers or their business associates in connection with the good faith participation in the operation of a COVID-19 Community-Based Testing Site (CBTS) during the COVID-19 nationwide public health emergency. This does not apply to health plans.

2. CMS announced new guidance and FAQs for state and local officials to ensure the safe reopening of nursing homes. The guidance details critical steps nursing homes and communities should take prior to relaxing restrictions implemented to prevent the spread of COVID-19, including rigorous infection prevention and control, adequate testing, and surveillance.

5/16/20

1. CMS understands that many states are now seeking ways to temporarily modify provider payment methodologies and capitation rates under their Medicaid managed care contracts to address the impacts of the public health emergency while preserving systems of care and access to services for Medicaid beneficiaries. CMS released guidance containing several options that states can consider under their Medicaid managed care contracts.

5/14/20

1. CMS announced a call for nominations for the new contractor-led Coronavirus Commission on Safety and Quality in Nursing Homes to help inform immediate and future responses to COVID-19 within these facilities. An independent contractor intends to convene the commission and manage all aspects of the process, including nomination and selection of members, facilitating meetings, and independently producing a final report to CMS Administrator Verma regarding findings and recommendations. The contractor is soliciting nominees for the commission from health industry professional, clinical, advocacy and consumer organizations known for their nursing home focus and expertise.

5/13/20

1. CMS issued an FAQ for Medicare Advantage Organizations in response to questions received related to the HPMS memos issued on 4/21 and 4/24.

2. CMS released a new toolkit developed to aid nursing homes, Governors, states, departments of health, and other agencies who provide oversight and assistance to these facilities, with additional resources to aid in the fight against the COVID-19 pandemic within nursing homes. The toolkit is comprised of best practices from a variety of front line health care providers, Governors' COVID-19 task forces, associations, and experts, and is intended to serve as a catalogue of resources dedicated to addressing the specific challenges facing nursing homes as they combat COVID-19.

5/12/20

1. CMS issued updated information regarding:

    a. Additional waivers to: expand hospitals' ability to offer long-term care services (swing beds); waive distance requirements, market share and bed requirements for Sole Community Hospitals; waive certain eligibility requirements for Medicare-Dependent, Small Rural Hospitals (MDHs); and update specific life safety code requirements for hospitals, hospice and long-term care facilities.

    b. An updated video that that answers common questions about the expanded Medicare telehealth services benefit during the COVID-19 public health emergency. New information includes how CMS adds services to the list of telehealth services, additional practitioners that can provide telehealth services, and the distant site services that Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) can provide. Further, the video includes information about audio-only telehealth services, telehealth services that hospitals, nursing homes and home health agencies can provide, along with how to correctly bill for telehealth services.

    c. An article for pharmacies and other suppliers that wish to enroll in Medicare temporarily as independent clinical diagnostic laboratories to help address the need for COVID-19 testing. Interested pharmacies and suppliers will need to apply for a Clinical Laboratory Improvement Amendments (CLIA) certificate.

5/11/20

1. CMS issued updated information for Medicare Advantage Organizations related it its previously issued April 21st guidance. This updated guidance addresses payment for contracted and non-contracted hospitals under the Inpatient Prospective Payment System (IPPS) for inpatient stays for individuals diagnosed with COVID-19, given the payment increase set forth in Section 3710 of the CARES Act.

5/07/20

1. CMS recently released an Interim Final Rule with comment period to build on the agency's efforts to give the healthcare system maximum flexibility to respond to the COVID-19 pandemic and a corresponding FAQ on Medicare Fee-for-Service Billing. CMS provided links to its various fact sheets that summarize changes made through regulatory actions in response to COVID-19. CMS also announced a COVID-19 stakeholder call scheduled for May 8th from 12:30-2PM ET.

2. CMS issued a news alert with:

    a. An FAQ to provide additional information on the updated obligations for long-term care facilities to notify the CDC, all residents/their representatives, and residents' families of confirmed and suspected COVID-19 cases among residents and staff.

    b. New FAQs and an updated comprehensive FAQ to help state Medicaid and CHIP agencies in their response to the COVID-19 pandemic.

    c. Links to the following waivers issued for state relief: Section 1135 waivers, Section 1115(a) waivers, 1915(c) waiver Appendix K Amendments, Medicaid State Plan Amendments, and CHIP State Plan Amendments.

3. CMS announced a one week extension of the Qualified Health Plan (QHP) certification and rate review timelines. This additional time will allow issuers and states to better collect and assess data around the effects of COVID-19 and thereby establish more accurate premium rates.

5/05/20

1. CMS announced to MA, Part D and MMP Plans that the exceptional conditions Special Enrollment Period (SEP) for Individuals Affected by a FEMA-Declared Weather Related Emergency or Major Disaster is applicable and available for beneficiaries who were eligible for -- but unable to make -- an election because they were affected by the COVID-19 pandemic. The SEP began March 1, 2020 and continues through July 1, 2020 (four full months after the start of the SEP).

5/01/20

1. CMS announced another round of regulatory waivers and rule changes in response to COVID-19. These changes include: (a) making it easier for Medicare and Medicaid beneficiaries to get tested for COVID-19 and announcing Medicare and Medicaid will cover certain COVID-19 antibody tests; (b) continuing CMS's efforts to further expand beneficiaries' access to telehealth services; (c) making adjustments to the financial methodology for ACOs to account for COVID-19 costs.

2. CMS issued FAQs clarifying requirements and considerations for hospitals and other providers related to the Emergency Medical Treatment and Labor Act (EMTALA) during the COVID-19 pandemic. The FAQs address questions around patient presentation to the emergency department, EMTALA applicability across facility types, qualified medical professionals, medical screening exams, patient transfer and stabilization, telehealth, and other topics.

3. CMS announced a new independent Commission that will conduct a comprehensive assessment of the nursing home response to the COVID-19 pandemic. The Commission will provide independent recommendations to the contractor to review and report to CMS to help inform immediate and future responses to COVID-19 in nursing homes.

4/27/20

1. CMS announced it will hold a conference call from 2-3PM ET on Wednesday, April 29, 2020 to discuss the 2021 Rate Announcement and COVID-19 guidance for MA, PACE and Part D organizations.

2. CMS announced the results of nursing home health inspections conducted on or after March 4, 2020, will be posted publicly, but will not be used to calculate a nursing home's health inspection star ratings. This action will start with the scheduled update to the Nursing Home Compare website on April 29, 2020. In addition, CMS is releasing information that shows the average number of staff each nursing home has onsite, each day (nursing staff and total staff), and aggregated by state and nationally. CMS also released FAQs to clarify certain actions the agency has taken related to nursing home visitation, surveys, waivers, and other guidance.

3. CMS issued revised guidance for infection control and prevention concerning COVID-19 in home health agencies and religious nonmedical healthcare institutions.

4/26/20

1. CMS announced it is reevaluating the amounts that will be paid under its Accelerated Payment Program and suspending its Advance Payment Program to Part B suppliers effective immediately. Beginning today, CMS will not be accepting any new applications for the Advance Payment Program, and CMS will be reevaluating all pending and new applications for Accelerated Payments in light of historical direct payments made available through the Department of Health & Human Services' (HHS) Provider Relief Fund.

4/24/20

1. As previously announced, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the prohibition on mid-year benefit enhancements. MAOs may provide smartphones and/or tablets as a supplemental benefit for primarily health related purposes, including in order to aid in the use of telehealth or remote access technology services in response to the covid-19 outbreak. A supplemental benefit is *not* primarily health related if it is an item or service that is solely or primarily used for cosmetic, comfort, general use, or social determinant purposes. Therefore, smartphones or tablets must only be used for primarily health related purposes, such as when the device is locked except for remote monitoring or to enable engagement with healthcare providers.

4/23/20

1. CMS announced the release of a new toolkit for states to help accelerate adoption of broader telehealth coverage policies in Medicaid and CHIP during the COVID-19 pandemic. Coverage and payment policies vary by state within federal parameters, and this toolkit will help states identify policies which may impede the rapid deployment of telehealth when providing care. The toolkit also includes a compilation of FAQs and other resources available to states.

4/22/20

1. Pursuant to Section 3709 of the CARES Act, CMS is suspending application of the sequestration 2%

payment reduction that would otherwise apply to MA, PACE, MMPs, cost-based MCOs and Part D payments for enrollment periods that fall between May 1, 2020 and December 31, 2020.

2. CMS announced it is providing additional blanket waivers related to care for patients in Long-Term Care Hospitals (LTCHs), temporary expansion locations of Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs), staffing and training modifications in Intermediate Care Facilities for individuals with Intellectual disabilities, and the limit for substitute billing arrangements (locum tenens). As part of this announcement, CMS reiterated it is allowing MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals, as previously announced on 3/30/20.

3. CMS and the Assistant Secretary of Preparedness and Response (ASPR) announced the release a COVID-19 Healthcare Workforce Toolkit to help state and local healthcare decision makers maximize workforce flexibilities when confronting COVID-19 in their communities. This toolkit, for individuals managing workforces during the COVID-19 pandemic, provides helpful information on funding flexibilities, liability protections, and workforce training all in one place. For example, state and local communities will be able to access the toolkit to see how and where workforce waivers can be applied based on information from other areas.

4/21/20

1. CMS issued a memo that supersedes the March 10, 2020 memo previously issued as guidance for Medicare Advantage Organizations (MAOs) and Part D sponsors. This memo sets forth some new guidance (e.g., MAOs must not charge cost-sharing for tests, vaccines and their administration for COVID-19, a COVID-19 vaccine and its administration will be covered under Part B (and therefore excluded from Part D coverage), Part D Sponsors must suspend all quantity and days' supply limits under 90 days for all covered Part D drugs except for safety edit limits, COVID-19 messages to enrollees are communications and do not require HPMS submission prior to distribution, etc.). It also sets forth new permissive actions MAOs and Part D Sponsors may choose to take. CMS will notify MAOs and Part D sponsors through HPMS when CMS is ending the enforcement discretion policies described in the memo.

2. In response to the COVID-19 public health emergency, CMS announced the extension of two quarterly submission due dates for Program of All-Inclusive Care for the Elderly (PACE) quality data reporting for 2020. CMS is extending the submission due dates for Quarter 1 and Quarter 2 as follows: Quarter 1 submission due date is extended from May 15th to July 15th, and Quarter 2 submission due date is extended from August 15th to October 1st.

3. HHS published a Notification of Enforcement Discretion in the Federal Register, informing the public that HHS is exercising its discretion in how it applies the Privacy, Security, and Breach Notification Rules under HIPAA. As a matter of enforcement discretion, the HHS Office for Civil Rights (OCR) will not impose penalties for noncompliance with the regulatory requirements under the HIPAA rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. This notification went into effect on March 17, 2020 and will remain in effect until the end of the public health emergency.

4/20/20

1. CMS announced that clinicians may now earn credit in the Merit-based Incentive Payment System (MIPS), a performance-based track of the Quality Payment Program that incentivizes quality and value, for participation in a COVID-19 clinical trial and reporting clinical information by attesting to the new COVID-19 Clinical Trials improvement activity. To receive credit for the new MIPS COVID-19 Clinical Trials improvement activity, clinicians must attest that they participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study.

4/19/20

1. CMS announced new regulatory requirements that will require nursing homes to inform residents, their families and representatives of COVID-19 cases in their facilities. In addition, CMS will now require nursing homes to report cases of COVID-19 directly to the Centers for Disease Control and Prevention (CDC). This information must be reported in accordance with existing privacy regulations and statute. Finally, CMS will also require nursing homes to fully cooperate with CDC surveillance efforts around COVID-19 spread.

2. CMS issued guidance on providing essential non-COVID-19 care to patients without symptoms of COVID-19 in regions with low and stable incidence of COVID-19. The new recommendations are specifically targeted to communities that are in Phase 1 of the Guidelines for Opening Up America Again with low incidence or relatively low and stable incidence of COVID-19 cases. The recommendations update earlier guidance provided by CMS on limiting non-essential surgeries and medical procedures.

4/15/20

1. CMS announced that the delay in the administration of the 2020 Health Outcomes Survey (HOS) until late summer, which was previously announced in the Interim Final Rule with Comment Period in response to COVID-19 (CMS-1744-IFC), also applies to the Health Outcomes Survey-Modified (HOS-M). CMS uses the HOS and HOS-M to calculate a frailty score, which is used to apply a frailty adjustment to the payments amounts for PACE organizations and FIDE SNPs. CMS anticipates fielding the surveys beginning in August.

2. CMS provided guidance to SNFs and/or long term care facilities regarding transferring or discharging residents between SNFs and/or nursing facilities based on COVID-19 status (i.e., positive, negative, unknown/under observation).

3. Effective April 14, 2020 and through the duration of the COVID-19 national emergency, Medicare Part B will pay $100 for COVID-19 clinical diagnostic lab tests making use of high-throughput technologies developed by the private sector. Local Medicare Administrative Contractors (MACs) remain responsible for developing the payment amount in their respective jurisdictions for other, non-high-throughput COVID-19 laboratory tests. MACs are currently paying approximately $51 for those tests. As with other laboratory tests, there is generally no beneficiary cost-sharing under Original Medicare.

4/13/20

1. In light of the current public health emergency declared for COVID-19, CMS is suspending the 2020 Data Validation of 2019 Part C and D reporting requirements data, with the exception of data for the following reporting sections: 1) Part C Special Needs Plans (SNPs) Care Management and 2) Part D Medication Therapy Management (MTM) Programs. Data validation for Part C SNPs Care Management and Part D MTM Programs reporting sections will begin on Monday, April 20, 2020, and end on Tuesday, June 30, 2020. CMS recommends that all data validation activities occur remotely during the public health emergency.

2. CMS announced that, in accordance with its October 7, 2019 HPMS memo, July 6, 2020 is still the deadline for D-SNPs to *initially* submit a new state Medicaid agency contract (SMAC), or an evergreen SMAC with a contract amendment that meets Medicaid integration and/or unified appeals and grievances requirements. However, in light of the COVID-19 pandemic, CMS is extending its review and approval timelines so that D-SNPs have until November 2, 2020 for *final* submissions of a new SMAC/SMAC contract amendment (rather than being required to submit final revisions by August 2020).

3. CMS announced it will hold an "Office Hours" teleconference on COVID-19, Tuesday, April 14th from 5:00 – 6:00 PM EST, for hospitals, health systems, and providers to ask questions of agency officials regarding CMS' COVID-19 temporary actions. Conference lines are limited, so CMS highly encourages joining via audio webcast, either on your computer or smartphone web browser.

4/11/20

1. CMS, together with the Departments of Labor and the Treasury, issued FAQs and announced the requirement for group health plans (including ERISA plans) and individual health insurance plans to cover COVID-19 diagnostic testing and certain related items and services provided during a medical visit with no cost sharing. This includes urgent care visits, emergency room visits, and in-person or telehealth visits to the doctor's office that result in an order for or administration of a COVID-19 test. It also ensures that COVID-19 antibody testing will also be covered. Once broadly available, a COVID-19 antibody test could become a key element in fighting the pandemic.

4/10/20

1. CMS released a revised Medicare Learning Network (MLN) article on "Medicare Fee-for-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19)". The revised article links to all the blanket waivers related to COVID-19, provides place of service coding guidance for telehealth claims, links to the telehealth video for COVID-19, adds information on the waiver of coinsurance and deductibles for certain testing and related services, adds information on the expanded use of ambulance origin/destination modifiers, provides new specimen collection codes for clinical diagnostic laboratories billing, and adds guidance regarding delivering notices to beneficiaries.

2. CMS announced that Medicare Advantage organizations and other organizations that submit diagnoses for risk adjusted payment are able to submit diagnoses for risk adjustment that are from telehealth visits when those visits meet all criteria for risk adjustment eligibility, which include being from an allowable inpatient, outpatient, or professional service, and from a face-to-face encounter. Diagnoses resulting from telehealth services can meet the risk adjustment face-to-face

requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication. This use of diagnoses from telehealth services applies both to submissions to the Risk Adjustment Processing System (RAPS), and those submitted to the Encounter Data System (EDS).

4/09/20

1. CMS released a new COVID-19 mailbox for Medicare Advantage organizations (MAOs) and Section 1876 Cost Plans. Effective immediately, MAOs and cost plans should submit any MAO and cost plan COVID-19 policy and benefit related questions to this mailbox here. CMS encourages plans to review the available resources in the COVID-19 mailbox before submitting a question.

2. CMS issued a COVID-19 FAQ for PACE organizations and state officials.

3. CMS issued new waivers to temporarily suspend a number of rules to allow hospitals, clinics and other healthcare facilities to boost their frontline medical staff in response to COVID-19. These changes affect doctors, nurses, and other clinicians nationwide, and focus on reducing supervision and certification requirements so that practitioners can be hired quickly and perform work to the fullest extent of their licenses. The new waivers expand the workforce flexibilities CMS announced on March 30th.

4/08/20

1. As a matter of enforcement discretion, effective immediately, the HHS Office for Civil Rights (OCR) will exercise its enforcement discretion and will not impose potential penalties for violations of certain provisions of the HIPAA Privacy Rule against covered health care providers or their business associates for uses and disclosures of protected health information by business associates for public health and health oversight activities during the COVID-19 nationwide public health emergency. Current regulations allow a HIPAA business associate to use and disclose protected health information for public health and health oversight purposes only if expressly permitted by its business associate agreement with a HIPAA covered entity. Some business associate agreements did not permit HIPAA business associates to use and disclose such information, which meant they were unable to respond to requests for disclosure of such PHI from federal public health authorities and oversight agencies, state and local health departments, and state emergency operations centers.

2. The United States Department of Homeland Security Cybersecurity and Infrastructure Security Agency, along with the United Kingdom's National Cyber Security Centre, issued a joint alert providing information on exploitation by cybercriminal and advanced persistent threat (APT) groups of the COVID-19 global pandemic. It includes a non-exhaustive list of indicators of compromise (IOCs) for detection as well as mitigation advice.

3. CMS announced it will hold an "Office Hours" teleconference on COVID-19, Thursday, April 9th from 5:00 – 6:00 PM EST, for hospitals, health systems, and providers to ask questions of agency officials regarding CMS' COVID-19 temporary actions. Conference lines are limited, so CMS highly encourages joining via audio webcast, either on your computer or smartphone web browser.

4. CMS issued updated guidance for infection control and prevention of COVID-19 in hospitals.

4/07/20

1. CMS posted a letter to clinicians that outlines a summary of COVID-19 Medicare-related actions it has taken regarding telehealth and virtual visits, testing and claims reporting, accelerated and advanced payments, workforce flexibilities allowing non-physicians to expand their scope of practice, and recent waiver information.

4/06/20

1. On April 3, 2020, CMS Administrator Seema Verma, Deborah Birx, MD from the White House Coronavirus Task Force, and officials from the FDA, CDC, and FEMA participated in a call on COVID-19 Flexibilities. Several physician guests on the front lines presented best practices from their COVID-19 experiences.

4/04/20

1. CMS approved its 45th Medicaid waiver to the District of Columbia. CMS also approved an additional Appendix K state waiver amendment request for Oklahoma to give emergency flexibilities in the state's programs that care for the elderly and people with disabilities, bringing the total to 18 Appendix K approvals across 16 states.

2. CMS announced, effective immediately, it is allowing Medicare-enrolled ambulatory surgical centers (ASCs) to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity.**4/03/20**

3. CMS is exercising its enforcement discretion to allow pharmacists to authorize emergency refills when prescribers are not available to provide refill renewal prescriptions, when consistent with State emergency declarations. In such situations and during a declared state of emergency, Part D Sponsors may submit prescription drug event (PDE) data that indicates the pharmacy is the prescriber.

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

1. 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.

3. 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. Put Patients Over Paperwork: 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

1. CMS sent a letter to the nation's hospitals on behalf of Vice President Pence 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

1. 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.

2. 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 FAQs on Medicare Provider Enrollment Relief related to COVID-19 including the toll-free hotlines available to Medicare Administrative Contractors (MACs)
    e. Released guidance on Payment and Grace Period Flexibilities for Issuers Offering Coverage on the Federally-facilitated Exchanges and State-based Exchanges on the Federal Platform.
    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

1. CMS released FAQs on Medicare Provider Enrollment Relief 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

1. 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

1. 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 all elective surgeries, non-essential medical, surgical, and dental exams and procedures be delayed 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 expanded Medicare telehealth coverage and said it will temporarily pay clinicians to provide telehealth services for beneficiaries residing across the entire country. CMS also published related telehealth FAQs.

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 fact sheet outlining several actions it was taking.

2. CMS announced new measures it is taking to significantly restrict visitors and nonessential personnel as well as restrict communal activities inside nursing homes.

3/13/20

1. In response to President Trump's declaration of a national emergency, CMS provided a Medicaid and CHIP Disaster Response Toolkit, 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 Essential Health Benefits (EHB) coverage 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.~~ **Superseded by HPMS memo issued on 4/21/20**
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 press release highlighting the telehealth benefits in the agency's Medicare program for use by patients and providers.
3. CMS delivered guidance 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 FAQ for providers regarding Medicare payment for lab tests and other services related to COVID-19.

3/05/20

1. CMS issued a second code 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 notification 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.