DEPARTMENT OF HEALTH AND HUMAN SERVICES

Regulatory Relief To Support Economic Recovery; Request for Information (RFI)

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: Under an Executive Order that directs federal agencies to address the economic emergency created by the COVID–19 pandemic by rescinding, modifying, waiving, or providing exemptions from regulations and other requirements that may inhibit economic recovery, consistent with applicable law and with protection of the public health and safety, with national and homeland security, and with budgetary priorities and operational feasibility. The Order directs agencies to ''identify regulatory standards that may inhibit economic recovery'' and to take appropriate action such as rescission or suspension of regulations, including by use of good cause or emergency authorities where appropriate. Agencies have likewise been called on to assess the various temporary deregulatory actions they have taken to fight COVID–19 and its impact on our economy to determine which temporary regulatory actions should be made permanent. The Order directs agencies to assist businesses and other entities in complying with the law through prompt issuance of pre-enforcement rulings and to formulate policies of enforcement discretion that recognize such entities' efforts to comply with the law.

DATES: To be assured consideration, comments must be received at the address provided below, no later than 11:59 p.m. on December 28, 2020.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted electronically at *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Allison Beattie, Department of Health and Human Services, 200 Independence Avenue SW, Room 713F, Washington, DC 20201. Email: *COVID.Regs@hhs.gov.* Telephone: (202) 690–7741.

SUPPLEMENTARY INFORMATION: Executive Order 13924, *Regulatory Relief To Support Economic Recovery,* 85 FR 31353 (May 19, 2020) calls on agencies to address the economic emergency caused by the COVID–19 pandemic by rescinding, modifying, waiving, or providing exemptions from regulations and other requirements that may inhibit economic recovery, consistent with applicable law and with protection of the public health and safety, with national and homeland security, and with budgetary priorities and operational feasibility. To implement the directives of E.O. 13924, the U.S. Department of Health and Human Services (''HHS'' or ''the Department'') identified in in response to this E.O. 382 regulatory actions that it is considering to make permanent or keep as temporary made in response to the COVID–19 crisis to improve access to care and reduce costs that it is considering to make permanent or keep as temporary. *See* Attachment A (this list is not intended to be comprehensive: Additional actions have been made by the Department and will continue to occur in response to the PHE and pandemic) HHS is issuing this Request for Information (RFI) to collect information for the purpose of considering the costs and benefits, consistent with applicable law and with protection of the public health and safety, of retaining these particular regulatory changes beyond the COVID–19 public health emergency. In addition to the costs and benefits of these actions, the Department seeks input on any barriers that may exist to making these deregulatory actions permanent including any evidence or experience that commenters have.

Invitation to Comment: HHS invites comments regarding the questions included in this notice. To ensure that your comments are clearly stated, please identify the specific question, or other section of this notice, that your comments address. Please also refer to any specific HHS policy or policies listed in the Appendix to this notice (*see* Attachment A), if applicable, by reference to the numbers associated in the Appendix with these policies.[1]

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments.

I. Background

In December 2019, a novel coronavirus known as SARS–CoV–2 (''the virus'') was first noted by the People's Republic of China as having been detected in Wuhan, Hubei Province, People's Republic of China, causing an outbreak of the disease COVID–19, which has now spread globally. The Secretary of Health and Human Services declared a public health emergency (PHE) effective January 27, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID–19, and has extended the declaration several times, most recently on October 2, 2020 effective October 23. In Proclamation 9994 of March 13, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak), President Trump declared that the COVID–19 outbreak in the United States constituted a national emergency, beginning March 1, 2020.

The federal government has taken sweeping action to control the spread of the virus in the United States. HHS and its federal partners are working together with state, local, tribal and territorial governments, public health officials, healthcare providers, researchers, private sector organizations and the public to execute a whole-of-America response to the COVID–19 pandemic to protect the health and safety of the American people.

In February 2020, Secretary Azar declared that circumstances justified the authorization of emergency use for tests to detect and diagnose COVID–19. In March 2020, the Secretary declared that circumstances justified the authorization of emergency use for drugs and biological products during the COVID–19 pandemic. Emergency Use Authorizations (EUAs) allow medical countermeasures to be authorized by the U.S. Food and Drug Administration (FDA), pursuant to certain criteria, during emergencies.[2] Operation Warp Speed is a partnership among components of HHS, the Department of Defense, and industry

[1] Commenters on FDA guidance may also wish to *refer to FDA's website* COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders, *available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders and submit comments to the relevant docket associated with each guidance listed, in addition to responding to this RFI.*

[2] *Coronavirus (COVID–19) Testing,* U.S. Dep't of Health and Human Serv.'s, *https://www.hhs.gov/coronavirus/testing/index.html* (last updated Aug. 19, 2020).

and academic partners with a goal to produce and deliver 300 million doses of safe and effective vaccines, with the initial doses available by January 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID–19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures).[3] The CDC is providing $10.25 billion to states, territories, and local jurisdictions, and the Indian Health Service is providing $750 million to tribal health programs for COVID–19 testing.[4] The CARES Act Provider Relief Fund supports American families, workers, and healthcare providers in the battle against the COVID–19 pandemic. HHS is distributing $175 billion to hospitals and healthcare providers on the front lines of the coronavirus response.[5]

During the COVID–19 PHE, HHS has taken steps to make it easier to provide telehealth services so patients may receive care without going to healthcare facilities.[6] For example, the HHS Office for Civil Rights (OCR) has issued guidance stating that OCR will not impose penalties for violations of the HIPAA Privacy, Security, and Breach Notification Rules when healthcare providers covered by the Health Insurance Portability and Accountability Act (HIPAA) in good faith, provide telehealth services to patients using remote communication technologies, such as commonly used apps—including FaceTime, Facebook Messenger, Google Hangouts, Zoom, or Skype—for telehealth services. CMS has issued temporary measures to make it easier for people enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) to receive medical care through telehealth services during the COVID–19 PHE. It also significantly expanded the list of covered telehealth services that can be covered by Medicare providers through telehealth. During the public health emergency, Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) may serve as distant telehealth sites and provide telehealth services to patients in their homes.[7]

[3] *Fact Sheet: Explaining Operation Warp Speed,* U.S. Dep't of Health and Human Serv.'s *https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html* (last updated Sep. 1, 2020).

[4] *Id.*

[5] *CARES Act Provider Relief Fund,* U.S. Dep't of Health and Human Serv.'s, *https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html* (last updated Aug. 14, 2020).

[6] *Telehealth: Delivering Care Safely During COVID–19,* U.S. Dep't of Health and Human Serv.'s, *https://www.hhs.gov/coronavirus/telehealth/index.html* (last updated Jul. 15, 2020).

[7] *Id.*

Likewise, FDA established a process to more rapidly disseminate and implement agency recommendations and policies related to COVID–19.[8]

To continue the federal response to the COVID–19 pandemic, President Trump signed Executive Order 13924 on May 19, 2020, to direct agencies to continue to remove regulatory barriers that could be stymying American economic recovery.[9] HHS is fulfilling this obligation by reviewing certain regulatory practices that could aid in economic recovery in ways that improve healthcare delivery.

II. Request for Information

To respond to the COVID–19 pandemic and its impact on the healthcare industry, HHS made changes to numerous regulations, agency guidance materials, or compliance obligations, or announced enforcement discretion (*see* Attachment A for a list of 382 of these actions) on either a temporary or permanent basis. Looking to the future, HHS intends that some of these regulatory changes (inclusive in this context of Agency guidance) will remain temporary and some will be made permanent, or permanent with modification. It may not be possible to make some of these changes permanent absent statutory changes, but HHS is still interested in comments to help us gauge the need for such changes. HHS will also consider phasing out or discontinuing regulatory changes that commenters show through evidence have negative impacts that outweigh the benefit of the regulatory change on a temporary basis or would have negative impacts that outweigh the benefits if continued beyond the PHE. Through this RFI, HHS seeks to gather feedback and relevant evidence from our stakeholders—healthcare providers and advocacy groups; industry trade groups; Medicare and Medicaid beneficiaries and caregivers; primary care and specialty providers; health insurance issuers offering health insurance coverage in the individual and group markets, group health plans sponsored by non-federal governmental entities, and supplemental insurers; [10] state, local, and territorial governments; research and policy experts; industry and professional associations; patients and patient advocacy groups; long-term care facilities, hospice providers, pharmacists, and pharmacy associations; nonprofit human services providers; and other interested members of the public. The information gathered in response to the RFI will be used to better inform HHS' decisions regarding which regulatory flexibilities used in the COVID–19 response should be kept temporary or made permanent. HHS and the entire U.S. government are committed to a healthy and resilient America. COVID–19 has had a sizable impact on the healthcare industry, which was forced to adjust to, among other things, remote and contactless care of patients in addition to caring for those directly affected by the virus, as well as on human services and other agencies working to promote well-being and economic mobility. Evidence-based feedback on how the 382 regulatory actions identified in Attachment A affect commenters' ability to provide or receive healthcare and services is welcome. Please note, however, that the Department may take or have taken steps to institutionalize or terminate items listed in Attachment A independent of the results of this RFI.

[8] United States, Food and Drug Administration. ''Process for Making Available Guidance Documents Related to Coronavirus Disease 2019.'' 85 FR 16949 (March 25, 2020).

[9] Exec. Order No. 13924 (May 19, 2020).

[10] *FAQs on Availability and Usage of Telehealth Services through Private Health Insurance Coverage in Response to Coronavirus Disease 2019 (COVID–19),* Ctrs. for Medicare & Medicaid Servs. Ctr. for Consumer Info. and Ins. Oversight (Mar. 24, 2020), *https://www.cms.gov/files/document/faqs-telehealth-covid-19.pdf.*

III. Key Questions

1. Of the regulatory changes that have been made by the HHS in response to the COVID–19 PHE and the pandemic, please identify which changes;

a. Have been beneficial to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems, and under what circumstances; or

b. Have been detrimental to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems, and under what circumstances; or

c. Have been beneficial to healthcare or human services providers, healthcare or human services systems, or to the patients and clients using these providers and systems on a temporary basis, but would be detrimental if continued, absent the exigencies of the COVID–19 PHE and pandemic.

Please explain and provide any evidence you have of benefit or detriment.

2. Of the regulatory changes that have been made by the Department of Health and Human Services in response to the COVID–19 PHE and the pandemic, please identify which changes:

a. Should be maintained only for the duration of the PHE and pandemic;

b. Should be maintained after the expiration of the PHE or the end of the pandemic; *i.e.,* made permanent;

c. Should be extended for a period of time after the expiration of the PHE or the end of the pandemic without being made permanent;

d. Should be modified but maintained after the expiration of the PHE or the end of the pandemic, and thus made permanent with modifications, and what modifications are being proposed; or

e. Should be discontinued immediately.

Please explain and provide the rationale for your recommendation, including evidence for or against the short-term or long-term suitability of these regulatory changes. Please describe all suggested modifications for those changes that should be maintained with modification. Of the regulatory changes that have been made or been issued by the Department of Health and Human Services in response to the COVID–19 PHE, please identify which changes should be discontinued only following a transition period, and what type of transition period is recommended.

IV. Submission of Comments and Collection of Information Requirements Exemption

Commenters may respond to any and all of the key questions as they pertain to any of the regulatory changes with which commenters have experience. HHS requests that commenters provide any evidence or experience they may have to support their recommendations. HHS asks that commenters identify by number the regulatory action(s) from Attachment A to which they are responding and submit their comments to the docket associated with this notice.[11] Commenters may otherwise provide their responses in any format compatible with the instructions in this Request for Information they believe is appropriate for presenting their responses. Finally, HHS asks commenters to provide feedback and evidence explaining any unintended consequences of the particular regulatory actions.

Please note, this is a RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that HHS will not respond to questions about potential policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received or a summary of those public comments.

Dated: November 5, 2020.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

ATTACHMENT A

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
1	HHS	SAMHSA	Other regulatory action.		42 CFR part 2 statement	SAMHSA provided guidance as to how 42 CFR part 2 may apply during the COVID–19 emergency (*https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf*).
2	HHS	SAMHSA	Guidance		Take home medication	SAMHSA provided a blanket exception to opioid treatment programs to permit take-home medication for patients receiving medication-assisted treatment of up to 28 days.
3	HHS	OIG	Guidance	n/a	FAQs–Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	OIG is accepting inquiries from the health care community regarding the application of OIG's administrative enforcement authorities, including the Federal anti-kickback statute and civil monetary penalty (CMP) provision prohibiting inducements to beneficiaries. On this website, OIG responds to fact-specific inquiries regarding arrangements that are directly connected to the public health emergency and implicate these authorities.
4	HHS	OCR	Other regulatory action.		Notification of Enforcement Discretion for Telehealth Remote Communications.	Exercise of enforcement discretion to not impose penalties for HIPAA violations against healthcare providers in connection with their good faith provision of telehealth using remote communication technologies during the COVID–19 nationwide public health emergency.

[11] Commenters on FDA guidance may also wish to *refer to FDA's website* COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders, *available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders and submit comments to the relevant docket associated with each guidance listed, in addition to responding to this RFI.*

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
5	HHS	OCR	Other regulatory action.		Notification of Enforcement Discretion for Business Associates.	Exercise of enforcement discretion to not impose penalties for violations of certain provisions of the HIPAA Privacy Rule against covered health care providers or their business associates for the good faith uses and disclosures of protected health information (PHI) by business associates for public health and health oversight activities during the COVID–19 nationwide public health emergency.
6	HHS	OCR	Other regulatory action.		Notification of Enforcement Discretion for Community-Based Testing Sites.	Exercise of enforcement discretion to not impose penalties for violations of the HIPAA Rules against covered entities or business associates in connection with the good faith participation in the operation of COVID–19 testing sites during the COVID–19 nationwide public health emergency.
7	HHS	NIH	Waiver		Flexibility with System for Awards Management ''SAM'' Registration (2 CFR § 200.205).	Allows applicants to submit applications for Federal awards without an active SAM registration. Provided automatic extension to expiring SAM registrations.
8	HHS	NIH	Waiver		Flexibility with Application Deadlines (2 CFR § 200.202).	Allows agencies to accept late applications due to the COVID–19 emergency.
9	HHS	NIH	Waiver		Waiver for Notice of Funding Opportunities (NOFOs) Publication. (2 CFR § 200.203).	Awarding agencies can publish emergency Notice of Funding Opportunities (NOFOs) for less than thirty (30) days without separately justifying shortening the timeframe for each NOFO.
10	HHS	NIH	Waiver		No-cost extensions on expiring awards. (2 CFR § 200.308).	Awarding agencies may extend awards which are active as of March 31, 2020 and scheduled to expire prior or up to December 31, 2020, automatically at no-cost for a period up to twelve (12) months.
11	HHS	NIH	Waiver		Abbreviated non-competitive continuation requests. (2 CFR § 200.308).	For continuation requests scheduled to come in from April 1, 2020 to December 31, 2020, from projects with planned future support, awarding agencies may accept a brief statement from recipients to verify that they are in a position to: (1) Resume or restore their project activities; and (2) accept a planned continuation award.
12	HHS	NIH	Waiver		Allowability of salaries and other project activities. (2 CFR § 200.403, 2 CFR § 200.404, 2 CFR § 200.405).	Awarding agencies may allow recipients to continue to charge salaries and benefits to currently active Federal awards consistent with the recipients' policy of paying salaries (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal.
13	HHS	NIH	Waiver		Allowability of Costs not Normally Chargeable to Awards. (2 CFR § 200.403, 2 CFR § 200.404, 2 CFR § 200.405).	Agencies may allow recipients to charge full cost of cancellation when the event, travel, or other activities are conducted under the auspices of the grant. Awarding agencies must advise recipients that they should not assume additional funds will be available should the charging of cancellation or other fees result in a shortage of funds to eventually carry out the event or travel.
14	HHS	NIH	Waiver		Prior approval requirement waivers. (2 CPR § 200.407).	Awarding agencies are authorized to waive prior approval requirements as necessary to effectively address the response.
15	HHS	NIH	Waiver		Exemption of certain procurement requirements. (2 CPR§ 200.319(b), 2 CPR§ 200.321).	Awarding agencies may waive the procurement requirements contained in 2 CPR§ 200.319(b) regarding geographical preferences and 2 CPR§ 200.321 regarding contracting small and minority businesses, women's business enterprises, and labor surplus area firms.
16	HHS	NIH	Waiver		Extension of financial, performance, and other reporting. (2 CPR§ 200.327, 2 CPR§ 200.328).	Awarding agencies may allow grantees to delay submission of financial, performance and other reports up to three (3) months beyond the normal due date.
17	HHS	NIH	Waiver		Extension of currently approved indirect cost rates. (2 CPR§ 200.414(c)).	Awarding agencies may allow grantees to continue to use the currently approved indirect cost rates (*i.e.,* predetermined, fixed, or provisional rates) to recover their indirect costs on Federal awards.
18	HHS	NIH	Waiver		Extension of closeout. (2 CPR§ 200.343).	Awarding agencies may allow the grantee to delay submission of any pending financial, performance and other reports required by the terms of the award for the closeout of expired projects, provided that proper notice about the reporting delay is given by the grantee to the agency.
19	HHS	NIH	Waiver		Extension of Single Audit submission. (2 CFR § 200.512).	Awarding agencies, in their capacity as cognizant or oversight agencies for audit, should allow recipients and subrecipients that have not yet filed their single audits with the Federal Audit Clearinghouse as of the date of the issuance of this memorandum that have fiscal year-ends through June 30, 2020, to delay the completion and submission of the Single Audit reporting package, as required under Subpart F of 2 CFR § 200.501—Audit Requirements, to six (6) months beyond the normal due date.
20	HHS	NIH	Waiver		OMB Memo M–20–20: Repurposing Existing Federal Financial Assistance Programs.	OMB is issuing a class exception that allows Federal awarding agencies to repurpose their federal assistance awards (in whole or part) to support the COVID–19 response, as consistent with applicable laws—includes donation of personal protective equipment.
21	HHS	NIH	Waiver		National Research Service Awards.	NIH has provided flexibility to NRSA recipients to continue charging stipends to NIH awards while no worked is performed due to COVID–19. This flexibility is in separate from salary flexibilities provided to employees of recipient institutions.
22	HHS	FDA	Guidance	N/A	Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of clinical electronic thermometers to address this public health emergency.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
23	HHS	FDA	Guidance	N/A	Enforcement Policy for Imaging Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability and capability of medical x-ray, ultrasound, and magnetic resonance imaging systems, and image analysis software that are used to diagnose and monitor medical conditions while mitigating circumstances that could lead to patient, healthcare provider, and healthcare technology management (HTM) exposure to COVID–19 for the duration of the COVID–19 public health emergency (PHE).
24	HHS	FDA	Guidance	N/A	Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID–19) Public Health Emergency (Revised).	FDA issued this guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering face piece respirators (including N95 respirators) for healthcare personnel (HCP)1 for the duration of the COVID–19 public health emergency.
25	HHS	FDA	Guidance	N/A	Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID–19 Public Health Emergency.	FDA issued this guidance to address questions FDA has received asking for clarification regarding FDA's enforcement of certain requirements relating to the distribution of drug samples under the Prescription Drug Marketing Act of 1987 (PDMA) during the COVID–19 public health emergency (PHE). PDMA is part of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the relevant implementing regulations regarding drug samples are in 21 CFR part 203 (part 203), subpart D.
26	HHS	FDA	Guidance	N/A	Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID–19 Pandemic.	FDA has been asked whether refrigerated food transport vehicles and refrigerated food storage units used for the temporary preservation of human remains during the COVID–19 pandemic subsequently can be used to transport and store human and animal food. FDA issued this guidance to provide information and resources related to the cleaning and disinfection of such vehicles and storage units to address food safety before they are used again to transport and store food. The recommendations in this guidance are intended to supplement existing food safety regulations and guidance.
27	HHS	FDA	Guidance	N/A	CVM GFI #271 Reporting and Mitigating Animal Drug Shortages during the COVID–19 Public Health Emergency.	FDA has been closely monitoring the animal drug supply chain for supply disruptions or shortages in the United States during the COVID–19 pandemic. FDA issued this guidance to assist sponsors in providing FDA timely, informative notifications about changes in the production of animal drugs that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of these products.
28	HHS	FDA	Guidance	N/A	CVM GFI #270—Guidance on the Conduct and Review of Studies to Support New Animal Drug Development during the COVID–19 Public Health Emergency.	FDA issued this guidance to provide recommendations for sponsors conducting studies to support new animal drug development to help ensure the safety of animals, their owners, and study personnel, maintain compliance with good laboratory practice regulations and good clinical practice, and maintain the scientific integrity of the data during the COVID–19 pandemic.
29	HHS	FDA	Guidance	N/A	Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act Guidance for Industry.	Due to the COVID–19 pandemic, FDA has been closely monitoring the medical product supply chain with the expectation that it may be impacted by the COVID–19 outbreak, potentially leading to supply disruptions or shortages of drug and biological products in the United States. FDA issued this guidance to assist applicants and manufacturers in providing FDA timely, informative notifications about changes in the production of certain drugs and biological products that will, in turn, help the Agency in its efforts to prevent or mitigate shortages of such products. The guidance discusses the requirement under section 506C of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356c) and FDA's implementing regulations for applicants and manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain products or an interruption in the manufacture of certain products that is likely to lead to a meaningful disruption in supply of that product in the United States. This guidance also recommends that applicants and manufacturers provide additional details and follow additional procedures to ensure FDA has the specific information it needs to help prevent or mitigate shortages. In addition, the guidance explains how FDA communicates information about products in shortage to the public.
30	HHS	FDA	Guidance	N/A	Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID–19 Public Health Emergency.	Due to the COVID–19 pandemic, FDA has been monitoring requests related to provisions of the Drug Supply Chain Security Act (DSCSA) because the provisions may affect the prescription drug supply chain during the COVID–19 outbreak. FDA issued this guidance to clarify the scope of the public health emergency exemption and exclusion under the DSCSA for the duration of the COVID–19 public health emergency (PHE), to help ensure adequate distribution of finished prescription drug products throughout the supply chain to combat COVID–19. In addition, this guidance announces FDA's policy regarding the exercise of its discretion in the enforcement of authorized trading partner requirements under section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act for certain distributions during the COVID–19 PHE involving other trading partners that may not be authorized trading partners.
31	HHS	FDA	Guidance	N/A	Alternative Procedures for Blood and Blood Components During the COVID–19 Public Health Emergency.	FDA issued this guidance to provide a notice of exceptions and alternatives to certain requirements in Title 21 of the Code of Federal Regulations (CFR) regarding blood and blood components. This notice of exception or alternatives to certain requirements is being issued under 21 CFR 640.120(b) to respond to a national public health need and address the urgent and immediate need for blood and blood components. We expect that the alternative procedures will improve availability of blood and blood components while helping to ensure adequate protections for donor health and maintaining a safe blood supply for patients.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
32	HHS	FDA	Guidance	N/A	Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic.	This guidance provides recommendations to industry regarding postmarketing adverse event reporting for drugs, biologics, medical devices, combination products, and dietary supplements during a pandemic. FDA anticipates that during a pandemic, industry and FDA workforces may be reduced because of high employee absenteeism while reporting of adverse events related to widespread use of medical products indicated for the treatment or prevention of the pathogen causing the pandemic may increase. The extent of these possible changes is unknown. This guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for medical products and dietary supplements during a pandemic.
33	HHS	FDA	Guidance	N/A	Institutional Review Board (IRB) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID–19 Public Health Emergency.	During the COVID–19 public health emergency, FDA has received a substantially increased volume of individual patient expanded access requests for COVID–19 investigational drugs. Although FDA has issued guidance on expanded access requests, including expanded access for individual patients, the Agency is aware that Institutional Review Boards (IRBs) seek clarity regarding the key factors and procedures IRBs should consider when reviewing individual patient expanded access submissions, including for reviews conducted by a single member of the IRB, to fulfill its obligations under 21 CFR part 56. Therefore, FDA issued this guidance to provide recommendations regarding the key factors and procedures IRBs should consider when reviewing expanded access submissions for individual patient access to investigational drugs for treating COVID–19.
34	HHS	FDA	Guidance	N/A	FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID–19 Public Health Emergency.	FDA issued this guidance to provide general considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity for the duration of the COVID–19 public health emergency. The appendix to this guidance further explains those general considerations by providing answers to questions that the Agency has received about conducting clinical trials during the COVID–19 public health emergency.
35	HHS	FDA	Guidance	N/A	COVID–19: Developing Drugs and Biological Products for Treatment or Prevention.	FDA issued this guidance to assist sponsors in the clinical development of drugs for the treatment or prevention of COVID–19. Preventative vaccines and convalescent plasma are not within the scope of this guidance.
36	HHS	FDA	Guidance	N/A	Investigational COVID–19 Convalescent Plasma; Guidance for Industry (Updated: May 1, 2020).	FDA issued this guidance to provide recommendations to health care providers and investigators on the administration and study of investigational convalescent plasma collected from individuals who have recovered from COVID–19 (COVID–19 convalescent plasma) during the public health emergency. The guidance also provides recommendations to blood establishments on the collection of COVID–19 convalescent plasma.
37	HHS	FDA	Guidance	N/A	Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products.	This revised guidance document provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection. We (FDA) are also recommending that you make corresponding revisions to your donor educational materials, donor history questionnaires and accompanying materials, along with revisions to your donor requalification and product management procedures. This guidance also incorporates certain other recommendations related to donor educational materials and supersedes the December 2015 guidance of the same title (Notice of Availability, 80 FR 79913 (December 17, 2015)). The recommendations contained in this guidance apply to the collection of blood and blood components, including Source Plasma. The recommendations in this revised guidance reflect the Agency's current thinking on donor deferral recommendations for individuals with increased risk for transmitting HIV infection. Based on the Agency's careful evaluation of the available data, including data regarding the detection characteristics of nucleic acid testing, FDA expects implementation of these revised recommendations will not be associated with any adverse effect on the safety of the blood supply. Furthermore, early implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing public health emergency.
38	HHS	FDA	Guidance	N/A	Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria.	The recommendations in this revised guidance reflect the Agency's current thinking on recommendations for reducing the risk of Transfusion-Transmitted Malaria (TTM). Based on the Agency's careful evaluation of the available scientific and epidemiological data on malaria risk, and data on FDA-approved pathogen reduction devices, FDA expects implementation of these revised recommendations will not be associated with any adverse effect on the safety of the blood supply. Furthermore, early implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing public health emergency.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
39	HHS	FDA	Guidance	N/A	CVM GFI #269—Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID–19 Outbreak.	FDA recognizes the vital role veterinarians play in protecting public health. FDA is aware that during the COVID–19 outbreak some States are modifying their requirements for veterinary telemedicine, including State requirements regarding the veterinarian-client-patient relationship (VCPR). Given that the Federal VCPR definition requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept, the Federal VCPR definition cannot be met solely through telemedicine. To further facilitate veterinarians' ability to utilize telemedicine to address animal health needs during the COVID–19 outbreak, FDA intends to temporarily suspend enforcement of a portion of the Federal VCPR requirements. Specifically, FDA generally intends not to enforce the animal examination and premises visit VCPR requirements relevant to FDA regulations governing Extralabel Drug Use in Animals (21 CFR part 530) and Veterinary Feed Directive Drugs (21 CFR 558.6). Given the temporary nature of this policy, we plan to reassess it periodically and provide revision or withdrawal of this guidance as necessary.
40	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Accredited Third-Party Certification Program Onsite Observation and Certificate Duration Requirements During the COVID–19 Public Health Emergency.	The Accredited Third-Party Certification Program regulation (21 CFR part 1, subpart M) establishes a voluntary program for the recognition of accreditation bodies (ABs) that accredit third-party certification bodies (CBs) to conduct food safety audits and issue food or facility certifications to eligible foreign entities for the purposes specified in sections 801(q) and 806 of the FD&C Act (21 U.S.C. 381 and 384b). The regulation requires that recognized ABs and accredited CBs perform certain onsite observations and examinations. Due to the impact of the public health emergency related to COVID–19, FDA issued this guidance to provide the Accredited Third-Party Certification Program's currently-recognized ABs and accredited CBs flexibility, in certain circumstances, regarding certain requirements.
41	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Preventive Controls and FSVP Food Supplier Verification Onsite Audit Requirements During the COVID–19 Public Health Emergency.	The purpose of this guidance is to state the current intent of the Food and Drug Administration (FDA, we, or the Agency), in certain circumstances related to the impact of the coronavirus outbreak (COVID–19), not to enforce requirements in three foods regulations to conduct onsite audits of food suppliers if other supplier verification methods are used instead. The three regulations are Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117) (''part 117''), Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507) (''part 507''), and Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR part 1 subpart L) (''FSVP regulation'').
42	HHS	FDA	Guidance	N/A	Temporary Policy During the COVID–19 Public Health Emergency Regarding the Qualified Exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.	FDA issued this guidance to announce flexibility in the eligibility criteria for the qualified exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) (21 CFR part 112) due to disruptions to the supply chain for the duration of the COVID–19 public health emergency.
43	HHS	FDA	Guidance	N/A	Reporting a Temporary Closure or Significantly Reduced Production by a Human Food Establishment and Requesting FDA Assistance During the COVID–19 Public Health Emergency.	FDA issued this guidance to provide certain FDA-regulated food establishments (*i.e.,* human food facilities and farms, but not restaurants and retail food establishments), with a convenient mechanism to voluntarily report to FDA if they have temporarily ceased or significantly reduced production or if they are considering doing so. This reporting mechanism may also be used to request dialogue with FDA on issues related to continuing or restarting safe food production during the pandemic.
44	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID–19 Public Health Emergency.	FDA issued this guidance to provide restaurants and food manufacturers with flexibility regarding nutrition labeling so that they can sell certain packaged foods during the COVID–19 pandemic. This guidance does not apply to foods prepared by restaurants.
45	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Certain Food Labeling Requirements During the COVID–19 Public Health Emergency: Minor Formulation Changes and Vending Machines.	FDA issued this guidance to food manufacturers to provide temporary and limited flexibilities in food labeling requirements under certain circumstances. Our goal is to provide regulatory flexibility, where fitting, to help minimize the impact of supply chain disruptions associated with the current COVID–19 pandemic on product availability. For example, we are providing flexibility for manufacturers to use existing labels, without making otherwise required changes, when making minor formula adjustments due to unforeseen shortages or supply chain disruptions brought about by the COVID–19 pandemic. Additionally, this guidance will provide temporary flexibility to the vending machine industry regarding the vending machine labeling requirements under section 403(q)(5)(H)(viii) of the FD&C Act (21 U.S.C. 343(q)(5)(H)(viii)) and 21 CFR 101.8 during the duration of the public health emergency.
46	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Enforcement of 21 CFR Part 118 (the Egg Safety Rule) During the COVID–19 Public Health Emergency.	We encourage all shell egg producers to continue to comply with applicable requirements of 21 CFR part 118 (the Egg Safety Rule). However, due to the increased consumer demand for eggs in the table egg market (*e.g.,* sold directly to consumers in retail establishments), we are providing temporary flexibility to allow producers who currently only sell eggs to facilities for further processing (*e.g.,* into ''egg products'') to sell to the table egg market, provided certain circumstances are present.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
47	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID–19 Public Health Emergency.	FDA issued this guidance to provide restaurants and food manufacturers with flexibility regarding nutrition labeling so that they can sell certain packaged foods during the COVID–19 pandemic. This guidance does not apply to foods prepared by restaurants.
48	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID–19 Public Health Emergency.	FDA issued this guidance to provide temporary flexibility regarding certain packaging and labeling requirements for shell eggs sold in retail food establishments so that industry can meet the increased demand for shell eggs during the COVID–19 pandemic.
49	HHS	FDA	Guidance	N/A	Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this pandemic.
50	HHS	FDA	Guidance	N/A	Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability and capability of sterilizers, disinfectant devices, and air purifiers during this public health emergency.
51	HHS	FDA	Guidance	N/A	Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide recommendations for sponsors of decontamination and bioburden reduction systems about what information should be included in a pre-Emergency Use Authorization (pre-EUA) and/or EUA request to help facilitate FDA's efficient review of such request. This guidance provides these recommendations based on the device's intended use with respect to the level (tier) of decontamination or bioburden reduction, based on the sponsor's available data. Decontamination and bioburden reduction systems play an important role in the ongoing efforts to help address shortages of surgical masks and respirators intended for a medical purpose during COVID–19 or reduce the bioburden of surgical masks and filtering face piece respirators (including N95 respirators) used as personal protective equipment (PPE) by healthcare personnel for the duration of the COVID–19 public health emergency.
52	HHS	FDA	Guidance	N/A	Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of digital health therapeutic devices for psychiatric disorders to facilitate consumer and patient use while reducing user and healthcare provider contact and potential exposure to COVID–19 during this pandemic.
53	HHS	FDA	Guidance	N/A	Enforcement Policy for Extracorporeal Membrane Oxygenation and Cardiopulmonary Bypass Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of devices used in extracorporeal membrane oxygenation (ECMO) therapy to address this public health emergency.
54	HHS	FDA	Guidance	N/A	Enforcement Policy for Infusion Pumps and Accessories During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability and remote capabilities of infusion pumps and their accessories for health care professionals during the COVID–19 pandemic.
55	HHS	FDA	Guidance	N/A	Enforcement Policy for Non-Invasive Fetal and Maternal Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability and capability of non-invasive fetal and maternal monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and potential exposure to COVID–19 during this pandemic.
56	HHS	FDA	Guidance	N/A	Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability and capability of non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID–19 for the duration of the COVID–19 public health emergency.
57	HHS	FDA	Guidance	N/A	Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of devices for remote reviewing and reporting of scanned digital images of pathology slides (''digital pathology slides'') during this pandemic.
58	HHS	FDA	Guidance	N/A	Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID–19 during this pandemic.
59	HHS	FDA	Guidance	N/A	Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of telethermographic systems used for body temperature measurements for triage use for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
60	HHS	FDA	Guidance	N/A	Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help expand the availability of ventilators as well as other respiratory devices and their accessories during this pandemic.
61	HHS	FDA	Guidance	N/A	Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID–19 Public Health Emergency.	FDA issued this guidance to implement section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351 et seq.), as added by section 3121 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as it relates to device shortages and potential device shortages occurring during the COVID–19 pandemic, for the duration of the COVID–19 public health emergency. Section 506J of the FD&C Act requires manufacturers to notify FDA of a permanent discontinuance in the manufacture of certain devices or an interruption in the manufacture of certain devices that is likely to lead to a meaningful disruption in supply of that device in the United States. This guidance is intended to assist manufacturers in providing FDA timely, informative notifications about changes in the production of certain medical device products that will help the Agency prevent or mitigate shortages of such devices during the COVID–19 public health emergency. This guidance also recommends that manufacturers voluntarily provide additional details to better ensure FDA has the specific information it needs to help prevent or mitigate shortages during the COVID–19 public health emergency.
62	HHS	FDA	Guidance	N/A	COVID–19 Public Health Emergency: General Considerations for Pre-IND Meeting Requests for COVID–19 Related Drugs and Biological Products.	FDA issued this guidance to provide general considerations to assist sponsors in preparing pre-investigational new drug application (pre-IND) meeting requests for COVID–19 related drugs for the duration of the COVID–19 public health emergency. As described in further detail in this guidance, FDA recommends that sponsors initiate all drug development interactions for COVID–19 related drugs through pre-IND meeting requests.
63	HHS	FDA	Guidance	N/A	Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications—Questions and Answers.	FDA issued this guidance to provide answers to frequently asked questions about regulatory and policy issues related to drug development for the duration of the COVID–19 public health emergency.
64	HHS	FDA	Guidance	N/A	Policy for Certain REMS Requirements During the COVID–19 Public Health Emergency Guidance for Industry and Health Care Professionals.	FDA issued this guidance to communicate its temporary policy for certain risk evaluation and mitigation strategies (REMS) requirements for the duration of the public health emergency (PHE) declared by the Secretary of Health and Human Services (HHS)1 on January 31, 2020.
65	HHS	FDA	Guidance	N/A	Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94(e)(1) For Oxygen and Nitrogen During the COVID–19 Public Health Emergency.	FDA issued this guidance to communicate its policy for the temporary use of certain gas containers for oxygen and nitrogen intended for medical use for the duration of the current public health emergency.
66	HHS	FDA	Guidance	N/A	Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID–19 Public Health Emergency.	FDA issued this guidance to communicate its temporary policy regarding the repackaging or combining of propofol drug products by a licensed pharmacist in a State licensed pharmacy, a Federal facility, or an outsourcing facility registered pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b) as outlined in this guidance for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, or for such shorter time as FDA may announce through updated guidance.
67	HHS	FDA	Guidance	N/A	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID–19 Public Health Emergency (Revised).	FDA issued this guidance to communicate its temporary policy for the compounding of certain human drug products for hospitalized patients by outsourcing facilities that have registered with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b).
68	HHS	FDA	Guidance	N/A	Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID–19 Public Health Emergency Guidance for Industry (Revised).	FDA has received a number of reports related to increased demand and supply interruptions involving FDA-approved drug products used in the treatment of hospitalized patients with COVID–19. Many of these drug products are needed to support COVID–19 patients who have been intubated, or for other procedures involved in the care of such patients. Some reports involve drug products that appear on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) (''FDA's drug shortage list''). In addition, with respect to certain other drug products needed to support hospitalized COVID–19 patients but that do not appear on FDA's drug shortage list, certain hospitals have concerns about accessing them due, for example, to regional disparities in COVID–19 infection rates, or other regional conditions that may evolve quickly during the public health emergency. FDA is working with manufacturers in the global pharmaceutical supply chain to prevent and mitigate drug shortages and access problems, using all of the Agency's authorities to restore or increase the supply of FDA-approved drug products.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
69	HHS	FDA	Guidance	N/A	Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID–19 Public Health Emergency.	Due to the COVID–19 pandemic, FDA has received a number of queries from compounders related to the impact of supply interruptions of face masks, gowns, gloves, and other garb, which we refer to collectively in this document as *personal protective equipment (PPE).* FDA issued this guidance to communicate its temporary policy related to PPE use during human drug compounding at State-licensed pharmacies or Federal facilities that are not registered with FDA as outsourcing facilities.
70	HHS	FDA	Guidance	N/A	Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency.	FDA issued this guidance to provide a policy to help address current manufacturing limitations or supply chain issues due to disruptions caused by the COVID–19 public health emergency.
71	HHS	FDA	Guidance	N/A	Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.	The Agency issued this guidance to communicate its policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities (referred to collectively in this guidance as compounders) for the duration of the public health emergency.
72	HHS	FDA	Guidance	N/A	Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19).	FDA issued this guidance in response to a number of queries from entities that are not currently registered drug manufacturers that would like to produce alcohol (ethanol) for incorporation into alcohol-based hand sanitizers. This policy does not extend to other types of active ingredients for incorporation into alcohol-based hand sanitizers, such as isopropyl alcohol. The Agency issued this guidance to communicate its policy for the temporary manufacture of ethanol products by firms that manufacture alcohol for incorporation into alcohol-based hand sanitizer products under the circumstances described in this guidance (alcohol production firms) for the duration of the public health emergency. At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdraw this guidance. FDA is continually assessing the needs and circumstances related to this temporary policy, and as relevant needs and circumstances evolve, FDA intends to update, modify, or withdraw this policy as appropriate.
73	HHS	FDA	Guidance	N/A	Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID–19).	FDA issued this guidance in response to a number of queries from entities that are not currently licensed or registered drug manufacturers that would like to prepare alcohol-based hand sanitizers, either for public distribution or for their own internal use. The Agency issued this guidance to communicate its policy for the temporary preparation of certain alcohol-based hand sanitizer products by firms that register their establishment with FDA as an over-the-counter (OTC) drug manufacturer, repackager, or re-labeler to prepare alcohol-based hand sanitizers under the circumstances described in this guidance (''firms'') for the duration of the public health emergency. At such time when the public health emergency is over, as declared by the Secretary, FDA intends to discontinue this enforcement discretion policy and withdraw this guidance.
74	HHS	FDA	Guidance	N/A	Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised).	FDA issued this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID–19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. Rapid detection of COVID–19 cases in the United States requires wide availability of testing to control the emergence of this rapidly spreading, severe illness. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States.
75	HHS	CDC	Interim Final Rule	0920–AA76	Control of Communicable Diseases; Foreign Quarantine: Suspension of Introduction of Persons into the US from Designated Foreign Countries or Places for Public Health.	Suspends the introduction of persons from designated countries into the U.S. for public health reasons.
76	HHS	CDC	Other regulatory action.		No Sail Order and Suspension of Further Embarkation.	Order applies to all cruise ships that do not voluntarily suspend operation.
77	HHS	ACF	Guidance		New Guidance on Caseworker Visits.	Modified policy to permit monthly child welfare caseworker visits to be conducted via videoconference instead of in-person; postponing title IV–E eligibility reviews and National Youth in Transition Database reviews.
78	HHS	ACF	Guidance		Permit provisional licensure of foster family homes.	Allows for abbreviated licensing and re-licensing process for foster family homes, so that the agency does not need to assess the home's safety and appropriateness during the pandemic in as rigorous of a fashion, which requires in-person interaction.
79	HHS	ACF	Guidance		Permit name-based criminal background checks on prospective foster parents and other care providers.	Allowed name-based background checks only, in the absence of FBI fingerprint checks, when fingerprint sites are unavailable.
80	HHS	ACF	Guidance		Simplify process for title IV–E assistance to youth age 18 and older.	Administrative streamlining allows for quicker access to title IV–E assistance for youth who may be aging out of the child welfare system in the absence of a permanent family, using the Stafford Act.
81	HHS	ACF	Guidance		Modify requirement for older youth to meet education or employment requirement.	Using Stafford Act flexibility, ACF temporarily waived the requirement that youth aging out of the foster care system be actively engaged in education and/or employment.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
82	HHS	ACF	Guidance		Qualified Residential Treatment Program claiming exemption.	Using Stafford Act flexibilities, this allows title IV–E agencies to continue claiming federal reimbursement for children in QRTP settings, even if the facility has not completed statutorily required accreditation due to the pandemic.
83	HHS	ACF	Guidance		Delegating authority to State CSBG agencies to approve equipment purchases.	Same as title. Prior internal practice required federal approval for CSBG-funded equipment purchases, even when states served as pass-through entities. The authority exists for pass-through entities to approve such purchases, and ACF would further emphasize this authority and encourage pass-through entities to utilize it.
84	HHS	ACF	Waiver		Allowability of Costs not Normally Chargeable to Awards (Item 7 from OMB M–20–17).	*Note:* Not an ACF regulation. Modify 45 CFR 75.405 (and 2 CFR 200.405) to allow the awarding agency to set an amount that may be charged that would not normally be allowed in dollar or percentage terms, with a reporting requirement if exercised. Alternatively, a class-wide exemption for CSBG may also address the issue (75.102).
85	HHS	ACF	Guidance		Streamlining CSBG eligibility determinations.	Guidance was provided to states that streamlined certain eligibility requirements, such as attestation to, rather than production of, documentation for emergency food assistance.
86	HHS	ACF	Guidance		Non-Competing Continuation (NCC) Grants application.	Allows abbreviated application process for grantees and eliminates burdens for non-competing continuation grant awards.
87	HHS	ACF	Guidance		Ability to pay salaries and other project activities.	Allows programs to continue paying salaries to grantee staff during business disruptions, and activities aligned with grant purpose but not in SOW, to do so. M–20–17.
88	HHS	ACF	Guidance		Increase in micro-purchase threshold.	HHS authorized an increase in the simplified acquisition thresholds for all COVID–19 acquisitions (to $20k for micro-purchase and $750k for simplified acquisition threshold).
89	HHS	ACF	Guidance		Waiver of detail and formality of acquisition plans above the simplified acquisition threshold.	HHS authorized this waiver for all COVID–19 related contracts and only required them to have an informal acquisition plan.
90	HHS	ACF	Guidance		Flexibility with Application Deadlines (2 CFR § 200.202).	This was applied by multiple ACF programs to provide relief during the period of the pandemic by providing additional time to complete grant applications.
91	HHS	ACF	Guidance		Enforcement discretion for Work Participation Rate failures during the pandemic.	Signals that ACF will exercise maximum enforcement discretion in levying financial penalties against states for their failure to meet the Temporary Assistance for Needy Families (TANF) program's work participation rate during the period of the pandemic, when such failure is attributable to the pandemic.
92	HHS	ACF	Waiver		Waiver of on-site health and safety inspections.	This waived the requirement that annual inspections of child care facilities occur, with an on-site component.
93	HHS	ACF	Waiver		Fingerprint background check waivers.	Waive the requirement that FBI fingerprint-based background checks be evaluated for child care workers, if fingerprinting sites are unavailable and name-based checks return no red flags.
94	HHS	ACF	Waiver		Waiver of 12 month continuing eligibility requirement.	Waives the requirement that those receiving CCDF child care support retain eligibility for not less than 12 months. This was used, for example, to provide short-term eligibility for emergency workers who did not require long-term services.
95	HHS	ACF	Waiver		Waive co-pays for all families	Allows states to fully pay for child care costs for parents, without cost-sharing.
96	HHS	ACF	NPRM		Provisional hire flexibility	Waiver allowed individuals who have not completed the comprehensive (7 component) inter-state background check process to start work as child care workers, to ensure adequate staffing in emergent situations.
97	HHS	ACF	Other regulatory action.		Grant match requirements	Provide Secretary authority to waive matching requirements in 42 U.S.C. 10407(a)(2)(A) in situations of public health emergencies.
98	HHS	ACF	Waiver		Waive declaration requirements for refugee assistance.	Allows waiver of requirements at 45 CFR 400.43, which require written attestation and documentation of certain eligibility requirements; allows for telephonic attestation until such time as providing this documentation and written declaration is possible.
99	HHS	ACF	Waiver		Waive certain income requirements for refugee assistance.	Allows waiver of certain components of 45 CFR 400.59 and § 400.66, such that one-time payments (*e.g.,* Economic Impact Payments) do not preclude eligibility based on income. Also, allows waiver of employment requirements at 45 CFR 400.75 when services are unavailable due to the public health emergency.
100	HHS	ACF	Waiver		Waive restrictions on Refugee Support Services funds use.	Allows funds for RSS to be used to meet emergent needs associated with the COVID–19 pandemic (*e.g.,* food, shelter). Waives requirements at 45 CFR 400.146.
101	HHS	ACF	Waiver		Extend eligibility period for Refugee Supportive Services.	Allows individuals receiving RSS support/services to continue receiving services if they would otherwise have exhausted the program's 60 month time limit at 45 CFR 400.152(b) during the period of the pandemic.
102	HHS	ACF	Waiver		Refugee medical screening timeframes.	Waive 90 day timeline for the medical screening to take place (at 45 CFR 400.107), if that is not possible given availability of medical services. Also encourage telehealth options as alternative if in-person screening is unavailable.
103	HHS	ACF	Waiver		Permitting virtual refugee consultations.	Quarterly stakeholder consultations are required in the refugee program. This flexibility allows such consultations to take place virtually rather than in-person.
104	HHS	ACF	NPRM		Various timeframe and administrative elements, Child Support Enforcement.	Utilizing Stafford Act flexibilities, OCSE granted waivers to many states on a host of service-related timeline requirements (separate attachment). Some of these timelines are in regulation, but the regulations do not provide authority to waive certain regulatory provisions in other disasters or health emergency situations. This rulemaking would provide such a provision in existing regulation.
105	HHS	ACF	Other regulatory action.		Raise prior approval requirement at 45 CFR § 75.407; 2 CFR § 200.407.	Raise prior approval threshold for purchases from $5k to $25k in the normal course.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
106	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Merit-based Incentive Payment System (MIPS) Updates.	BB. MIPS Improvement Activities Inventory Update to add new or make modifications to existing improvement activities in the Inventory through notice-and-comment rulemaking. 1. Table 1 in RIN 0938–AU31 outlines the new improvement activity: COVID–19 Clinical Trials. 2. To provide additional relief to individual clinicians, groups, and virtual groups for whom sufficient MIPS measures and activities may not be available for the 2019 MIPS performance period due to the PHE for the COVID–19 pandemic, extending the deadline to submit an application for reweighting the quality, cost and improvement activities performance categories based on extreme and uncontrollable circumstances from 12/31/19 to 4/30/20. Also, modifying existing policy for the 2019 performance period/2021 MIPS payment year only.
107	HHS	CMS	Interim Final Rule	RIN 0938–AU32	Update to the Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) Policy.	The Hospital Value-Based Purchasing (VBP) Program Extraordinary Circumstance Exception (ECE) policy was revised to allow CMS to grant an exception to hospitals located in an entire region or locale without having to make an individual request and we codified the updated policy at CFR 412.165(c). This policy was updated as a permanent change in the interim final rule with comment period when it became effective on April 30, 2020.
108	HHS	CMS	Interim Final Rule	RIN 0938–AU33	Quality Reporting: Updates to the Extraordinary Circumstances Exceptions (ECE) Granted for Four Value-Based Purchasing Programs in Response to the PHE for COVID–19, and Update to the Performance Period for the FY 2022 SNF VBP Program.	This IFC updates the extraordinary circumstances exceptions (ECEs) we granted on March 22, 2020 for the ESRD Quality Incentive Program (QIP), Hospital-Acquired Condition (HAC) Reduction Program, Hospital Readmissions Reduction Program, and Hospital Value-Based Purchasing (VBP) Program in response to the COVID–19 PHE, revises the FY 2022 performance period under the Skilled Nursing Facility (SNF) VBP Program as a result of the COVID–19 PHE, and changes the Extraordinary Circumstances Exception (ECE) policies for the Hospital VBP, HAC Reduction, Hospital Readmissions Reduction, ESRD QIP, and SNF VBP Programs, to provide that if, as a result of the extension of the ECE for the whole country or the submission of individual ECE requests, we do not have enough data to reliably compare national performance on measures, we would not score facilities based on such limited data or make the associated payment adjustments for the affected program year.
109	HHS	CMS	Interim Final Rule	RIN 0938–AU31	National Coverage Determination.	National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) on Respiratory Related Devices, Oxygen and Oxygen Equipment, Home Infusion Pumps and Home Anticoagulation Therapy: Clinicians now have maximum flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home. The current NCDs and LCDs that restrict coverage of these devices and services to patients with certain clinical characteristics do not apply during the public health emergency.
110	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Independent Lab Payment for Specimen collection.	During the PHE, Medicare established two new level II HCPCS Codes for Medicare payment of a nominal specimen collection fee and associated travel allowance. Independent labs must use one of these HCPCS codes when billing Medicare for the nominal specimen fee for COVID–19 testing for the duration of the PHE for COVID–19 pandemic.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
111	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Communication Technology-Based Services (CTBBS).	D. Medicare routinely pays for many kinds of services that are furnished via telecommunications technology (83 FR 59482), but are not considered Medicare telehealth services. These communication technology-based services (CTBS) include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), and interpretations of diagnostic tests when furnished remotely. In the context of the PHE for the COVID–19 pandemic, when brief communications with practitioners and other non-face-to-face services might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we believe that these services should be available to as large a population of Medicare beneficiaries as possible. During the PHE for the COVID–19 pandemic, we are finalizing that these services, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients. Consent to receive these services can be documented by auxiliary staff under general supervision. We are finalizing on an interim basis during the PHE for the COVID–19 pandemic that, while consent to receive these services must be obtained annually, it may be obtained at the same time that a service is furnished. We are re-emphasizing that this consent may be obtained by auxiliary staff under general supervision, as well as by the billing practitioner. In the context of the PHE for the COVID–19 pandemic, where communications with practitioners might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we do not believe the limitation of these services to established patients is warranted. While some of the code descriptors refer to ''established patient,'' during the PHE, we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. We will not conduct review to consider whether those services were furnished to established patients. On an interim basis, during the PHE for the COVID–19 pandemic, we are also broadening the availability of HCPCS codes G2010 and G2012 that describe remote evaluation of patient images/video and virtual check-ins. We recognize that in the context of the PHE for the COVID–19 pandemic, practitioners such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech-language pathologists might also utilize virtual check-ins and remote evaluations instead of other, in-person services within the relevant Medicare benefit to facilitate the best available appropriate care while mitigating exposure risks. We note that this is not an exhaustive list and we are seeking input on other kinds of practitioners who might be furnishing these kinds of services as part of the Medicare services they furnish in the context of the PHE for the COVID–19 pandemic. To facilitate billing of the CTBS services by therapists for the reasons described above, we are designating HCPCS codes G2010, G2012, G2061, G2062, or G2063 as CTBS ''sometimes therapy'' services that would require the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services. CTBS therapy services include those furnished to a new or established patients that the occupational therapist, physical therapist, and speech-language pathologist practitioner is currently treating under a plan of care.
112	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Direct Supervision by Interactive Telecommunications Technology.	For the duration of the PHE for the COVID–19 pandemic, for purposes of limiting exposure to COVID–19, we adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR 19245). We recognized that in some cases, the physical proximity of the physician or practitioner might present additional infection exposure risk to the patient and/or practitioner.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
113	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Telephone Evaluation and Management (E/M) Services Codes.	S. We are finalizing, on an interim basis for the duration of the PHE for the COVID–19 pandemic, separate payment for CPT codes 98966–98968 and CPT codes 99441–99443. For these codes, we are finalizing on an interim basis for the duration of the PHE for the COVID–19 pandemic, work RVUs as recommended by the AMA Health Care Professionals Advisory Committee (HCPAC), and work RVUs as recommended by the AMA Relative Value Scale Update Committee (RUC). We are finalizing the HCPAC and RUC-recommended direct PE inputs which consist of 3 minutes of post-service RN/LPN/MTA clinical labor time for each code. Similar to the CTBS described in section II.D. of this IFC, we believe it is important during the PHE to extend these services to both new and established patients. While some of the code descriptors refer to ''established patient,'' during the PHE we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Specifically, we will not conduct review to consider whether those services were furnished to established patients. CPT codes 98966–98968 described assessment and management services performed by practitioners who cannot separately bill for E/Ms. We are noting that these services may be furnished by, among others, LCSWs, clinical psychologists, and physical therapists, occupational therapists, and speech language pathologists when the visit pertains to a service that falls within the benefit category of those practitioners. To facilitate billing of these services by therapists, we are designating CPT codes 98966–98968 as CTBS ''sometimes therapy'' services that would require the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services.
114	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Clarification of Homebound Status under the Medicare Home Health Benefit.	Homebound Definition: Broadening homebound definition to include beneficiaries whose physician advises them not to leave the home because of a confirmed or suspected COVID–19 diagnosis or if patient has a condition that makes them more susceptible to contract COVID–19.
115	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Use of Telecommunications Technology Under the Medicare Home Health Benefit.	H. For the duration of the PHE for the COVID–19 pandemic, we are amending the hospice regulations at 42 CFR 418.204 on an interim basis to specify that when a patient is receiving routine home care, hospices may provide services via a telecommunications system if it is feasible and appropriate to do so to ensure that Medicare patients can continue receiving services that are reasonable and necessary for the palliation and management of a patients' terminal illness and related conditions without jeopardizing the patients' health or the health of those who are providing such services during the PHE for the COVID–19 pandemic. To appropriately recognize the role of technology in furnishing services under the hospice benefit, the use of such technology must be included on the plan of care. The inclusion of technology on the plan of care must continue to meet the requirements at § 418.56, and must be tied to the patient-specific needs as identified in the comprehensive assessment and the measurable outcomes that the hospice anticipates will occur as a result of implementing the plan of care. There is no payment beyond the per diem amount for the use of technology in providing services under the hospice benefit. For the purposes of the hospice claim submission, only in-person visits (with the exception of social work telephone calls) should be reported on the claim. However, hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care during the PHE for the COVID–19 pandemic as ''other patient care services'' using Worksheet A, cost center line 46, or a subscript of line 46 through 46.19, cost center code 4600 through 4619, and identifying this cost center as ''PHE for COVID–19''.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
116	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Use of Telecommunications Technology Under the Medicare Hospice Benefit.	H. For the duration of the PHE for the COVID–19 pandemic, we are amending the hospice regulations at 42 CFR 418.204 on an interim basis to specify that when a patient is receiving routine home care, hospices may provide services via a telecommunications system if it is feasible and appropriate to do so to ensure that Medicare patients can continue receiving services that are reasonable and necessary for the palliation and management of a patients' terminal illness and related conditions without jeopardizing the patients' health or the health of those who are providing such services during the PHE for the COVID–19 pandemic. To appropriately recognize the role of technology in furnishing services under the hospice benefit, the use of such technology must be included on the plan of care. The inclusion of technology on the plan of care must continue to meet the requirements at §418.56, and must be tied to the patient-specific needs as identified in the comprehensive assessment and the measurable outcomes that the hospice anticipates will occur as a result of implementing the plan of care. There is no payment beyond the per diem amount for the use of technology in providing services under the hospice benefit. For the purposes of the hospice claim submission, only in-person visits (with the exception of social work telephone calls) should be reported on the claim. However, hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care during the PHE for the COVID–19 pandemic as ''other patient care services'' using Worksheet A, cost center line 46, or a subscript of line 46 through 46.19, cost center code 4600 through 4619, and identifying this cost center as ''PHE for COVID–19''.
117	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations and Required ''Hands-on'' Visits for ESRD Monthly Capitation Payments.	B. Given our assessment that under the PHE for the COVID–19 pandemic, there is a patient population that would otherwise not have access to clinically appropriate in-person treatment, we do not believe these frequency limitations are appropriate or necessary. In our prior analysis, for example, we were concerned that patients might not receive the necessary in-person services for nursing facility or hospital inpatient services. Since in the context of this PHE, telehealth visits mitigate exposure risk, fewer in-person visits may reflect the most appropriate care, depending on the needs of individual patients. Consequently, on an interim basis, we are removing the frequency restrictions for each of the following listed codes for subsequent inpatient visits and subsequent NF visits furnished via Medicare telehealth for the duration of the PHE for the COVID–19 pandemic. Similarly, we note that we previously limited critical care consultations through telehealth to only once per day, given the patient acuity involved in critical care. However, we also understand that critical care patients have significant exposure risks such that more frequent services furnished via telehealth may reflect the best available care in the context and for the duration of the PHE for the COVID–19 pandemic. For this reason, we are also removing the restriction that critical care consultation codes may only be furnished to a Medicare beneficiary once per day. These restrictions were established through rulemaking and implemented through systems edits.
118	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital.	CC. Understanding that our current policy may inhibit use of capacity in settings that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing our arrangements policy during the PHE for the COVID–19 pandemic so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital. We are changing our under arrangements policy during the PHE for the COVID–19 pandemic beginning March 1, 2020, so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital. Hospitals would be treating patients in locations outside the hospital for a variety of reasons, including limited beds and/or limited specialized equipment such as ventilators, and for a limited time period. While we are changing our under arrangements policy during the PHE for the COVID–19 pandemic to allow hospitals broader flexibilities in furnishing inpatient services, we emphasize that we are not changing our policy that a hospital needs to exercise sufficient control and responsibility over the use of hospital resources in treating patients, as discussed in the FY 2012 IPPS/LTCH PPS final rule and Section 10.3 of Chapter 5 of the Medicare General Information, Eligibility, and Entitlement Manual (Pub. 100–01). Nothing in the current PHE for the COVID–19 pandemic has changed our policy or thinking with respect to this issue and we are making no modifications to this aspect of the policy. Hospitals need to continue to exercise sufficient control and responsibility over the use of hospital resources in treating patients regardless of whether that treatment occurs in the hospital or outside the hospital under arrangements. If a hospital cannot exercise sufficient control and responsibility over the use of hospital resources in treating patients outside the hospital under arrangements, the hospital should not provide those services outside the hospital under arrangements.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
119	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement.	J. During the PHE for the COVID–19 pandemic, we believe that it is essential to temporarily allow the face-to-face visit requirements at §§ 412.622(a)(3)(iv) and 412.29(e) to be conducted via telehealth to safeguard the health and safety of Medicare beneficiaries and the rehabilitation physicians treating them. This allows rehabilitation physicians to use telehealth services as defined in section 1834(m)(4)(F) of the Act, to conduct the required 3 physician visits per week during the PHE for the COVID–19 pandemic. By increasing access to telehealth, this IFC will provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health. To effectuate these changes, on an interim basis we are finalizing revisions to the regulations at §§ 412.622(a)(3)(iv) and 412.29(e) during the PHE for the COVID–19 pandemic. In § 412.622(a)(3)(iv), we are revising this paragraph to state that physician supervision by a rehabilitation physician is required, except that during the PHE, as defined in § 400.200, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). In § 412.29(e), we are revising this paragraph to state that a procedure must be in effect to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process, except that during the PHE, as defined in § 400.200, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act).
120	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Removal of the IRF Post-Admission Physician Evaluation Requirement.	K. We are removing the post-admission physician evaluation requirement at § 412.622(a)(4)(ii) for all IRFs during the PHE for the COVID–19 pandemic. We believe that removal of this requirement will greatly reduce the amount of time rehabilitation physicians in IRFs spend on completing paperwork requirements when a patient is admitted to the IRF, and will free up their time to focus instead on caring for patients and helping where they may be needed with the PHE for the COVID–19 pandemic. Accordingly, we are amending § 412.622(a)(4)(ii) to note that the post-admission physician evaluation is not required during the PHE for the COVID–19 pandemic. To effectuate this change, on an interim basis, we are revising § 412.622(a)(4)(ii) to specify that the post-admission physician evaluation is not required during the PHE for the COVID–19 pandemic.
121	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Requirements for Opioid Treatment Programs (OTP).	N. In light of the PHE for the COVID–19 pandemic, during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio-video communication technology may not be available to all beneficiaries, we are revising § 410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE for the COVID–19 pandemic if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met.
122	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Physician Supervision Flexibility for Outpatient Hospitals—Outpatient Hospital Therapeutic Services Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision.	T. We changed the minimum default level of supervision to general supervision for NSEDTS during the initiation of the service to give providers additional flexibility they need to handle the burdens created by the PHE for the COVID–19 pandemic. We assigned, on an interim basis, all outpatient hospital therapeutic services that fall under § 410.27(a)(1)(iv)(E), a minimum level of general supervision to be consistent with the minimum default level of general supervision that applies for most outpatient hospital therapeutic services, and we revised § 410.27(a)(1)(iv)(E) to reflect this change in the minimum level of supervision. General supervision, as defined in our regulation at § 410.32(b)(3)(i) means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure.
123	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Rural Health Clinics (RHC) and Federally Qualified Health Centers (FQHC) Telehealth.	Allow Professionals working at Rural Health Clinics (RHCs) and Federally-Qualified Health Centers (FQHCs) to furnish telehealth services. We are expanding the services that can be included in the payment for HCPCS code G0071, and update payment rates of other codes.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
						We are finalizing that all virtual communication services that are billable using HCPCS code G0071 will also be available to new patients that have not been seen in the RHC or FQHC within the previous 12 months. Also, in situations where obtaining prior beneficiary consent would interfere with the timely provision of these services, or the timely provision of the monthly care management services, during the PHE for the COVID–19 pandemic consent can obtained when the services are furnished instead of prior to the service being furnished, but must be obtained before the services are billed. We will also allow patient consent to be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication and monthly care management codes during the PHE for the COVID–19 pandemic.
124	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Change to Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy.	V. The 2019 MIPS data submission deadline will be extended by 30 days until April 30, 2020, to give eligible clinicians more time to report quality and other data for purposes of MIPS. The MIPS automatic extreme and uncontrollable circumstances policy will apply to MIPS eligible clinicians, who do not submit their MIPS data by the extended timeline. Under this automatic extreme and uncontrollable circumstances policy, MIPS eligible clinicians, who are not participants in APMs, who do not submit any MIPS data will have all performance categories reweighted to zero percent, resulting in a score equal to the performance threshold, and a neutral MIPS payment adjustment. However, under the policy, if a MIPS eligible clinician submits data on two or more MIPS performance categories, they will be scored and receive a 2021 MIPS payment adjustment based on their final score.
125	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Payment for Medicare Telehealth Services Under Section 1834(m) of the Act.	A. To facilitate the use of telecommunications technology as a safe substitute for in-person services, we are, on an interim basis, adding many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks. The list of telehealth services, including the additions described later in this section, can be located on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.* Additional CPT Codes and explanations provided in the IFC.
126	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Telehealth and the Medicare Hospice Face-to-Face Encounter Requirement.	I. We are amending the regulations at § 418.22(a)(4) on an interim basis to allow the use of telecommunications technology by the hospice physician or NP for the face-to-face visit when such visit is solely for the purpose of recertifying a patient for hospice services during the PHE for the COVID–19 pandemic. By telecommunications technology, we mean the use of multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient (from home, or any other site permissible for receiving services under the hospice benefit) and distant site hospice physician or hospice NP.
127	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Home Health Orders from APPs	Z. Allow a home health patient to be under the care of a NP or clinical nurse specialist or a PA and allow such practitioner to: (1) Order home health services; (2) establish and periodically review a plan of care for home health services; and (3) certify and re-certify that the patient is eligible for Medicare home health services.
128	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Health Insurance Issuer Standards under the ACA, Including Standards related to Exchanges: Separate Billing and Segregation of Funds for Abortion Services.	X. For Qualified health plan (QHP) issuers to devote resources to respond to the COVID–19 PHE, revising 45 CFR 156.280(e)(2)(ii) to delay implementation of the separate billing policy for 60 days from the effective date for those offering coverage of non-Hyde abortion services for the portion of their premium. Under the Program Integrity rule, issuers of individual market QHPs are required to begin separately billing policy holders for the portion of the policy holder's premium attributable to non-Hyde abortion services on or before the QHP issuer's first billing cycle following June 27, 2020. The date has been changed to the QHP issuer's first billing cycle following August 26, 2020.
129	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Updates to the Quality Payment Program: Merit-based Incentive Payment System (MIPS) Third Party Intermediary Approval Criteria.	R. Delaying the implementation by 1 year that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period so that they can complete QCDR measure testing and collect data.
130	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Application of Certain National Coverage Determination and Local Coverage Determination Requirements: CGMs.	S. Continuous Glucose Monitors: CMS will not enforce certain clinical criteria in LCDs that limit access to therapeutic continuous glucose monitors for beneficiaries with diabetes.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
131	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Reporting Requirement for Facilities to Report Nursing Home Residents and Staff Infections, Potential Infections, and Deaths.	Y. Revising the requirements to establish explicit reporting requirements for confirmed or suspected cases. Specifically, we are revising our requirements by adding a new provision at § 483.80(g)(1), to require facilities to electronically report information about COVID–19 in a standardized format specified by the Secretary. The report includes, but is not limited to, information on: Suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19; total deaths and COVID–19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID–19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary. At § 483.80(g)(3), we are adding a new provision to require facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID–19 cases in the facility among residents and staff. This reporting requirement supports the overall health and safety of residents by ensuring they are informed participants in the care that they receive as well as providing assurances of the mitigating steps the facility is taking to prevent and control the spread of COVID–19. Facilities must inform residents, their representatives, and families by 5 p.m. the next calendar day following the occurrence of either: A single confirmed infection of COVID–19; or three or more residents or staff with new-onset of respiratory symptoms that occur within 72 hours of each other. Also, cumulative updates to residents, their representatives, and families must be provided at least weekly by 5 p.m. the next calendar day following the subsequent occurrence of either: Each time a confirmed infection of COVID–19 is identified; or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.
132	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Delayed Adoption of the Transfer of Health (TOH) Information Measures and Standard Patient Assessment Data Elements (SPADEs).	T. We are delaying the compliance date by which IRFs, LTCH, and HHAs must collect and report data on two Transfer of Health (TOH) Information quality measures and certain Standardized Patient Assessment Data Elements (SPADEs) adopted for the IRF QRP, LTCH QRP, and HH QRP. Specifically, we will require IRFs to use IRF–PAI V4.0 and LTCHs to use LTCH CARE Data Set V5.0 to begin collecting data on the two TOH Information Measures beginning with discharges on October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. For example, if the COVID–19 PHE ends on September 20, 2020, IRFs and LTCHs will be required to begin collecting data on these measures beginning with patients discharged on October 1, 2021. We will also require IRFs and LTCHs to begin collecting data on the SPADEs for admissions and discharges (except for the hearing, vision, race, and ethnicity SPADEs, which would be collected for admissions only) on October 1st of the year that is at least 1 full fiscal year after the end of the COVID–19 PHE. HHAs will be required to use OASIS–E to begin collecting data on the two TOH Information Measures beginning with discharges and transfers on January 1st of the year that is at least 1 full calendar year after the end of the COVID–19 PHE. For example, if the COVID–19 PHE ends on September 20, 2020, HHAs will be required to begin collecting data on those measures beginning with patients discharged or transferred on January 1, 2022.
133	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Care Planning for Medicare Home Health Services.	J. NPs, CNSs, and PAs would be able to practice to the top of their state licensure to certify eligibility for home health services, as well as establish and periodically review the home health plan of care. We are also amending the regulations at parts 409, 424, and 484 to define a NP, a CNS, and a PA (as such qualifications are defined at §§ 410.74 through 410.76) as an ''allowed practitioner''. This means that in addition to a physician, as defined at section 1861(r) of the Act, an ''allowed practitioner'' may certify, establish and periodically review the plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. Additionally, we are amending the regulations to reflect that we would expect the allowed practitioner to also perform the face-to-face encounter for the patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed NPP, as set out at 42 CFR 424.22(a)(1)(v)(A), in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. These regulation changes will become permanent and are not time limited to the period of the PHE for COVID–19.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
134	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Inpatient Rehabilitation—Intensity of Therapy Requirement (''3-Hour Rule'') and Related IRF Coverage Requirements.	K. In the March 31st COVID–19 IFC (85 FR 19252, 19287), we provided a clarification regarding § 412.622(a)(3)(ii) (commonly referred to as the ''3-hour rule''). On March 27, 2020, the CARES Act was enacted and further addressed § 412.622(a)(3)(ii). Specifically, section 3711(a) of the CARES Act requires the Secretary to waive § 412.622(a)(3)(ii) during the emergency period described in section 1135(g)(1)(B) of the Act. This waiver was issued on April 15 2020, and is available at *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*. We note that the clarification provided in the March 31st COVID–19 IFC does not address section 3711(a) of the CARES Act as it was developed prior to the enactment of the CARES Act. Because § 412.622(a)(3)(ii) is more directly and comprehensively addressed by section 3711(a) of the CARES Act, the clarification provided in the March 31st COVID–19 IFC is moot and hereby rescinded.
135	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	IRF Coverage Criteria—Surge Capacity.	C. We are amending § 412.622(a)(3)(i), (ii), (iii), and (iv) to state that these IRF coverage criteria continue to be required, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE, as defined in § 400.200. Similarly, in § 412.622(a)(4), we are amending this paragraph to state that the IRF documentation requirements must be present in the IRF medical record, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE, as defined in § 400.200. In § 412.622(a)(5), we are amending this paragraph to state that an interdisciplinary team approach to care is required, except for care furnished to patients in a freestanding IRF hospital solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE, as defined in § 400.200.
136	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Laboratory Tests: Payment for COVID–19 Specimen Collection to Physicians, Non-Physician Practitioners and Hospitals.	BB. We are providing additional payment for assessment and COVID–19 specimen collection to support testing by HOPDs, and physicians and other practitioners, to recognize the significant resources involved in safely collecting specimens from many beneficiaries during a pandemic. We are also allowing physicians and practitioners to bill for services provided by clinical staff to assess symptoms and take specimens for COVID–19 laboratory testing for all patients, not just established patients. We are creating and updating payment codes to account for these changes.
137	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Indirect Medical Education	Indirect Medical Education. Beds temporarily added during the COVID–19 PHE do not reduce a teaching hospital's Indirect Medical Education payments.
138	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Medical Education: Time Spent by Residents at Another Hospital during the COVID–19 PHE.	Direct Graduate Medical Education and Indirect Medical Education. During the COVID–19 PHE, hospitals may claim time spent by residents training at another hospital so that a hospital which sends residents to another hospital can claim those FTE residents on its Medicare cost report while they are training at another hospital in its FTE count, if certain conditions are met. Also the presence of residents in the receiving hospital would not trigger per-resident amounts.
139	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Medicare Shared Savings Programs.	L. We are modifying Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (2) clarify the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the COVID–19 PHE; (3) adjust program calculations to mitigate the impact of COVID–19 on ACOs; and (4) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We are revising our policies under the Shared Savings Program to exclude from Shared Savings Program calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19, triggered by an inpatient service, and as specified on Parts A and B claims with dates of service during the episode. We are relying on our authority under section 1899(d)(1)(B)(ii) of the Act to adjust benchmark expenditures for other factors in order to remove COVID–19-related expenditures from the determination of benchmark expenditures. As discussed elsewhere in this section, we are also exercising our authority under section 1899(i)(3) of the Act to apply this adjustment to certain other program calculations, including the determination of performance year expenditures.
140	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Opioid Treatment Programs (OTP)—Furnishing Periodic Assessments via Communication Technology.	D. Allow telehealth in place of required visits for opioid treatment programs (OTP).

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
141	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Furnishing Hospital Outpatient Services Remotely.	F. Hospital and CMHC staff can furnish certain outpatient therapy, counseling, and educational services (including PHP services) incident to a physician's service during the COVID–19 PHE to a beneficiary in their home or other temporary expansion location using telecommunications technology. In these circumstances, the hospital can furnish services to a beneficiary in a temporary expansion location (including the beneficiary's home) if that beneficiary is registered as an outpatient; and the CMHC can furnish services in an expanded CMHC (including the beneficiary's home) to a beneficiary who is registered as an outpatient. We also clarified that hospitals can furnish clinical staff services (for example, drug administration) in the patient's home, which is considered provider-based to the hospital during the COVID–19 PHE, and to bill and be paid for these services when the patient is registered as a hospital outpatient. Further, we clarified that when a patient is receiving a professional service via telehealth in a location that is considered a hospital PBD, and the patient is a registered outpatient of the hospital, the hospital in which the patient is registered may bill the originating site facility fee for the service. Finally, we clarified the applicability of section 603 of the BBA 2015 to hospitals furnishing care in the beneficiaries' homes (or other temporary expansion locations), and whether those locations are considered relocated, partially relocated, or new PBDs.
142	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Treatment of New and Certain Relocating Provider-Based Departments.	E. We are adopting a temporary extraordinary circumstances relocation exception policy for excepted off-campus PBDs that relocate off-campus during the COVID–19 PHE. We are extending that temporary policy to on-campus PBDs that relocate off-campus during the COVID–19 PHE, and permitting the relocating PBDs to continue to be paid under the OPPS. Finally, we are streamlining the process for relocating PBDs to obtain the temporary extraordinary circumstances policy exception.
143	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Payment for Remote Physiologic Monitoring (RPM) Services.	CC. We are establishing a policy on an interim final basis for the duration of the COVID–19 PHE to allow RPM codes to be billed for a minimum of 2 days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period as provided in the CPT code descriptors.
144	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Rural Health Clinics (RHC)	H. Due to the COVID–19 pandemic, health care providers such as hospitals have been or are planning to increase inpatient bed capacity to address the surge in need for inpatient care. Given this, we do not believe that RHCs that are currently exempt from the national per-visit payment limit should now be subject to the per-visit payment limit due to the COVID–19 PHE, and we do not want to discourage them from increasing bed capacity if needed. Allowing for these provider-based RHCs to continue to receive the payment amounts they would otherwise receive in the absence of the PHE will help maintain their ability to provide necessary health care services to underserved communities. We are implementing, on an interim basis, a change to the period of time used to determine the number of beds in a hospital at § 412.105(b) for purposes of determining which provider-based RHCs are subject to the payment limit. For the duration of the PHE, we will use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for application of this policy. As such, RHCs with provider-based status that were exempt from the national per-visit payment limit in the period prior to the effective date of the PHE (January 27, 2020) would continue to be exempt for the duration of the PHE for the COVID–19 pandemic, as defined at § 400.200.
145	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Scope of Practice: Supervision of Diagnostic Tests by Certain Non-Physician Practitioners.	Allow nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs) and certified nurse-midwives (CNMs) to supervise the performance of diagnostic tests in addition to physicians.
146	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Scope of Practice: Pharmacists Working Incident to a Physicians' Service.	B. 4. We are clarifying explicitly that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.
147	HHS	CMS	Interim Final Rule	RIN 0938–AU31	COVID–19 Serology Testing	Section V of the rule. Antibody Testing: Medicare will cover certain serology (antibody) tests, which may aid in determining whether a person may have developed an immune response and may not be at immediate risk for COVID–19 reinfection. FDA approved or cleared COVID–19 serology testing as a Medicare covered diagnostic test for patients that have reason to believe they have been exposed to COVID–19. The serology test for COVID–19 is a covered service under Medicare Parts A and B and may be considered a hospital service (section 1861(b) of the Act) or diagnostic laboratory test (section 1861(s)(3) of the Act).

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
148	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Additional Flexibility under the Teaching Physician Regulations.	M. Allow the teaching physician to meet the requirement to review the service with the resident, during or immediately after the visit, through virtual or remote means via interactive audio/video real-time communications technology. Given the circumstances of the COVID–19 PHE, the teaching physician may be under quarantine or otherwise not physically available to review the service with the resident. We are reinstating the former paragraph (b) and adding a new paragraph (c) to allow that, on an interim basis for the duration of the PHE for the COVID–19 pandemic, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via audio/video real time communications technology.
149	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Updating the Medicare Telehealth List on a Sub-regulatory Basis.	AA. Due to the urgency of minimizing unnecessary contact between beneficiaries and practitioners, we believe that, for purposes of the PHE for the COVID–19 pandemic, we should modify the process we established for adding or deleting services from the Medicare telehealth services list under our regulation at § 410.78(f) to allow for an expedited process during the PHE that does not involve notice and comment rulemaking. Therefore, for the duration of the PHE for the COVID–19 pandemic, we are revising our regulation at § 410.78(f) to specify that, during a PHE, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list. While we are not codifying a specific process to be in effect during the PHE for the COVID–19 pandemic, we note that we could add services to the Medicare telehealth list on a subregulatory basis by posting new services to the web listing of telehealth services when the agency receives a request to add (or identifies through internal review) a service that can be furnished in full, as described by the relevant code, by a distant site practitioner to a beneficiary in a manner that is similar to the in-person service. We also note that any additional services added using the revised process would remain on the list only during the PHE for the COVID–19 pandemic.
150	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Therapy—Therapy Assistants Furnishing Maintenance Therapy (PFS).	B. 2. To increase availability of needed health care services during the COVID–19 PHE, we believe it is appropriate to synchronize our Part B payment policies as suggested by the stakeholders, and to permit the PT or OT who established the maintenance program to delegate the performance of maintenance therapy services to a PTA or OTA when clinically appropriate. We believe that, by allowing PTAs and OTAs to perform maintenance therapy services, PTs and OTs will be freed up to furnish other services, including such services as non-medication pain management therapies that may reduce reliance on opioids or other medications, as well as those services related to the COVID–19 PHE that require a therapist's assessment and evaluation skills, including communication technology-based services (CTBS) that were made available for PTs, OTs and speech-language pathologists (SLPs) during the PHE in the March 31st COVID–19 IFC (85 FR 19245 and 19265 through 19266).

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
151	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Modification to Medicare Provider Enrollment Provision Concerning Certification of Home Health Services.	W. Several of our previous provider enrollment rulemaking efforts have focused on strengthening existing enrollment procedures and eliminating existing vulnerabilities; in other words, the objectives have been to enhance our ability to: (1) Conduct strict screening activities; (2) take prompt action against problematic providers and suppliers; and (3) implement important safeguards against improper Medicare payments. Yet we believe that the current COVID–19 PHE requires us to undertake provider enrollment rulemaking for a different reason; specifically, the need to help providers and suppliers concentrate their resources on treating those beneficiaries affected by COVID–19. Therefore, as discussed in section III. of this IFC, ''Waiver of Proposed Rulemaking,'' we believe the urgency of this COVID–19 PHE constitutes good cause to waive the normal notice-and-comment process under the Administrative Procedure Act and statute. Accordingly, this IFC contains an important revision to part 424, subpart P that will give providers and suppliers certain flexibilities in their activities during the existing COVID–19 PHE. Section 3708 of the CARES Act made several important amendments to sections 1814(a)(2) and 1835(a)(2) of the Act (as well as other related sections of the statute). One amendment was that NPs, CNSs, and PAs (as those terms are defined in section 1861(aa)(5) of the Act) working in accordance with state law may also certify the need for home health services. Section 3708(f) of the CARES Act authorizes us to promulgate an interim final rule, if necessary, to implement the provisions in section 3708 by the statutory deadline. Further, given the need for flexibility in the provision of health care services in the COVID–19 PHE, we believe it is appropriate to implement these statutory changes in this IFC, rather than through notice-and-comment rulemaking. Consequently, we are revising § 424.507(b)(1) to include ordering/certifying physicians, PAs, NPs, and CNSs as individuals who can certify the need for home health services. We note that, for reasons similar to those related to our other modifications to Medicare rules concerning the certification and provision of home health services, this change to § 424.507 is final and applicable to services provided on or after March 1, 2020.We will review and respond to any comments thereon in the CY 2021 HH PPS final rule or in another future rule.
152	HHS	CMS	Waiver		Verbal Orders	Waiving the requirements of 42 CFR § 482.23, § 482.24 and § 485.635(d)(3) to provide additional flexibility related to verbal orders where read-back verification is required, but authentication may occur later than 48 hours. This will allow more efficient treatment of patients in surge situations.
153	HHS	CMS	Waiver		Medical Records	Waiving requirements under 42 CFR § 482.24(a) through (c), which cover the subjects of the organization and staffing of the medical records department, requirements for the form and content of the medical record, and record retention requirements, and these flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. CMS is waiving § 482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic. CMS is waiving § 482.24(c)(4)(viii) related to medical records to allow flexibility in completion of medical records within 30 days following discharge from a hospital. This flexibility will allow clinicians to focus on the patient care at the bedside during the pandemic.
154	HHS	CMS	Waiver		Nursing Care Plan	Waiving the requirements at 42 CFR § 482.23(b)(4), which requires the nursing staff to develop and keep current a nursing care plan for each patient, and § 482.23(b)(7), which requires the hospital to have policies and procedures in place establishing which outpatient departments are not required to have a registered nurse present. These waivers allow nurses increased time to meet the clinical care needs of each patient and allow for the provision of nursing care to an increased number of patients. In addition, we expect that hospitals will need relief for the provision of inpatient services and as a result, the requirement to establish nursing-related policies and procedures for outpatient departments is likely of lower priority. These flexibilities apply to both hospitals and CAHs § 485.635(d)(4), and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
155	HHS	CMS	Waiver		Upkeep of current therapeutic diet manual.	Food and Dietetic Services—Manual. CMS is waiving the requirement at paragraph 42 CFR § 482.28(b)(3), which requires providers to have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. Such manuals would not need to be maintained at surge capacity sites. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. Removing these administrative requirements will allow hospitals to focus more resources on providing direct patient care.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
156	HHS	CMS	Waiver		Written policies and procedures for appraisal of emergencies at off campus hospital departments.	Waiving 42 CFR § 482.12(f)(3), emergency services, with respect to surge facilities only, such that written policies and procedures for staff to use when evaluating emergencies are not required for surge facilities. This removes the burden on facilities to develop and establish additional policies and procedures at their surge facilities or surge sites related to the assessment, initial treatment, and referral of patients. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
157	HHS	CMS	Waiver		Emergency Preparedness Policies and Procedures.	Waiving 42 CFR § 482.15(b) and § 485.625(b), which requires the hospital and CAH to develop and implement emergency preparedness policies and procedures, and § 482.15(c)(1)–(5) and § 485.625(c)(1)–(5) which requires that the emergency preparedness communication plans for hospitals and CAHs to contain specified elements with respect to the surge site. The requirement under the communication plan requires hospitals and CAHs to have specific contact information for staff, entities providing services under arrangement, patients' physicians, other hospitals and CAHs, and volunteers. This would not be an expectation for the surge site. This waiver applies to both hospitals and CAHs, and removes the burden on facilities to establish these policies and procedures for their surge facilities or surge sites.
158	HHS	CMS	Waiver		Emergency Preparedness	CMS is waiving the requirements at 42 CFR § 494.62(d)(1)(iv) which requires ESRD facilities to demonstrate as part of their Emergency Preparedness Training and Testing Program, that staff can demonstrate that, at a minimum, its patient care staff maintains current CPR certification. CMS is waiving the requirement for maintenance of CPR certification during the COVID–19 emergency due to the limited availability of CPR classes.
159	HHS	CMS	Waiver		Reporting Requirements	Waiving the requirements at 42 CFR § 482.13(g)(1)(i)–(ii), which require that hospitals report patients in an intensive care unit whose death is caused by their disease, but who required soft wrist restraints to prevent pulling tubes/IVs, no later than the close of business on the next business day. Due to current hospital surge, CMS is waiving this requirement to ensure that hospitals are focusing on increased patient care demands and increased patient census, provided any death where the restraint may have contributed is still reported within standard time limits (*i.e.,* close of business on the next business day following knowledge of the patient's death).
160	HHS	CMS	Waiver		Extension for Inpatient Prospective Payment System (IPPS) Wage Index Occupational Mix Survey Submission.	CMS collects data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. Completed 2019 Occupational Mix Surveys, Hospital Reporting Form CMS–10079, for the Wage Index Beginning FY 2022, are due to the Medicare Administrative Contractors (MACs) on the Excel hospital reporting form available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html* by July 1, 2020. CMS is currently granting an extension for hospitals nationwide affected by COVID–19 until August 3, 2020. If hospitals encounter difficulty meeting this extended deadline date, hospitals should communicate their concerns to CMS via their MAC, and CMS may consider an additional extension if CMS determines it is warranted.
161	HHS	CMS	Waiver		HHA Reporting	CMS is providing relief to HHAs on the timeframes related to OASIS Transmission through the following actions below: • Extending the 5-day completion requirement for the comprehensive assessment to 30 days. • Waiving the 30-day OASIS submission requirement. Delayed submission is permitted during the PHE.
162	HHS	CMS	Waiver		SNF Reporting Minimum Data Set.	Waiving 42 CFR 483.20 to provide relief to SNFs on the timeframe requirements for Minimum Data Set assessments and transmission.
163	HHS	CMS	Waiver		SNF Staffing Data Submission	Waiving 42 CFR 483.70(q) to provide relief to long-term care facilities on the requirements for submitting staffing data through the Payroll-Based Journal system.
164	HHS	CMS	Waiver		Physical Environment.	CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR § 482.41 and § 485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that the location is approved by the state (ensuring that safety and comfort for patients and staff are sufficiently addressed) and so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.
165	HHS	CMS	Waiver		CAH Status and Location	Waiving the requirement at 42 CFR § 485.610(b) that the CAH be located in a rural area or an area being treated as being rural, allowing the CAH flexibility in the establishment of surge site locations. CMS is also waiving the requirement at § 485.610(e) regarding the CAH's off-campus and co-location requirements, allowing the CAH flexibility in establishing temporary off-site locations. In an effort to facilitate the establishment of CAHs without walls, these waivers will suspend restrictions on CAHs regarding their rural location and their location relative to other hospitals and CAHs. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
166	HHS	CMS	Waiver		Hospitals Classified as Sole Community Hospitals (SCH).	Waiving certain eligibility requirements at 42 CFR § 412.92(a) for hospitals classified as SCHs prior to the PHE. Specifically, CMS is waiving the distance requirements at paragraphs (a), (a)(1), (a)(2), and (a)(3) of 42 CFR § 412.92, and is also waiving the ''market share'' and bed requirements (as applicable) at 42 CFR § 412.92(a)(1)(i) and (ii). CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID–19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.
167	HHS	CMS	Waiver		RHC and FQHC Temporary Expansion Locations.	Waiving the requirements at 42 CFR § 491.5(a)(3)(iii) which require RHCs and FQHCs be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS is temporarily waiving this requirement removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand services locations to meet the needs of Medicare beneficiaries. This flexibility includes areas which may be outside of the location requirements 42 CFR § 491.5(a)(1) and (2) but will end when the HHS Secretary determines there is no longer a PHE due to COVID–19.
168	HHS	CMS	Waiver		Care for Excluded Inpatient Psychiatric and Inpatient Rehabilitation Unit Patients in the Acute Care Unit of a Hospital.	CMS is allowing acute care hospitals with excluded distinct part inpatient psychiatric units and inpatient rehabilitation units to relocate inpatients from the excluded distinct part psychiatric unit or inpatient rehabilitation unit to an acute care bed and unit as a result of a disaster or emergency. The hospital should continue to bill for inpatient psychiatric services or inpatient rehabilitation services under the Inpatient Psychiatric Facility Prospective Payment System or Inpatient Rehabilitation Facility Prospective Payment System for these patients and annotate the medical record to indicate the patient is a psychiatric inpatient being cared for in an acute care bed because of capacity or other exigent circumstances related to the COVID–19 emergency. This waiver may be utilized where the hospital's acute care beds are appropriate for psychiatric patients or rehabilitation patients and the staff and environment are conducive to safe care. For psychiatric patients, this includes assessment of the acute care bed and unit location to ensure those patients at risk of harm to self and others are safely cared for.
169	HHS	CMS	Waiver		Specific Life Safety Code (LSC) Waivers for Multiple Providers: Temporary Construction.	CMS is waiving requirements that would otherwise not permit temporary walls and barriers between patients. Refer to: 2012 LSC, sections 18/19.3.3.2.
170	HHS	CMS	Waiver		Community Mental Health Clinics (CMHC) Provision of Service.	42 CFR 485.918(b)(1)(iii). We are waiving the specific requirement at § 485.918(b)(1)(iii) that prohibits CMHCs from providing partial hospitalization services and other CMHC services in an individual's home so that clients can safely shelter in place during the PHE while continuing to receive needed care and services from the CMHC. This waiver is a companion to recent regulatory changes that clarify how CMHCs should bill for services provided in an individual's home, and how such services should be documented in the medical record. While this waiver will now allow CMHCs to furnish services in client homes, including through the use of using telecommunication technology, CMHCs continue to be, among other things, required to comply with the nonwaived provisions of 42 CFR Part 485, Subpart J, requiring that CMHCs: (1) Assess client needs, including physician certification of the need for partial hospitalization services, if needed; (2) implement and update each client's individualized active treatment plan that sets forth the type, amount, duration, and frequency of the services; and (3) promote client rights, including a client's right to file a complaint.
171	HHS	CMS	Waiver		RAPs	CMS is allowing Medicare Administrative Contractors (MACs) to extend the auto-cancellation date of Requests for Anticipated Payment (RAPs) during emergencies.
172	HHS	CMS	Waiver		Utilization Review (UR)	CMS is waiving certain requirements under 42 CFR § 482.1(a)(3) and 42 CFR § 482.30 which address the statutory basis for hospitals and includes the requirement that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.
173	HHS	CMS	Waiver		Training Program and Periodic Audits.	CMS is waiving the requirement at 42 CFR § 494.40(a) related to the condition on Water & Dialysate Quality, specifically that ontime periodic audits for operators of the water/dialysate equipment are waived to allow for flexibilities.
174	HHS	CMS	Waiver		Appeals Extensions	CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program pursuant to 42 CFR § 405.942 and 42 CFR § 405.962 (including for MA and Part D plans), as well as the MA and Part D Independent Review Entities (IREs) under 42 CFR § 422.562, 42 CFR § 423.562, 42 CFR § 422.582 and 42 CFR § 423.582, to allow extensions to file an appeal. CMS is allowing MACs and QICs in the FFS program under 42 CFR § 405.950 and 42 CFR § 405.966 and the MA and Part D IREs to waive requests for timeliness requirements for additional information to adjudicate appeals.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
						• CMS is allowing MACs and QICs in the FFS program under 42 CFR § 405.910 and MA and Part D plans, as well as the MA and Part D IREs, to process an appeal even with incomplete Appointment of Representation forms as outlined under 42 CFR § 422.561 and 42 CFR § 423.560. However, any communications will only be sent to the beneficiary. • CMS is allowing MACs and QICs in the FFS program under 42 CFR § 405.950 and 42 CFR § 405.966 (also including MA and Part D plans), as well as the MA and Part D IREs, to process requests for appeals that do not meet the required elements using information that is available as outlined within 42 CFR § 422.561 and 42 CFR § 423.560. • CMS is allowing MACs and QICs in the FFS program under 42 CFR § 405.950 and 42 CFR § 405.966 (also including MA and Part D plans), as well as the MA and Part D IREs under 42 CFR § 422.562 and 42 CFR § 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.
175	HHS	CMS	Waiver		Risk Adjusted Factor (RAF) Extensions.	CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: The enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1).
176	HHS	CMS	Waiver		SNF 3-Day Prior Hospitalization and 60-day ''wellness period''.	Using the authority under Section 1812(f) of the Act, CMS is waiving the requirement for a 3-day prior hospitalization for coverage of a SNF stay, which provides temporary emergency coverage of SNF services without a qualifying hospital stay, for those people who experience dislocations, or are otherwise affected by COVID–19. In addition, for certain beneficiaries who recently exhausted their SNF benefits, it authorizes a one-time renewal of SNF coverage without first having to start a new benefit period (this waiver will apply only for those beneficiaries who have been delayed or prevented by the emergency itself from commencing or completing the process of ending their current benefit period and renewing their SNF benefits that would have occurred under normal circumstances).
177	HHS	CMS	Waiver		Supporting Care for Patients in Long-Term Care Acute Hospitals (LTCHs).	CMS has determined it is appropriate to issue a blanket waiver to long-term care hospitals (LTCHs) to exclude patient stays where an LTCH admits or discharges patients in order to meet the demands of the emergency from the 25-day average length of stay requirement, which allows these facilities to be paid as LTCHs. In addition, during the applicable waiver time period, we would also apply this waiver to facilities not yet classified as LTCHs, but seeking classification as an LTCH.
178	HHS	CMS	Waiver		CAH Bed Count and Length of Stay.	Waiving the requirements that CAHs limit the number of beds to 25, and that the length of stay be limited to 96 hours under the Medicare conditions of participation for number of beds and length of stay at 42 CFR § 485.620.
179	HHS	CMS	Waiver		Hospitals Classified as Medicare-Dependent, Small Rural Hospitals (MDH).	For hospitals classified as MDHs prior to the PHE, CMS is waiving the eligibility requirement at 42 CFR § 412.108(a)(1)(ii) that the hospital has 100 or fewer beds during the cost reporting period, and the eligibility requirement at 42 CFR § 412.108(a)(1)(iv)(C) that at least 60 percent of the hospital's inpatient days or discharges were attributable to individuals entitled to Medicare Part A benefits during the specified hospital cost reporting periods. CMS is waiving these requirements for the duration of the PHE to allow these hospitals to meet the needs of the communities they serve during the PHE, such as to provide for increased capacity and promote appropriate cohorting of COVID–19 patients. MACs will resume their standard practice for evaluation of all eligibility requirements after the conclusion of the PHE period.
180	HHS	CMS	Waiver		Hospice Aide Competency testing Allow Use of Pseudo Patients.	Temporarily modifying the requirement in § 418.76(c)(1) that a hospice aide must be evaluated by observing an aide's performance of certain tasks with a patient. This modification allows hospices to utilize pseudo patients such as a person trained to participate in a role-play situation or a computer-based mannequin device, instead of actual patients, in the competency testing of hospice aides for those tasks that must be observed being performed on a patient. This increases the speed of performing competency testing and allows new aides to begin serving patients more quickly without affecting patient health and safety during the public health emergency (PHE).
181	HHS	CMS	Waiver		Onsite Visits for Hospice Aide Supervision.	Waiving the requirements at 42 CFR § 418.76(h), which require a nurse to conduct an onsite supervisory visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
182	HHS	CMS	Waiver		Patient Self Determination Act Requirements (Advance Directives).	Waiving the requirements at sections 1902(a)(58) and 1902(w)(1)(A) of the Act (for Medicaid); 1852(i) of the Act (for Medicare Advantage); and 1866(f) of the Act and 42 CFR § 489.102 (for Medicare), which require hospitals and CAHs to provide information about their advance directive policies to patients. CMS is waiving this requirement to allow staff to more efficiently deliver care to a larger number of patients.
183	HHS	CMS	Waiver		Resident Roommates and Grouping.	Waiving the requirements in 42 CFR 483.10(e) (5), (6), and (7) solely for the purposes of grouping or cohorting residents with respiratory illness symptoms and/or residents with a confirmed diagnosis of COVID–19, and separating them from residents who are asymptomatic or tested negative for COVID–19. This action waives a facility's requirements, under 42 CFR 483.10, to provide for a resident to share a room with his or her roommate of choice in certain circumstances, to provide notice and rationale for changing a resident's room, and to provide for a resident's refusal a transfer to another room in the facility. This aligns with CDC guidance to preferably place residents in locations designed to care for COVID–19 residents, to prevent the transmission of COVID–19 to other residents.
184	HHS	CMS	Waiver		Defer Equipment Maintenance & Fire Safety Inspections.	Waiving the requirement at 42 CFR § 494.60(b) for on-time preventive maintenance of dialysis machines and ancillary dialysis equipment. Additionally, CMS is also waiving the requirements under § 494.60(d) which requires ESRD facilities to conduct on-time fire inspections. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency.
185	HHS	CMS	Waiver		Ability to Delay Some Patient Assessments.	CMS is not waiving subsections (a) or (c) of 42 CFR § 494.80, but is waiving the following requirements at 42 CFR § 494.80(b) related to the frequency of assessments for patients admitted to the dialysis facility. CMS is waiving the ''on time'' requirements for the initial and follow up comprehensive assessments within the specified timeframes as noted below. This waiver applies to assessments conducted by members of the interdisciplinary team, including: A registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian. These waivers are intended to ensure that dialysis facilities are able to focus on the operations related to the Public Health Emergency. Specifically, CMS is waiving: • § 494.80(b)(1): An initial comprehensive assessment must be conducted on all new patients (that is, all admissions to a dialysis facility), within the latter of 30 calendar days or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. • § 494.80(b)(2): A follow up comprehensive reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care specified in § 494.90.
186	HHS	CMS	Waiver		SNF-Waiving Pre-Admission Screening and Annual Resident Review (PASARR).	Waiving 42 CFR 483.20(k), allowing nursing homes to admit new residents who have not received Level 1 or Level 2 Preadmission Screening. Level 1 assessments may be performed post-admission. On or before the 30th day of admission, new patients admitted to nursing homes with a mental illness (MI) or intellectual disability (ID) should be referred promptly by the nursing home to State PASARR program for Level 2 Resident Review.
187	HHS	CMS	Waiver		Physician Self-Referral Regulations.	Waivers of Sanctions under the Stark Law. CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. These flexibilities include: (1) Hospitals and other health care providers can pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties may pay below fair market value to rent equipment or purchase items or services. (2) Health care providers can support each other financially to ensure continuity of health care operations. (3) Hospitals can provide benefits to their medical staffs, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients. (4) Health care providers may offer certain items and services that are solely related to COVID–19 Purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap; (5) Physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law; (6) Some of the restrictions when a group practice can furnish medically necessary designated health services (DHS) in a patient's home are loosened. (7) Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
188	HHS	CMS	Waiver		Medicare Graduate Medical Education (GME) Affiliation Agreement.	Due to the COVID–19 Public Health Emergency (PHE), under the authority of section 1135(b)(5) of the Social Security Act (the Act), CMS is waiving the July 1 submission deadline under 42 CFR 413.79(f)(1) for new Medicare GME affiliation agreements and the June 30 deadline under the May 12, 1998 Health Care Financing Administration Final Rule (63 FR 26318, 26339, 26341) for amendments of existing Medicare GME affiliation agreements. That is, during the COVID–19 PHE, instead of requiring that new Medicare GME affiliation agreements be submitted to CMS and the MACs by July 1, 2020 (for the academic year starting July 1, 2020), and that amendments to Medicare GME affiliation agreements be submitted to CMS and the MACS by June 30, 2020 (for academic year ending June 30, 2020), CMS is allowing hospitals to submit new and/or amended Medicare GME affiliation agreements as applicable to CMS and the MACs by October 1, 2020. As under existing procedures, hospitals should email new and/or amended agreements to CMS at *Medicare_GME_Affiliation_Agreement@cms.hhs.gov,* and indicate in the subject line whether the affiliation agreement is a new one or an amended one.
189	HHS	CMS	Waiver		Allow use of audio-only equipment to furnish audio-only telephone E/M, counseling, and educational services.	Pursuant to authority granted under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes *https://www.cms.gov/Medicare/MedicareGeneral-Information/Telehealth/Telehealth-Codes*). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.
190	HHS	CMS	Waiver		Hospital Telemedicine	Waiving the provisions related to telemedicine at 42 CFR § 482.12(a)(8)–(9) for hospitals and § 485.616(c) for CAHs, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital.
191	HHS	CMS	Waiver		Hospital Care of Patients	Waiving requirements under 42 CFR § 482.12(c)(1)–(2) and § 482.12(c)(4), which requires that Medicare patients be under the care of a physician. This waiver may be implemented so long as it is not inconsistent with a state's emergency preparedness or pandemic plan. This allows hospitals to use other practitioners to the fullest extent possible.
192	HHS	CMS	Waiver		Responsibilities of Physicians in Critical Access Hospitals (CAHs).	42 CFR § 485.631(b)(2). CMS is waiving the requirement for CAHs that a doctor of medicine or osteopathy be physically present to provide medical direction, consultation, and supervision for the services provided in the CAH at § 485.631(b)(2). CMS is retaining the regulatory language in the second part of the requirement at § 485.631(b)(2) that a physician be available ''through direct radio or telephone communication, or electronic communication for consultation, assistance with medical emergencies, or patient referral.'' Retaining this longstanding CMS policy and related longstanding subregulatory guidance that further described communication between CAHs and physicians will assure an appropriate level of physician direction and supervision for the services provided by the CAH. This will allow the physician to perform responsibilities remotely, as appropriate. This also allows CAHs to use nurse practitioners and physician assistants to the fullest extent possible, while ensuring necessary consultation and support as needed.
193	HHS	CMS	Waiver		Anesthesia Services	Waiving requirements under 42 CFR § 482.52(a)(5), § 485.639(c)(2), and § 416.42 (b)(2) that a certified registered nurse anesthetist (CRNA) is under the supervision of a physician in paragraphs § 482.52(a)(5) and § 485.639(c)(2). CRNA supervision will be at the discretion of the hospital and state law. This waiver applies to hospitals, CAHs, and Ambulatory Surgical Centers (ASCs). These waivers will allow CRNAs to function to the fullest extent of their licensure, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
194	HHS	CMS	Waiver		Physician Supervision of NPs in RHCs and FQHCs.	42 CFR 491.8(b)(1). We are modifying the requirement that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
195	HHS	CMS	Waiver		Staffing Requirements for RCHs and FQHCs.	Waiving the requirement in the second sentence of § 491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50 percent of the time the RHC operates. CMS is not waiving the first sentence of § 491.8(a)(6) that requires a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist to be available to furnish patient care services at all times the clinic or center operates. This will assist in addressing potential staffing shortages by increasing flexibility regarding staffing mixes during the PHE.
196	HHS	CMS	Waiver		CAH Staff Licensure	Deferring to staff licensure, certification, or registration to state law by waiving 42 CFR § 485.608(d) regarding the requirement that staff of the CAH be licensed, certified, or registered in accordance with applicable federal, state, and local laws and regulations. This waiver will provide maximum flexibility for CAHs to use all available clinicians. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
197	HHS	CMS	Waiver		CAH Personnel Qualifications	Waiving the minimum personnel qualifications for clinical nurse specialists at paragraph 42 CFR § 485.604(a)(2), nurse practitioners at paragraph § 485.604(b)(1)–(3), and physician assistants at paragraph § 485.604(c)(1)–(3). Removing these Federal personnel requirements will allow CAHs to employ individuals in these roles who meet state licensure requirements and provide maximum staffing flexibility. These flexibilities should be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
198	HHS	CMS	Waiver		Physician Delegation of Tasks in SNFs.	42 CFR 483.30(e)(4). Waiving the requirement in § 483.30(e)(4) that prevents a physician from delegating a task when the regulations specify that the physician must perform it personally. This waiver gives physicians the ability to delegate any tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who meets the applicable definition in 42 CFR 491.2 or, in the case of a clinical nurse specialist, is licensed as such by the State and is acting within the scope of practice laws as defined by State law. We are temporarily modifying this regulation to specify that any task delegated under this waiver must continue to be under the supervision of the physician. This waiver does not include the provision of § 483.30(e)(4) that prohibits a physician from delegating a task when the delegation is prohibited under State law or by the facility's own policy.
199	HHS	CMS	Waiver		Allow Occupational Therapists (OTs), Physical Therapists (PTs), and Speech Language Pathologists (SLPs) to Perform Initial and Comprehensive Assessment for all Patients.	CMS is waiving the requirements in 42 CFR § 484.55(a)(2) and § 484.55(b)(3) that rehabilitation skilled professionals may only perform the initial and comprehensive assessment when only therapy services are ordered. This temporary blanket modification allows any rehabilitation professional (OT, PT, or SLP) to perform the initial and comprehensive assessment for all patients receiving therapy services as part of the plan of care, to the extent permitted under state law, regardless of whether or not the service establishes eligibility for the patient to be receiving home care. The existing regulations at § 484.55(a) and (b)(2) would continue to apply; rehabilitation skilled professionals would not be permitted to perform assessments in nursing only cases. We would continue to expect HHAs to match the appropriate discipline that performs the assessment to the needs of the patient to the greatest extent possible. Therapists must act within their state scope of practice laws when performing initial and comprehensive assessments, and access a registered nurse or other professional to complete sections of the assessment that are beyond their scope of practice. Expanding the category of therapists who may perform initial and comprehensive assessments provides HHAs with additional flexibility that may decrease patient wait times for the initiation of home health services.
200	HHS	CMS	Waiver		Physician Visits	42 CFR 483.30(c)(3). CMS is waiving the requirement at § 483.30(c)(3) that all required physician visits (not already exempted in § 483.30(c)(4) and (f)) must be made by the physician personally. We are modifying this provision to permit physicians to delegate any required physician visit to a nurse practitioner (NPs), physician assistant, or clinical nurse specialist who is not an employee of the facility, who is working in collaboration with a physician, and who is licensed by the State and performing within the state's scope of practice laws.
201	HHS	CMS	Waiver		Practitioner Locations	42 CFR 424.510 (d)(2)(III)(A). CMS is temporarily waiving requirements that out-of-state practitioners be licensed in the state where they are providing services when they are licensed in another state. CMS will waive the physician or non-physician practitioner licensing requirements when the following four conditions are met: (1) Must be enrolled as such in the Medicare program; (2) must possess a valid license to practice in the state, which relates to his or her Medicare enrollment; (3) is furnishing services—whether in person or via telehealth—in a state in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and, (4) is not affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
						• In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving state or local licensure requirements or any requirement specified by the state or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the state. Therefore, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the state also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home state.
202	HHS	CMS	Waiver		Waive Onsite Visits for HHA Aide Supervision.	CMS is waiving the requirements at 42 CFR § 484.80(h), which require a nurse to conduct an onsite visit every two weeks. This would include waiving the requirements for a nurse or other professional to conduct an onsite visit every two weeks to evaluate if aides are providing care consistent with the care plan, as this may not be physically possible for a period of time. This waiver is also temporarily suspending the 2-week aide supervision by a registered nurse for home health agencies requirement at § 484.80(h)(1), but virtual supervision is encouraged during the period of the waiver.
203	HHS	CMS	Waiver		ESRD Telemedicine and Report Patient Care.	For Medicare patients with End Stage Renal Disease (ESRD), clinicians no longer must have one ''hands on'' visit per month for the current required clinical examination of the vascular access site.
204	HHS	CMS	Waiver		ESRD Telemedicine and Report Patient Care.	For Medicare patients with ESRD, we are exercising enforcement discretion on the following requirement so that clinicians can provide this service via telehealth: Individuals must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.
205	HHS	CMS	Waiver		Medical Staff Eligibility	Waiving requirements under 42 CFR § 482.22(a)(1)–(4) to allow for physicians whose privileges will expire to continue practicing at the hospital and for new physicians to be able to practice before full medical staff/governing body review and approval to address workforce concerns related to COVID–19. CMS is waiving § 482.22(a)(1)–(4) regarding details of the credentialing and privileging process.
206	HHS	CMS	Waiver		Physician Visits in Skilled Nursing Facilities/Nursing Facilities.	CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
207	HHS	CMS	Waiver		12 hour Annual in-service Training Requirement for Hospice Aides.	42 CFR 418.76(d). CMS is waiving the requirement that hospices must assure that each hospice aide receives 12 hours of in-service training in a 12 month period. This allows aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care.
208	HHS	CMS	Waiver		Dialysis Patient Care Technician (PCT) Certification.	Modifying the requirement at 42 CFR § 494.140(e)(4) for dialysis PCTs that requires certification under a state certification program or a national commercially available certification program within 18 months of being hired as a dialysis PCT for newly employed patient care technicians. CMS is aware of the challenges that PCTs are facing with the limited availability and closures of testing sites during the time of this crisis. CMS will allow PCTs to continue working even if they have not achieved certification within 18 months or have not met on time renewals.
209	HHS	CMS	Waiver		Transferability of Physician Credentialing.	Modifying the requirement at 42 CFR § 494.180(c)(1) which requires that all medical staff appointments and credentialing are in accordance with state law, including attending physicians, physician assistants, nurse practitioners, and clinical nurse specialists. These waivers will allow physicians that are appropriately credentialed at a certified dialysis facility to function to the fullest extent of their licensure to provide care at designated isolation locations without separate credentialing at that facility, and may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
210	HHS	CMS	Waiver		Remote Patient Monitoring Reporting.	Clinicians can provide remote patient monitoring services to both new and established patients. These services can be provided for both acute and chronic conditions and can now be provided for patients with only one disease. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry. (CPT codes 99091, 99457–99458, 99473–99474, 99493–99494).
211	HHS	CMS	Waiver		Remote Evaluations, Virtual Check-Ins & E-Visits.	Medicare patients may have a brief communication service with practitioners via a number of communication technology modalities including synchronous discussion over a telephone or exchange of information through video or image. Clinicians can provide remote evaluation of patient video/images and virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients. These services were previously limited to established patients.
212	HHS	CMS	Waiver		Remote Evaluations, Virtual Check-Ins & E-Visits.	111 E-visits are non-face-to-face communications with their practitioner by using online patient portals. (HCPCS codes G2061–G2063).

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
213	HHS	CMS	Waiver		Flexibility for IRF Regarding the ''60 Percent Rule''.	Allowing IRFs to exclude patients from the freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the ''60 percent rule'') if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, we would also apply the exception to facilities not yet classified as IRFs, but that are attempting to obtain classification as an IRF.
214	HHS	CMS	Waiver		LTCH Site Neutral Payment Rate Provisions.	As required by section 3711(b) of the CARES Act, during the Public Health Emergency (PHE) due to COVID–19, certain provisions of section 1886(m)(6) of the Social Security Act have been waived relating to certain site neutral payment rate provisions for long-term care hospitals (LTCHs). • Section 3711(b)(1) of the CARES Act waives the payment adjustment under section 1886(m)(6)(C)(ii) of the Act for LTCHs that do not have a discharge payment percentage (DPP) for the period that is at least 50 percent during the COVID–19 public health emergency period. Under this provision, for the purposes of calculating an LTCH's DPP, all admissions during the COVID–19 public health emergency period will be counted in the numerator of the calculation. In other words, LTCH cases that were admitted during the COVID–19 public health emergency period will be counted as discharges paid the LTCH PPS standard Federal payment rate. • Section 3711(b)(2) of the CARES Act provides a waiver of the application of the site neutral payment rate under section 1886(m)(6)(A)(i) of the Act for those LTCH admissions that are in response to the public health emergency and occur during the COVID–19 public health emergency period. Under this provision, all LTCH cases admitted during the COVID–19 public health emergency period will be paid the relatively higher LTCH PPS standard Federal rate. A new LTCH PPS Pricer software package released in April 2020 includes this temporary payment policy effective for claims with an admission date occurring on or after January 27, 2020 and continuing through the duration of the COVID–19 public health emergency period. Claims received on or after April 21, 2020, will be processed in accordance with this waiver. Claims received April 20, 2020, and earlier will be reprocessed. LTCHs should add the ''DR'' condition code to applicable claims.
215	HHS	CMS	Waiver		Eligibility for Telehealth	Pursuant to authority granted under the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that broadens the waiver authority under section 1135 of the Social Security Act, the Secretary has authorized additional telehealth waivers. CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.
216	HHS	CMS	Waiver		IRF Intensity of Therapy Requirement (''3-Hour Rule'').	As required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, during the COVID–19 public health emergency, the Secretary has waived 42 CFR 412.622(a)(3)(ii) which provides that payment generally requires that patients of an inpatient rehabilitation facility receive at least 15 hours of therapy per week. This waiver clarifies information provided in ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' (RIN 0938–AU31). (85 **Federal Register** 19252, 19287, April 6, 2020). The information in that rulemaking (RIN 0938–AU31) about Inpatient Rehabilitation Facilities was contemplated prior to the passage of the CARES Act.
217	HHS	CMS	Waiver		Emergency Medical Treatment & Labor Act (EMTALA) Section 1867(a).	Waiving the enforcement of section 1867(a) of the Act. This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID–19, so long as it is not inconsistent with a state's emergency preparedness or pandemic plan.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
218	HHS	CMS	Waiver		Quality Assessment and Performance Improvement (QAPI) Program.	Waiving 42 CFR 482.21(a)–(d) and (f), and 485.641(a), (b), and (d), which provide details on the scope of the program, the incorporation, and setting priorities for the program's performance improvement activities, and integrated Quality Assurance & Performance Improvement programs (for hospitals that are part of a hospital system). These flexibilities, which apply to both hospitals and CAHs, may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan. We expect any improvements to the plan to focus on the Public Health Emergency (PHE). While this waiver decreases burden associated with the development of a hospital or CAH QAPI program, the requirement that hospitals and CAHs maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program will remain. This waiver applies to both hospitals and CAHs.
219	HHS	CMS	Waiver		Signature and Proof of Delivery Requirements.	CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID–19.
220	HHS	CMS	Guidance		Accelerated/Advance Payments	In order to increase cash flow to providers impacted by COVID–19, CMS has expanded our current Accelerated and Advance Payment Program. An accelerated/advance payment is a payment intended to provide necessary funds when there is a disruption in claims submission and/or claims processing. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider/supplier who submits a request to the appropriate Medicare Administrative Contractor (MAC) and meets the required qualifications. Each MAC will work to review requests and issue payments within seven calendar days of receiving the request. Traditionally repayment of these advance/accelerated payments begins at 90 days, however for the purposes of the COVID–19 pandemic, CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment. CMS has amended existing regulation to allow for the lowering of interest rates on overpayments related to accelerated and advance payments issued during the PHE associated with COVID–19.
221	HHS	CMS	Guidance		Part D ''Refill-Too-Soon'' Edits and Maximum Day Supply.	Consistent with section 3714 of the CARES Act, during the public health emergency for COVID–19, Part D sponsors must permit enrollees to obtain the total supply prescribed for a covered Part D drug up to a 90-day supply in one fill or refill if requested by the enrollee, prior authorization or step therapy requirements have been satisfied, and no safety edits otherwise limit the quantity or days' supply. Part D plan also sponsors must relax their ''refill-too-soon'' edits. Part D sponsors continue to have operational discretion as to how these edits are relaxed as long as access to Part D drugs is provided at the point of sale. For purposes of section 3714 of the CARES Act, relaxed refill-too-soon edits are safety edits, and Part D sponsors must not permit enrollees to obtain a single fill or refill that is inconsistent with a safety edit.
222	HHS	CMS	Guidance		Long-Term Care Dispensing	CMS intends to exercise enforcement discretion with respect to the requirement at 42 CFR 423.154(a)(1)(i) that limits dispensing of solid oral doses of brand-name drugs, as defined in § 423.4, to enrollees in long-term care (LTC) facilities to no greater than 14-day increments at a time. For enrollees residing in LTC facilities, Part D sponsors may permit pharmacies to expand the use of submission clarification code 21 (LTC dispensing, 14 days or less not applicable) to allow for greater than 14 day supplies for all applicable Part D drugs to provide more flexibility for LTC facilities and pharmacies to coordinate with each other.
223	HHS	CMS	Guidance		Audit Reviews	CMS is reprioritizing scheduled program audits and contract-level Risk Adjustment Data Validation audits for MA organizations, Part D sponsors, Medicare-Medicaid Plans, and Programs of All-Inclusive Care for the Elderly organizations. Reprioritizing these audit activities will allow providers, CMS and the organizations to focus on patient care.
224	HHS	CMS	Guidance		Part D Enforcement Discretion	CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with, but not limited to, the following: • Waiving Part D medication delivery documentation and signature log requirements; • Relaxing to the greatest extent possible prior authorization requirements, where appropriate; and/or • Suspending plan-coordinated pharmacy audits.
225	HHS	CMS	Guidance		Special Requirements	MAOs must follow the requirements for disasters and emergencies outlined in 42 CFR 422.100(m). Under 42 CFR 422.100(m), MAOs must ensure access to benefits in the following manner: • Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3), which requires that facilities that furnish covered A/B benefits have participation agreements with Medicare. • Waive, in full, requirements for gatekeeper referrals where applicable.

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						• Provide the same cost-sharing for the enrollee as if the service or benefit had been furnished at a plan-contracted facility. • Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3). (Such changes could include reductions in cost-sharing and waiving prior authorizations as described below.)
226	HHS	CMS	Guidance		Prior Authorization	Consistent with flexibilities available to Medicare Advantage Organizations absent a disaster, declaration of a state of emergency, or public health emergency, Medicare Advantage Organizations may choose to waive or relax plan prior authorization requirements at any time in order to facilitate access to services with less burden on beneficiaries, plans, and providers. Any such relaxation or waiver must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency. We encourage plans to consider utilizing this flexibility.
227	HHS	CMS	Guidance		Home or Mail Delivery of Part D Drugs.	In situations when a disaster or emergency makes it difficult for enrollees to get to a retail pharmacy, or enrollees are prohibited from going to a retail pharmacy (*e.g.,* in a quarantine situation), Part D sponsors are permitted to voluntarily relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery, for retail pharmacies that choose to offer these delivery services in these instances.
228	HHS	CMS	Guidance		Pharmacies Enrolling as Labs	Pharmacies may enroll in Medicare as a Clinical Laboratory Improvement Act (CLIA) laboratory if they have their CLIA certification.
229	HHS	CMS	Guidance	Survey Guidance QSO–20–12–All.	Suspension of Enforcement Activities.	During the prioritization period, the following surveys will not be authorized: • Standard surveys for long term care facilities (nursing homes), hospitals, home health agencies (HHAs), intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and hospices. This includes the life safety code and Emergency Preparedness elements of those standard surveys; • Revisits that are not associated with IJ. As a result, the following enforcement actions will be suspended, until revisits are again authorized: ○ For nursing homes—Imposition of Denial of Payment for New Admissions (DPNA), including situations where facilities that are not in substantial compliance at 3 months, will be lifted to allow for new admissions during this time; ○ For HHAs—Imposition of suspension of payments for new admissions (SPNA) following the last day of the survey when termination is imposed will be lifted to allow for new admissions during this time; ○ For nursing homes and HHAs—Suspend per day civil money penalty (CMP) accumulation, and imposition of termination for facilities that are not in substantial compliance at 6 months. • For CLIA, we intend to prioritize immediate jeopardy situations over recertification surveys.
230	HHS	CMS	Guidance		Medicare Provider Enrollment Relief.	42 CFR 424.514 42 CFR 424.518. Exercise 1135 waiver authority to establish toll-free hotlines to allow certain providers and suppliers to enroll and receive temporary Medicare billing privileges. Waive certain screening requirements for providers and suppliers (*e.g.,* finger-print based criminal background checks, site visits, etc.). All enrollment applications received on or after March 1, 2020 will be expedited. Expedite pending applications as well. Postpone all revalidation actions.
231	HHS	CMS	Guidance		Temporary Expansion Locations	Temporary Expansion Locations: Waiving requirements at 42 CFR 491.5(a)(3)(iii) which require RHCs and FQHCs be independently considered for Medicare approval if services are furnished in more than one permanent location. This flexibility includes areas which may be outside of the location requirements 42 CFR 491.5(a)(1) and (2) for the duration of the PHE.
232	HHS	CMS	Waiver		Long Term Care Facility Training and Certification of Nurse Aides.	Waive requirements at 42 CFR 483.35(d) (with the exception of 42 CFR 483.35(d)(1)(i)), which require that a SNF and NF may not employ anyone for longer than four months unless they met the training and certification requirements under § 483.35(d).
233	HHS	CMS	Waiver		Modification of Substitute Billing Arrangements Timetable.	Allows a physician or physical therapist to use the same substitute for the entire time he or she is unavailable to provide services during the COVID–19 emergency plus an additional period of no more than 60 continuous days after the public health emergency expires.
234	HHS	CMS	Waiver		Ambulatory Surgical Centers & Freestanding Emergency Departments (EDs) Hospital Conversion.	During the PHE, CMS has created streamlined and temporary enrollment process for ASCs and licensed Freestanding EDs that wish to convert to a hospital in order to expand capacity and treat patients. ASCs and Freestanding EDs that convert to become a hospital must meet the Hospital Conditions of Participation that remain in effect during the PHE, including 24–7 nursing and others. They must also be able to act as a hospital, and cannot (for example) act as just an outpatient surgical department of a hospital.
235	HHS	CMS	Waiver	42 CFR 424.36E	Beneficiary claims signature requirements for ambulance services.	CMS has determined that there is good cause to accept transport staff signatures in cases where it would not be possible or practical (such as a difficult to clean surface) to disinfect an electronic patient reporting device used after being touched by a beneficiary with known or suspected COVID–19; documentation should note the verbal consent.

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236	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Durable Medical Equipment Interim Pricing in the CARES Act.	I. Changes to the Medicare regulations to revise payment rates for certain durable medical equipment and enteral nutrients, supplies, and equipment as part of implementation of section 3712 of the CARES Act. We are making conforming changes to § 414.210(g)(9), consistent with section 3712(a) and (b) of the CARES Act, but we are omitting the language in section 3712(b) of the CARES Act that references an effective date that is 30 days after the date of enactment of the law. We are revising § 414.210(g)(9)(iii), which describes the 50/50 fee schedule adjustment blend for items and services furnished in rural and noncontiguous areas, to address dates of service from June 1, 2018 through December 31, 2020 or through the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), whichever is later. We are also adding § 414.210(g)(9)(v) which will state that, for items and services furnished in areas other than rural or noncontiguous areas with dates of service from March 6, 2020, through the remainder of the duration of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)), based on the fee schedule amount for the area is equal to 75 percent of the adjusted payment amount established under ''this section'' (by which we mean § 414.210(g)(1) through (8)), and 25 percent of the unadjusted fee schedule amount. For items and services furnished in areas other than rural or noncontiguous areas with dates of service from the expiration date of the emergency period described in section 1135(g)(1)(B) of the Act (42 U.S.C. 1320b–5(g)(1)(B)) through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (referred to as ''this section'' in the regulation text). In addition, we are revising § 414.210(g)(9)(iv) to specify for items and services furnished in areas other than rural and noncontiguous areas with dates of service from June 1, 2018 through March 5, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under § 414.210(g)(1) through (8) (''this section'' in the regulation text).
237	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Basic Health Program Blueprint Revisions.	This IFC revises 42 CFR § 600.125(b) and adds the new paragraph 42 CFR 600.125(c) to permit states operating a BHP to submit revised BHP Blueprints for temporary substantial changes that could be effective retroactive to the first day the COVID–19 PHE. These changes must be directly tied to the PHE for the COVID–19 pandemic and increase access to coverage, and must not be restrictive in nature. For example, states might want to revise a BHP Blueprint retroactively during the COVID–19 PHE to implement provisions such as temporarily allowing continuous eligibility or temporarily waiving limitations on certain benefits covered under its BHP to ensure enrollees have access to necessary services. The state would need to demonstrate to HHS that the significant changes in its revised Blueprint are tied to the COVID–19 PHE and that the changes are not restrictive in nature. This flexibility is similar to the flexibility that states currently have with Medicaid and CHIP state plan amendments.
238	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Flexibility for Medicaid Laboratory Services.	This IFC amends the CMS regulation at 42 CFR 440.30 to provide flexibility with respect to Medicaid coverage of certain COVID–19 related laboratory tests in a greater variety of circumstances and settings. For example, the IFC provides states with flexibility to cover, under their Medicaid programs, a COVID–19 test without it being first ordered by a physician or other licensed practitioner, as well as to cover COVID–19 tests administered in certain non-office settings that are intended to minimize transmission of COVID–19, such as parking lots. Given the nature and scope of the pandemic, it is important to accommodate the evolution of COVID–19 diagnostic mechanisms. The regulatory updates would also allow Medicaid to cover laboratory processing of self-collected COVID–19 tests that the FDA has authorized for home use.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
239	HHS	CMS	Interim Final Rule ..	RIN 0938–AU31	Improving Care Planning for Medicaid Home Health Services.	P. Section 3708 of the CARES Act amended Medicare requirements at sections 1814(a) and 1835(a) of the Act to expand the list of practitioners who can order home health services. Specifically, sections 1814(a)(2)(C) of the Act under Part A and section 1835(a)(2)(A) of the Act under Part B of the Medicare program were amended to allow an NP, CNS or PA to order home health services in addition to physicians so long as these NPPs are permitted to provide such services under the scope of practice laws in the state. Section 3708(e) of the CARES Act also provides that the requirements for ordering home health services shall apply under title XIX in the same manner and to the same extent as such requirements apply under title XVIII of such Act. In accordance with this language on applying these requirements ''in the same manner'' as Medicare is, in light of the urgent need to provide these flexibilities during the COVID–19 PHE, and because this provision will increase flexibility in the delivery of benefits and make Medicaid coverage of home health services more available, the Medicaid regulations discussed in this section will take effect on the same date as the Medicare regulations implementing section 3708 discussed in section II.J. of this IFC, ''Care Planning for Medicare Home Health Services.'' Further, the language in section 3708 of the CARES Act is not time limited to the period of the COVID–19 PHE; the revisions to the Medicaid home health program will be permanently in effect. The purpose of this regulation is to implement this statutory directive in the CARES Act within the Medicaid program. In implementing the CARES Act home health provisions, it is important to note the structural differences between the Medicare home health benefit and the Medicaid home health benefit that require some adaptation for the requirement to apply the new Medicare rules in section 3708 of the CARES Act to Medicaid ''in the same manner and to the same extent as such requirements apply'' under Medicare. Under the Medicare program, the home health benefit includes skilled part-time or intermittent nursing, home health aide service, therapies and medical social services. DME is a separate benefit under Medicare, and could already be ordered, prior to the enactment of section 3708 of the CARES Act, by a more extensive list of NPPs than the practitioners identified in section 3708 of the CARES Act for Medicare home health services. Comparatively, as noted previously in this section of the IFC, the Medicaid home health benefit includes part-time or intermittent nursing, home health aide services, and medical supplies, equipment and appliances, also known as DME. Therapy services can be included at the state's option. As discussed earlier in this section, Medicare allows a more extensive list of NPPs to order DME, than the practitioners identified for Medicaid or the practitioners identified in the CARES Act. Because DME (''medical supplies, equipment and appliances'') is covered under the Medicaid home health benefit, this would mean applying the current Medicare rules on who can order DME under that Medicare benefit to that component of the Medicaid home health benefit. We believe that aligning the Medicaid program with Medicare regarding who can order medical supplies, equipment and appliances promotes access to services for Medicaid beneficiaries, including those who are dually eligible, and will eliminate burden to states and providers on dealing with inconsistencies between the Medicare and Medicaid programs. Specifically, we are amending the home health regulation at § 440.70(a)(3) to allow other licensed practitioners, to order medical equipment, supplies and appliances in addition to physicians, when practicing in accordance with state laws. For other services covered under the Medicaid home health benefit, we are applying the new list of practitioners set forth in section 3708 of the CARES Act to who can order those services, specifically, part-time or intermittent nursing services, home health aide services, and if included in the state's home health benefit, therapy services. Specifically, § 440.70(a)(2) is amended to allow a NP, CNS and PA to order home health services described in § 440.70(b)(1), (2) and (4). Through this IFC, we are also amending the current regulation to remove the requirement that the NPPs described in § 440.70(a)(2) have to communicate the clinical finding of the face-to-face encounter to the ordering physician. With expanding authority to order home health services, the CARES Act also provides that such practitioners are now capable of independently performing the face-to-face encounter for the patient for whom they are the ordering practitioner, in accordance with state law. If state law does not allow such flexibility, the NPP is required to work in collaboration with a physician. Finally, we note that the flexibility allowed in this IFC to NPs, CNSs and PAs to order home health services must be done in accordance with state law. Individual states have varying requirements for conditions of practice, which determine whether a practitioner may work independently, without a written collaborative agreement or supervision from a physician, or whether general or direct supervision and collaboration is required. State Medicaid Agencies can consult the specific practitioner association or relevant state agency website to ensure that practitioners are working within their scope of practice and prescriptive authority.

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240	HHS	CMS	Interim Final Rule	RIN 0938–AU31	Clarification on Reporting Under the Home Health Value-Based Purchasing Model for CY 2020.	A. Through this IFC, we are implementing a policy to align the Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program (HH QRP) during the PHE for COVID–19. We are also implementing a policy for granting exceptions to the New Measures data reporting requirements under the HHVBP Model during the PHE for COVID–19. Specifically, during the PHE for COVID–19, to the extent that the data that participating HHAs in the nine HHVBP Model states are required to report are the same data that those HHAs are also required to report for the HH QRP, HHAs are required to report those data for the HHVBP Model in the same time, form and manner that HHAs are required to report those data for the HH QRP. As such, if CMS grants an exception or extension that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP Model. In addition, in this IFC, we are adopting a policy to allow exceptions or extensions to New Measure reporting for HHAs participating in the HHVBP Model during the PHE for COVID–19. As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process. All Medicare certified HHAs providing services in Arizona, Florida, Iowa, Nebraska, North Carolina, Tennessee, Maryland, Massachusetts, and Washington are required to compete in the Model. The HHVBP Model uses the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act based on the competing HHAs' performance on applicable measures. The maximum payment adjustment percentage increases incrementally over the course of the HHVBP Model in the following manner, upward or downward: (1) 3 percent in CY 2018; (2) 5 percent in CY 2019; (3) 6 percent in CY 2020; (4) 7 percent in CY 2021; and (5) 8 percent in CY 2022. Payment adjustments are based on each HHA's Total Performance Score (TPS) in a given performance year (PY), which is comprised of performance on: (1) A set of measures already reported via the Outcome and Assessment Information Set (OASIS), 5 completed Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) surveys, and select claims data elements; and (2) three New Measures for which points are achieved for reporting data.
241	HHS	CMS	Waiver		Respiratory Care Services	Waiving the requirements at 42 CFR § 482.57(b)(1) that require hospitals to designate in writing the personnel qualified to perform specific respiratory care procedures and the amount of supervision required for personnel to carry out specific procedures. These flexibilities may be implemented so long as they are not inconsistent with a state's emergency preparedness or pandemic plan.
242	HHS	CMS	Waiver		Documentation of Progress Notes.	Scope of authority extended for non-physician practitioners to document progress notes of patients receiving services in psychiatric hospitals.
243	HHS	CMS	Waiver		DMEPOS Replacement Requirements.	Where Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) is lost, destroyed, irreparably damaged, or otherwise rendered unusable, DME Medicare Administrative Contractors have the flexibility to waive replacements requirements under Medicare such that the face-to-face requirement, a new physician's order, and new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency.
244	HHS	CMS	Waiver		Modified Discharge Planning	Waiving the requirement 42 CFR § 482.43(a)(8), § 482.61(e), and § 485.642(a)(8) to provide detailed information regarding discharge planning, described below: • The hospital, psychiatric hospital, and CAH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. The hospital must ensure that the postacute care data on quality measures and resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. • CMS is maintaining the discharge planning requirements that ensure a patient is discharged to an appropriate setting with the necessary medical information and goals of care.

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245	HHS	CMS	Waiver		Detailed Information Sharing for Discharge Planning for Home Health Agencies.	Waiving the requirements of 42 CFR § 484.58(a) to provide detailed information regarding discharge planning, to patients and their caregivers, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, (another) home health agency (HHA), skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), and long-term care hospital (LTCH) quality measures and resource use measures. • This temporary waiver provides facilities the ability to expedite discharge and movement of residents among care settings. CMS is maintaining all other discharge planning requirements.
246	HHS	CMS	Waiver		DMEPOS Signature on Orders ..	DMEPOS items, except for Power Mobility Devices (PMDs), can be provided via a verbal order. A signature is required prior to submitting claims for payment but the order can be signed electronically. PMDs require a signed, written order prior to delivery.
247	HHS	CMS	Waiver		Specific Physical Environment Waivers for Inspection, Testing and Maintenance.	42 CFR § 482.41(d) for hospitals, § 485.623(b) for CAH, § 418.110(c)(2)(iv) for inpatient hospice, § 483.470(j) for ICF/IID; and § 483.90 for SNFs/NFs all require these facilities and their equipment to be maintained to ensure an acceptable level of safety and quality. CMS is temporarily modifying these requirements to the extent necessary to permit these facilities to adjust scheduled inspection, testing and maintenance (ITM) frequencies and activities for facility and medical equipment.
248	HHS	CMS	Waiver		Special Purpose Renal Dialysis Facilities (SPRDF) Designation Expanded.	Authorizes the establishment of SPRDFs under 42 CFR § 494.120 to address access to care issues due to COVID–19 and the need to mitigate transmission among this vulnerable population. This will not include the normal determination regarding lack of access to care at § 494.120(b) as this standard has been met during the period of the national emergency. Approval as a Special Purpose Renal Dialysis Facility related to COVID–19 does not require Federal survey prior to providing services.
249	HHS	CMS	Waiver		Expanded Ability for Hospitals to Offer Long-term Care Services (''Swing-Beds'') for Patients Who do not Require Acute Care but do Meet the Skilled Nursing Facility (SNF) Level of Care Criteria as Set Forth at 42 CFR 409.31.	Under section 1135(b)(1) of the Act, CMS is waiving the requirements at 42 CFR 482.58, ''Special Requirements for hospital providers of long-term care services (''swing-beds'')'' subsections (a)(1)–(4) ''Eligibility'', to allow hospitals to establish SNF swing beds payable under the SNF prospective payment system (PPS) to provide additional options for hospitals with patients who no longer require acute care but are unable to find placement in a SNF. In order to qualify for this waiver, hospitals must: • Not use SNF swing beds for acute level care. • Comply with all other hospital conditions of participation and those SNF provisions set out at 42 CFR 482.58(b) to the extent not waived. • Be consistent with the state's emergency preparedness or pandemic plan currently not willing to accept or able to take patients because of the COVID–19 public health emergency (PHE); Hospitals must call the CMS Medicare Administrative Contractor (MAC) enrollment hotline to add swing bed services. The hospital must attest to CMS that: • They have made a good faith effort to exhaust all other options; • There are no skilled nursing facilities within the hospital's catchment area that under normal circumstances would have accepted SNF transfers, but are currently not willing to accept or able to take patients because of the COVID–19 public health emergency (PHE); • The hospital meets all waiver eligibility requirements; and • They have a plan to discharge patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier. This waiver applies to all Medicare enrolled hospitals, except psychiatric and long term care hospitals that need to provide post-hospital SNF level swing-bed services for non-acute care patients in hospitals, so long as the waiver is not inconsistent with the state's emergency preparedness or pandemic plan. The hospital shall not bill for SNF PPS payment using swing beds when patients require acute level care or continued acute care at any time while this waiver is in effect. This waiver is permissible for swing bed admissions during the COVID–19 PHE with an understanding that the hospital must have a plan to discharge swing bed patients as soon as practicable, when a SNF bed becomes available, or when the PHE ends, whichever is earlier.
250	HHS	CMS	Waiver		Housing Acute Care Patients in the IRF or IPF Excluded Distinct Part Units.	Waiving requirements to allow acute care hospitals to house acute care inpatients in excluded distinct part units, such as excluded distinct part unit IRFs or IPFs, where the distinct part unit's beds are appropriate for acute care inpatients. The Inpatient Prospective Payment System (IPPS) hospital should bill for the care and annotate the patient's medical record to indicate the patient is an acute care inpatient being housed in the excluded unit because of capacity issues related to the disaster or emergency.
251	HHS	CMS	Waiver		Resident Transfer and Discharge.	Waiving requirements in 42 CFR 483.10(c)(5); 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), (c)(9), and (d); and § 483.21(a)(1)(i), (a)(2)(i), and (b)(2)(i) (with some exceptions) to allow a long term care (LTC) facility to transfer or discharge residents to another LTC facility solely for the following cohorting purposes:

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						• Transferring residents with symptoms of a respiratory infection or confirmed diagnosis of COVID–19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents; • Transferring residents without symptoms of a respiratory infection or confirmed to not have COVID–19 to another facility that agrees to accept each specific resident, and is dedicated to the care of such residents to prevent them from acquiring COVID–19; or • Transferring residents without symptoms of a respiratory infection to another facility that agrees to accept each specific resident to observe for any signs or symptoms of a respiratory infection over 14 days. Exceptions: • These requirements are only waived in cases where the transferring facility receives confirmation that the receiving facility agrees to accept the resident to be transferred or discharged. Confirmation may be in writing or verbal. If verbal, the transferring facility needs to document the date, time, and person that the receiving facility communicated agreement. • In § 483.10, we are only waiving the requirement, under § 483.10(c)(5), that a facility provide advance notification of options relating to the transfer or discharge to another facility. Otherwise, all requirements related to § 483.10 are not waived. Similarly, in § 483.15, we are only waiving the requirement, under § 483.15(c)(3), (c)(4)(ii), (c)(5)(i) and (iv), and (d), for the written notice of transfer or discharge to be provided before the transfer or discharge. This notice must be provided as soon as practicable. • In § 483.21, we are only waiving the timeframes for certain care planning requirements for residents who are transferred or discharged for the purposes explained in 1–3 above. Receiving facilities should complete the required care plans as soon as practicable, and we expect receiving facilities to review and use the care plans for residents from the transferring facility, and adjust as necessary to protect the health and safety of the residents the apply to. • These requirements are also waived when the transferring residents to another facility, such as a COVID–19 isolation and treatment location, with the provision of services ''under arrangements,'' as long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department. In these cases, the transferring LTC facility need not issue a formal discharge, as it is still considered the provider and should bill Medicare normally for each day of care. The transferring LTC facility is then responsible for reimbursing the other provider that accepted its resident(s) during the emergency period. ○ If the LTC facility does not intend to provide services under arrangement, the COVID–19 isolation and treatment facility is the responsible entity for Medicare billing purposes. The LTC facility should follow the procedures described in 40.3.4 of the Medicare Claims Processing Manual (*https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Downloads/clm104c06.pdf*) to submit a discharge bill to Medicare. The COVID–19 isolation and treatment facility should then bill Medicare appropriately for the type of care it is providing for the beneficiary. If the COVID–19 isolation and treatment facility is not yet an enrolled provider, the facility should enroll through the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area to establish temporary Medicare billing privileges. We remind LTC facilities that they are responsible for ensuring that any transfers (either within a facility, or to another facility) are conducted in a safe and orderly manner, and that each resident's health and safety is protected. We also remind states that under 42 CFR 488.426(a)(1), in an emergency, the State has the authority to transfer Medicaid and Medicare residents to another facility.
252	HHS	CMS	Waiver		Furnishing Dialysis Services on the Main Premises.	ESRD requirements at 42 CFR 494.180(d) require dialysis facilities to provide services directly on its main premises or on other premises that are contiguous with the main premises. CMS is waiving this requirement to allow dialysis facilities to provide service to its patients who reside in the nursing homes, long-term care facilities, assisted living facilities and similar types of facilities, as licensed by the state (if applicable). CMS continues to require that services provided to these patients or residents are under the direction of the same governing body and professional staff as the resident's usual Medicare-certified dialysis facility. Further, in order to ensure that care is safe, effective and is provided by trained and qualified personnel, CMS requires that the dialysis facility staff: (1) Furnish all dialysis care and services; (2) provide all equipment and supplies necessary; (3) maintain equipment and supplies in off-premises location; (4) and complete all equipment maintenance, cleaning and disinfection using appropriate infection control procedures and manufacturer's instructions for use.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
253	HHS	CMS	Waiver		Specific Physical Environment Waiver for Outside Window and Outside Door Requirements.	42 CFR 482.41(b)(9) for hospitals, § 485.623(c)(7) for CAHs, § 418.110(d)(6) for inpatient hospices, § 483.470(e)(1)(i) for ICF/IIDs, and § 483.90(a)(7) for SNFs/NFs require these facilities to have an outside window or outside door in every sleeping room. CMS will permit a waiver of these outside window and outside door requirements to permit these providers to utilize facility and non-facility space that is not normally used for patient care to be utilized for temporary patient care or quarantine.
254	HHS	CMS	Waiver		Temporary Expansion Locations	For the duration of the PHE related to COVID–19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR 482.41 and § 485.623 (as noted elsewhere in this waiver document) and the provider-based department requirements at § 413.65 to allow hospitals to establish and operate as part of the hospital any location meeting those conditions of participation for hospitals that continue to apply during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the state or local pandemic plan. This extends to any entity operating as a hospital (whether a current hospital establishing a new location or an Ambulatory Surgical Center (ASC) enrolling as a hospital during the PHE pursuant to a streamlined enrollment and survey and certification process) so long as the relevant location meets the conditions of participation and other requirements not waived by CMS. This waiver will enable hospitals to meet the needs of Medicare beneficiaries.
255	HHS	CMS	Waiver	RIN 0938–AU31	IRF and IPF Teaching Status Adjustment Payments.	To ensure that teaching IRFs and IPFs can alleviate bed capacity issues by taking patients from the inpatient acute care hospitals without being penalized by lower teaching status adjustments, we are freezing the IRFs' and IPFs' teaching status adjustment payments at their values prior to the PHE. For the duration of the COVID–19 PHE, an IRF's teaching status adjustment payments will be the same as they were on the day before the COVID–19 PHE was declared.
256	HHS	CMS	Waiver		Care for Patients in Extended Neoplastic Disease Care Hospitals.	CMS is allowing extended neoplastic disease care hospitals to exclude inpatient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the greater than 20-day average length of stay requirement, which allows these facilities to be excluded from the hospital inpatient prospective payment system and paid an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost based reimbursement rules as authorized under Section 1886(d)(1)(B)(vi) of the Act and 42 CFR 412.22(i).
257	HHS	CMS	Waiver		Community Mental Health Clinic (CMHC) 40 Percent Rule.	Waiving the requirement at § 485.918(b)(1)(v) that a CMHC provides at least 40 percent of its items and services to individuals who are not eligible for Medicare benefits. Waiving the 40 percent requirement will facilitate appropriate timely discharge from inpatient psychiatric units and prevent admissions to these facilities because CMHCs will be able to provide PHP services to Medicare beneficiaries without restrictions on the proportion of Medicare beneficiaries that they are permitted to treat at a time. This will allow communities greater access to health services, including mental health services.
258	HHS	CMS	Waiver		Resident Groups	Waiving the requirements at 42 CFR 483.10(f)(5), which ensure residents can participate in-person in resident groups. This waiver would only permit the facility to restrict in-person meetings during the national emergency given the recommendations of social distancing and limiting gatherings of more than ten people. Refraining from in-person gatherings will help prevent the spread of COVID–19.
259	HHS	CMS	Waiver		Non-Core Services	Waiving the requirement for hospices to provide certain noncore hospice services during the national emergency, including the requirements at 42 CFR 418.72 for physical therapy, occupational therapy, and speech-language pathology.
260	HHS	CMS	Waiver		Time Period for Initiation of Care Planning and Monthly Physician Visits.	Modifying two requirements related to care planning, specifically: • 42 CFR 494.90(b)(2): CMS is modifying the requirement that requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments. • § 494.90(b)(4): CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, *e.g.,* phone calls, to ensure patient safety.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
261	HHS	CMS	Waiver		Dialysis Home Visits to Assess Adaptation and Home Dialysis Machine Designation.	Waiving the requirement at 42 CFR 494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, referenceQSO–20–19–ESRD.
262	HHS	CMS	Waiver		ICF/IID Suspension of Community Outings.	Waiving the requirements at 42 CFR 483.420(a)(11) which requires clients have the opportunity to participate in social, religious, and community group activities. The federal and/or state emergency restrictions will dictate the level of restriction from the community based on whether it is for social, religious, or medical purposes. States may have also imposed more restrictive limitations. CMS is authorizing the facility to implement social distancing precautions with respect to on and off campus movement. State and Federal restrictive measures should be made in the context of competent, person-centered planning for each client.
263	HHS	CMS	Waiver		ICF/IID Modification of Adult Training Programs and Active Treatment.	CMS is waiving those components of beneficiaries' active treatment programs and training that would violate current state and local requirements for social distancing, staying at home, and traveling for essential services only. For example, although day habilitation programs and supported employment are important opportunities for training and socialization of clients at intermediate care facilities for individuals with developmental disabilities, these programs pose too high of a risk to staff and clients for exposure to a person with suspected or confirmed COVID–19. In accordance with § 483.440(c)(1), any modification to a client's Individual Program Plan (IPP) in response to treatment changes associated with the COVID–19 crisis requires the approval of the interdisciplinary team. For facilities that have interdisciplinary team members who are unavailable due to the COVID–19, CMS would allow for a retroactive review of the IPP under 483.440(f)(2) in order to allow IPPs to receive modifications as necessary based on the impact of the COVID–19 crisis.
264	HHS	CMS	Waiver		Timeframes for Hospice Comprehensive Assessments.	CMS is waiving certain requirements at 42 CFR 418.54 related to updating comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment found at § 418.54(d). Hospices must continue to complete the required assessments and updates; however, the timeframes for updating the assessment may be extended from 15 to 21 days.
265	HHS	CMS	Waiver		Clinical Records for Long-Term Care (LTC) Facilities.	Pursuant to section 1135(b)(5) of the Act, CMS is modifying the requirement at 42 CFR 483.10(g)(2)(ii) which requires long-term care (LTC) facilities to provide a resident a copy of their records within two working days (when requested by the resident). Specifically, CMS is modifying the timeframe requirements to allow LTC facilities ten working days to provide a resident's record rather than two working days.
266	HHS	CMS	Waiver		Clinical Records for HHAs	In accordance with section 1135(b)(5) of the Act, CMS is extending the deadline for completion of the requirement at 42 CFR 484.110(e), which requires HHAs to provide a patient a copy of their medical record at no cost during the next visit or within four business days (when requested by the patient). Specifically, CMS will allow HHAs ten business days to provide a patient's clinical record, instead of four.
267	HHS	CMS	Waiver		Ambulance Services: Medicare Ground Ambulance Data Collection System.	Modifying the data collection period and data reporting period, as defined at 42 CFR § 414.626(a), for ground ambulance organizations (as defined at 42 CFR § 414.605) that were selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2020 and December 31, 2020 (year 1) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626. Under this modification, these ground ambulance organizations can select a new continuous 12-month data collection period that begins between January 1, 2021 and December 31, 2021, collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument during their selected data collection period, and submit a completed Medicare Ground Ambulance Data Collection Instrument during the data reporting period that corresponds to their selected data collection period. CMS is modifying this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020–2021 so that they can focus on their operations and patient care. As a result of this modification, ground ambulance organizations selected for year 1 data collection and reporting will collect and report data during the same period of time that will apply to ground ambulance organizations selected by CMS under 42 CFR § 414.626(c) to collect data beginning between January 1, 2021 and December 31, 2021 (year 2) for purposes of complying with the data reporting requirements described at 42 CFR § 414.626.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
268	HHS	CMS	Waiver		Paid Feeding Assistants for Long-Term Care Facilities (LTCF).	Modifying the requirements at 42 CFR 483.60(h)(1)(i) and 483.160(a) regarding required training of paid feeding assistants. Specifically, CMS is modifying the minimum timeframe requirements in these sections, which require this training to be a minimum of 8 hours. CMS is modifying to allow that the training can be a minimum of 1 hour in length. CMS is not waiving any other requirements under 42 CFR 483.60(h) related to paid feeding assistants or the required training content at 42 CFR 483.160(a)(1)–(8), which contains infection control training and other elements. Additionally, CMS is also not waiving or modifying the requirements at 42 CFR 483.60(h)(2)(i), which requires that a feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).
269	HHS	CMS	Waiver	42 CFR 483.430(e)(1).	ICF/IID Mandatory Training Requirements Suspension.	Waiving, in-part, the requirements at 42 CFR 483.430(e)(1) related to routine staff training programs unrelated to the public health emergency. CMS is not waiving 42 CFR 483.430(e)(2)–(4) which requires focusing on the clients' developmental, behavioral and health needs and being able to demonstrate skills related to interventions for inappropriate behavior and implementing individual plans. We are not waiving these requirements as we believe the staff ability to develop and implement the skills necessary to effectively address clients' developmental, behavioral and health needs are essential functions for an ICF/IID. CMS is also not waiving initial training for new staff hires or training for staff around prevention and care for the infection control of COVID–19. It is critical that new staff gain the necessary skills and understanding of how to effectively perform their role as they work with this complex client population and that staff understand how to prevent and care for clients with COVID–19.
270	HHS	CMS	Waiver		Requirement for Hospices to Use Volunteers.	Waiving the requirement at 42 CFR 418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID–19 surge and potential quarantine.
271	HHS	CMS	Waiver		ICF/IID Staffing Flexibilities	Waiving the requirements at 42 CFR 483.430(c)(4), which requires the facility to provide sufficient Direct Support Staff (DSS) so that Direct Care Staff (DCS) are not required to perform support services that interfere with direct client care. DSS perform activities such as cleaning of the facility, cooking, and laundry services. DSC perform activities such as teaching clients appropriate hygiene, budgeting, or effective communication and socialization skills. During the time of this waiver, DCS may be needed to conduct some of the activities normally performed by the DSS. This will allow facilities to adjust staffing patterns, while maintaining the minimum staffing ratios required at § 483.430(d)(3).
272	HHS	CMS	Waiver		Ambulatory Surgical Center (ASC) Medical Staff.	Waiving the requirement at § 416.45(b) that medical staff privileges must be periodically reappraised, and the scope of procedures performed in the ASC must be periodically reviewed. This will allow for physicians whose privileges will expire to continue practicing at the ambulatory surgical center, without the need for reappraisal, and for ASCs to continue operations without performing these administrative tasks during the PHE. This waiver will improve the ability of ASCs to maintain their current workforce during the PHE.
273	HHS	CMS	Waiver		Sterile Compounding	Waiving requirements (also outlined in USP797) at 42 CFR 482.25(b)(1) and 485.635(a)(3) in order to allow used face masks to be removed and retained in the compounding area to be re-donned and reused during the same work shift in the compounding area only. This will conserve scarce face mask supplies. CMS will not review the use and storage of face masks under these requirements.
274	HHS	CMS	Waiver		Patient Rights	Waiving requirements under 42 CFR 482.13 only for hospitals that are considered to be impacted by a widespread outbreak of COVID–19. Hospitals that are located in a state which has widespread confirmed cases (*i.e.,* 51 or more confirmed cases*) as updated on the CDC website, CDC States Reporting Cases of COVID–19, at *https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html,* would not be required to meet the following requirements: • § 482.13(d)(2)—With respect to timeframes in providing a copy of a medical record. • § 482.13(h)—Related to patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID–19 isolation and quarantine processes. • § 482.13(e)(1)(ii)—Regarding seclusion.
275	HHS	CMS	Waiver		Certification related to Long-Term Care Facilities (Physical Environment).	Waiving requirements related at 42 CFR 483.90, specifically the following: • Provided that the state has approved the location as one that sufficiently addresses safety and comfort for patients and staff, CMS is waiving requirements under § 483.90 to allow for a non-SNF building to be temporarily certified and available for use by a SNF in the event there are needs for isolation processes for COVID–19 positive residents, which may not be feasible in the existing SNF structure to ensure care and services during treatment for COVID–19 are available while protecting other vulnerable adults.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
						• CMS believes this will also provide another measure that will free up inpatient care beds at hospitals for the most acute patients while providing beds for those still in need of care. CMS will waive certain conditions of participation and certification requirements for opening a NF if the state determines there is a need to quickly stand up a temporary COVID–19 isolation and treatment location. • CMS is also waiving requirements under 42 CFR 483.90 to temporarily allow for rooms in a long-term care facility not normally used as a resident's room, to be used to accommodate beds and residents for resident care in emergencies and situations needed to help with surge capacity. Rooms that may be used for this purpose include activity rooms, meeting/conference rooms, dining rooms, or other rooms, as long as residents can be kept safe, comfortable, and other applicable requirements for participation are met. This can be done so long as it is not inconsistent with a state's emergency preparedness or pandemic plan, or as directed by the local or state health department.
276	HHS	CMS	Guidance		Review Choice Demonstration for Home Health Services Claims Processing Requirements.	Effective March 29, 2020, certain claims processing for the Review Choice Demonstration (RCD) for Home Health Services will be paused in Illinois, Ohio, and Texas, until the PHE for the COVID–19 pandemic has ended. During the pause, the MACs will process claims submitted prior to the emergency period under normal claims processing requirements. Claims for home health services furnished on or after March 29, 2020 and before the end of the PHE for the COVID–19 pandemic in these states will not be subject to the review choices made by the home health agency under the demonstration. However, the MAC will continue to review any pre-claim review requests that have already been submitted, and providers may continue to submit new pre-claim review requests for review during the pause. Claims that have received a provisional affirmative pre-claim review decision and are submitted with an affirmed Unique Tracking Number (UTN) will continue to be excluded from future medical review. Home health agencies participating in pre-claim review may submit their claims without requesting such approval from the MAC and claims submitted without a UTN will not be stopped for prepayment review and will not receive a 25% payment reduction. HHAs participating in the other review choices (prepayment or postpayment review) will not receive Additional Documentation Requests (ADRs) during the pause, and ADRs that were issued prior to the PHE will be released and processed as normal. Following the end of the PHE for the COVID–19 pandemic, the MAC will conduct postpayment review on claims subject to the demonstration that were submitted and paid during the pause. The demonstration will not begin in North Carolina and Florida on May 4, 2020, as previously scheduled. CMS will provide notice on its demonstration website rescheduling the start of the demonstration, once the PHE has ended.
277	HHS	CMS	Guidance		Cost and Utilization Management Requirements.	Part D sponsors must suspend all quantity and days' supply limits under 90 days for all covered Part D drugs (as defined in 42 CFR 423.100) other than such limits resulting from safety edits (discussed below). Part D sponsors may otherwise continue to utilize their formularies, tiered cost-sharing benefit structures, and approved prior authorization (PA) and step therapy (ST) requirements. There are no alterations to mid-year formulary change requirements, and we remind sponsors that new drugs may be added and utilization management requirements removed at any time.
278	HHS	CMS	Guidance		Opioid Safety Edits	Part D sponsors are expected to continue to apply existing opioid point-of-sale safety edits during the COVID–19 emergency, including the care coordination edit at 90 morphine milligram equivalents (MME) per day, optional hard edit at 200 MME per day or more, hard edit for seven-day supply limit for initial opioid fills (opioid naïve), soft edit for concurrent opioid and benzodiazepine use, and soft edit for duplicative long-acting (LA) opioid therapy. However, due to the increased burden on the healthcare system as a result of the COVID–19 pandemic, we encourage plans to waive requirements for pharmacist consultation with the prescriber to confirm intent to lessen the administrative burden on prescribers and pharmacists. Additionally, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with any Part D medication delivery documentation and signature log requirements related to these edits during the COVID–19 emergency, as noted above.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
279	HHS	CMS	Guidance		Additional or Expanded Benefit Offerings.	In response to the unique circumstances resulting from the outbreak of COVID–19, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the prohibition on mid-year benefit enhancements (73 **Federal Register** 43628), such as expanded or additional benefits or more generous cost-sharing under the conditions outlined in this memorandum, when such mid-year benefit enhancements are provided in connection with the COVID–19 outbreak, are beneficial to enrollees, and are provided uniformly to all similarly situated enrollees. MAOs may implement additional or expanded benefits that address issues or medical needs raised by the COVID–19 outbreak, such as covering meal delivery or medical transportation services to accommodate the efforts to promote social distancing during the COVID–19 public health emergency. CMS will exercise its enforcement discretion regarding the administration of MAOs' benefit packages as approved by CMS until it is determined that the exercise of this discretion is no longer necessary in conjunction with the COVID–19 outbreak.
280	HHS	CMS	Guidance		Medicare Advantage Cost-Sharing.	MAOs may waive or reduce enrollee cost-sharing for beneficiaries enrolled in their Medicare Advantage plans impacted by the outbreak. For example, Medicare Advantage Organizations may waive or reduce enrollee cost-sharing for COVID–19 treatment, telehealth benefits or other services to address the outbreak provided that Medicare Advantage Organizations waive or reduce cost-sharing for all similarly situated plan enrollees on a uniform basis. CMS clarifies that this flexibility is limited to when a waiver or reduction in cost-sharing can be tied to the COVID–19 outbreak. CMS consulted with the HHS Office of Inspector General (OIG) and HHS OIG advised that should an Medicare Advantage Organization choose to voluntarily waive or reduce enrollee cost-sharing, as approved by CMS herein, such waivers or reductions would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(l).
281	HHS	CMS	Guidance		Telehealth	Medicare Advantage Organizations may also provide enrollees access to Medicare Part B services via telehealth in any geographic area and from a variety of places, including beneficiaries' homes. Should a Medicare Advantage Organization wish to expand coverage of telehealth services beyond those approved by CMS in the plan's benefit package for similarly situated enrollees impacted by the outbreak, CMS will exercise its enforcement discretion regarding the administration of Medicare Advantage Organizations' benefit packages as approved by CMS until it is determined that the exercise of this discretion is no longer necessary in conjunction with the PHE. CMS consulted with the HHS OIG and HHS OIG advised that should a Medicare Advantage Organization choose to expand coverage of telehealth benefits, as approved by CMS herein, such additional coverage would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(l).
282	HHS	CMS	Guidance		Model of Care Flexibility	CMS also recognizes that in light of the COVID–19 outbreak, an MAO with one or more special needs plans (SNPs) may need to implement strategies that do not fully comply with their approved SNP model of care (MOC) in order to provide care to enrollees while ensuring that enrollees and health care providers are also protected from the spread of COVID–19. CMS will consider the special circumstances presented by the COVID–19 outbreak when conducting MOC monitoring or oversight activities.
283	HHS	CMS	Guidance		Involuntary Disenrollment—Temporary Absence Flexibilities.	Due to the public health emergency posed by COVID–19 and the urgent need to ensure that enrollees have continued coverage and access to sufficient health care items and services to meet their medical needs, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement with respect to MA organizations that choose to delay to a later date the involuntary disenrollment of enrollees who are temporarily absent from the service area for greater than 6 months when that absence is due to the COVID–19 national emergency. CMS will not enforce the requirement at § 422.74(d)(4) and will allow MA organizations to extend the period of time members may remain enrolled while temporarily absent from the plan service area through the end of the year, or the end of the public health emergency, whichever is earlier. Individuals who remain absent from the service area will be disenrolled January 1, 2021, if the public health emergency is still in effect at that time, or 6 months after the individual left the service area, whichever is later.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
284	HHS	CMS	Guidance		Involuntary Disenrollment—Loss of Special Needs Status.	Due to the public health emergency posed by COVID–19 and the urgent need to ensure that enrollees have continued coverage and access to sufficient health care items and services to meet their medical needs, CMS will also exercise enforcement discretion during calendar year 2020 to adopt a temporary policy of relaxed enforcement with respect to MA organizations that choose to delay to a later date the involuntary disenrollment of enrollees who are losing special needs status and cannot recertify SNP eligibility due to the COVID–19 national emergency. Under this policy, CMS will also not take action against MA organizations that have a policy of deemed continued eligibility and choose to delay to a later date the involuntary disenrollment of enrollees who fail to regain special needs status during the period of deemed continued eligibility (see § 422.52(d)) due to the COVID–19 national emergency. CMS will not enforce the requirement for mandatory disenrollment at § 422.74(b)(2)(iv) and will allow MA organizations to extend the period of deemed continued eligibility under § 422.52(d) during 2020. Individuals who do not regain eligibility must be disenrolled the later of January 1, 2021, or upon expiration of the usual period of deemed continued eligibility that begins the first of the month following the month in which information regarding the loss is available to the MA organization and communicated to the enrollee, including cases of retroactive Medicaid terminations. SNPs are not required under existing regulations to have a policy of deemed continued eligibility; however, plans must apply the same policy consistently for all enrollees of the applicable SNP. For those SNPs that have elected not to have a policy of deemed continued eligibility, CMS encourages the SNP to consider establishing one. For those plans that have a policy of deemed continued eligibility for a period of less than 6 months, CMS encourages the SNP to increase this to 6 months. SNPs may make these types of changes mid-year as long as the change is applied to everyone in the plan and the plan notifies its CMS account manager.
285	HHS	CMS	Guidance		Prior Authorization	Consistent with flexibilities available to Medicare Advantage Organizations absent a disaster, declaration of a state of emergency, or public health emergency, Medicare Advantage Organizations may choose to waive or relax plan prior authorization requirements at any time in order to facilitate access to services with less burden on beneficiaries, plans, and providers. Any such relaxation or waiver must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency. We encourage plans to consider utilizing this flexibility.
286	HHS	CMS	Guidance		Medicare Advantage Organization (MAO) and Part D Sponsors Additional Flexibilities.	Given both the rapidly changing landscape and the need for Part D sponsors to act quickly to ensure enrollee and employee safety during this pandemic, we encourage Part D sponsors to take the actions you deem reasonable and necessary to keep your enrollees and employees safe and curb the spread of this virus, while still ensuring beneficiary access to needed Part D drugs (example actions listed below). CMS fully supports plans taking actions to accommodate the efforts to promote social distancing. We recognize that there may be circumstances where a Part D sponsor may need to implement strategies or actions they deem reasonable and necessary, but which do not fully comply with program requirements, in order to provide qualified prescription drug coverage to enrollees while ensuring their enrollees and employees are also protected from the spread of COVID–19. CMS will consider the special circumstances presented by the COVID–19 outbreak when conducting monitoring or oversight activities.
287	HHS	CMS	Guidance		Reimbursements for Enrollees for Prescriptions Obtained from Out-of-Network Pharmacies.	Consistent with § 423.124(a) of the Part D regulations, Part D sponsors must ensure enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Enrollees remain responsible for any cost sharing under their plan and additional charges (*i.e.,* the out-of-network pharmacy's usual and customary charge), if any, that exceed the plan allowance.
288	HHS	CMS	Guidance		Prior Authorization for Part D Drugs.	As is the case for Medicare Advantage Organizations, consistent with flexibilities available to Part D Sponsors absent a disaster or emergency, Part D Sponsors may choose to waive prior authorization requirements at any time that they otherwise would apply to Part D drugs used to treat or prevent COVID–19, if or when such drugs are identified. Sponsors can also choose to waive or relax PA requirements at any time for other formulary drugs in order to facilitate access with less burden on beneficiaries, plans, and providers. Any such waiver must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency. We encourage plans to consider utilizing this flexibility.
289	HHS	CMS	Guidance		Drug Shortages	Part D plan sponsors should follow the existing drug shortage guidance in Section 50.13 of Chapter 5 of the Prescription Drug Benefit Manual in response to any shortages that result from this emergency.

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Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
290	HHS	CMS	Guidance		Involuntary Disenrollment—MA and Part D Premium and Grace Period Flexibilities.	To ensure that Medicare Advantage and Part D beneficiaries continue to have access to needed care during the COVID–19 national emergency, CMS would like to remind plans of their ability to apply flexible policies to members who are unable to pay plan premiums. Plans are not required under existing regulations to disenroll members due to failure to pay plan premiums; however, plans must apply the same policy consistently for all enrollees of the applicable plan. For those plans that have elected a policy to disenroll for non-payment of premium, we encourage you to consider changing the policy so that the plan would not disenroll members for non-payment of premium. If a plan chooses not to eliminate its disenrollment policy, we encourage the plan to increase the mandatory grace period (at least two months) to a longer period of time. Plans may make these types of changes mid-year as long as the change is applied to everyone in the plan and the plan notifies its CMS account manager. Detailed information regarding disenrollment and non-payment of premiums requirements are at § 422.74(b)(1)(i) and section 50.3.1 of Chapter 2 of the Medicare Managed Care Manual for MA and at § 423.44(b)(1)(i) and section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D.
291	HHS	CMS	Guidance		MA and Part D Plan Flexibility to Waive Cost Sharing and to Provide Expanded Telehealth Benefits.	MAOs may waive or reduce enrollee cost-sharing for beneficiaries enrolled in their Medicare Advantage plans impacted by the outbreak. For example, Medicare Advantage Organizations may waive or reduce enrollee cost-sharing for COVID–19 treatment, telehealth benefits or other services to address the outbreak provided that Medicare Advantage Organizations waive or reduce cost-sharing for all similarly situated plan enrollees on a uniform basis. CMS clarifies that this flexibility is limited to when a waiver or reduction in cost-sharing can be tied to the COVID–19 outbreak. CMS consulted with the HHS Office of Inspector General (OIG) and HHS OIG advised that should an Medicare Advantage Organization choose to voluntarily waive or reduce enrollee cost-sharing, as approved by CMS herein, such waivers or reductions would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(l).
292	HHS	CMS	Guidance		Coverage of Testing and Testing-Related Services for COVID–19.	Under Section 6003 of the Families First Coronavirus Response Act and Section 3713 of the CARES Act, MAOs must not charge cost sharing (including deductibles, copayments, and coinsurance) for: • Clinical laboratory tests for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 and the administration of such tests; • specified COVID–19 testing-related services (as described in section 1833(cc)(1)) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2); and • COVID–19 vaccines and the administration of such vaccines, as described in section 1861(s)(10)(A). The limit on cost sharing (including deductibles, copayments, and coinsurance) for COVID–19 testing and specified testing-related services applies to services furnished on or after March 18, 2020, and during the emergency period identified in section 1135(g)(1)(B) of the Act (that is, the public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, entitled ''Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus,'' and any extensions thereof) (''applicable emergency period''). In addition, MAOs may not impose any prior authorization or other utilization management requirements with respect to the coverage of these services when those items or services are furnished on or after March 18, 2020, and during the applicable emergency period.
293	HHS	CMS	Waiver		In-Service Training	Modifying the nurse aide training requirements at § 483.95(g)(1) for SNFs and NFs, which requires the nursing assistant to receive at least 12 hours of in-service training annually.
294	HHS	CMS	Waiver		12-hour Annual In-service Training Requirement for Home Health Aides.	Modifying the requirement at 42 CFR 484.80(d) that home health agencies must assure that each home health aide receives 12 hours of in-service training in a 12-month period. In accordance with section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID–19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This will allow aides and the registered nurses (RNs) who teach in-service training to spend more time delivering direct patient care and additional time for staff to complete this requirement.
295	HHS	CMS	Waiver		Annual Training for Hospice Aides.	Modifying the requirement at 42 CFR 418.100(g)(3), which requires hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required. Pursuant to section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID–19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This does not alter the minimum personnel requirements at 42 CFR 418.114. Selected hospice staff must complete training and have their competency evaluated in accordance with unwaived provisions of 42 CFR part 418.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
296	HHS	CMS	Waiver		Training and Assessment of HHA and Hospice Aides.	Waiving the requirement at 42 CFR 418.76(h)(2) for Hospice and 42 CFR 484.80(h)(1)(iii) for HHAs, which require a registered nurse, or in the case of an HHA a registered nurse or other appropriate skilled professional (physical therapist/occupational therapist, speech language pathologist) to make an annual on-site supervisory visit (direct observation) for each aide that provides services on behalf of the agency. In accordance with section 1135(b)(5) of the Act, we are postponing completion of these visits. All postponed onsite assessments must be completed by these professionals no later than 60 days after the expiration of the PHE.
297	HHS	CMS	Guidance	N/A	Repetitive Scheduled Non-Emergent Ambulance Transport Claims Processing Requirements.	Effective March 29, 2020, certain claims processing requirements for the Repetitive, Scheduled Non-Emergent Ambulance Transport Prior Authorization Model will be paused in the model states of Delaware, the District of Columbia, Maryland, New Jersey, North Carolina, Pennsylvania, South Carolina, Virginia, and West Virginia until the PHE for the COVID–19 pandemic has ended. During the pause, claims for repetitive, scheduled non-emergent ambulance transports submitted on or after March 29, 2020, and before the end of the PHE for the COVID–19 pandemic in these states will not be stopped for pre-payment review if prior authorization has not been requested by the fourth round trip in a 30-day period. During the pause, the MAC will continue to review any prior authorization requests that have already been submitted, and ambulance suppliers may continue to submit new prior authorization requests for review during the pause.
298	HHS	CMS	Section 1135 Waiver.	N/A	Temporarily relax provider enrollment requirements.	Allows states to apply for the ability to: Waive payment of application fee to temporarily enroll a provider. Waive criminal background checks associated with temporarily enrolling providers. Waive site visits to temporarily enroll a provider. Permit providers located out-of-state/territory to provide care to an emergency State's Medicaid enrollee and be reimbursed for that service. Streamline provider enrollment requirements when enrolling providers. Postpone deadlines for revalidation of providers who are located in the state or otherwise directly impacted by the emergency. Waive requirements that physicians and other health care professionals be licensed in the state in which they are providing services, so long as they have equivalent licensing in another state. Waive conditions of participation or conditions for coverage for existing providers for facilities for providing services in alternative settings, including using an unlicensed facility, if the provider's licensed facility has been evacuated.
299	HHS	CMS	Section 1135 Waiver.	N/A	Suspend PASRR Assessments	Suspend PASRR Level I and Level II Assessments for 30 Days.
300	HHS	CMS	Section 1135 Waiver.	N/A	Extend Fair Hearing Requests and Appeal Timelines.	Allow managed care enrollees to proceed almost immediately to a state fair hearing without having a managed care plan resolve the appeal first by permitting the state to modify the timeline for managed care plans to resolve appeals to one day so the impacted appeals satisfy the exhaustion requirements. Give enrollees more than 120 days (if a managed care appeal) or more than 90 days (if an eligibility for fee-for-service appeal) to request a state fair hearing by permitting extensions of the deadline for filing those appeals by a set number of days (*e.g.,* an additional 120 days).
301	HHS	CMS	Section 1135 Waiver.	N/A	Temporarily Suspend Medicaid FFS Prior Authorization Requirements.	Suspend Medicaid fee-for-service prior authorization requirements. Section 1135(b)(1)(C) allows for a waiver or modification of pre-approval requirements if prior authorization processes are outlined in detail in the State Plan for particular.
302	HHS	CMS	Section 1135 Waiver.	N/A	Permit Provision of Services in Alternative Settings.	Waive conditions of participation or conditions for coverage for existing providers for facilities for providing services in alternative settings, including using an unlicensed facility, if the provider's licensed facility has been evacuated.
303	HHS	CMS	Section 1135 Waiver.	N/A	Extend Pre-Existing Prior Authorizations through PHE.	Require fee-for-service providers to extend pre-existing authorizations through which a beneficiary has previously received prior authorization through the termination of the emergency declaration.
304	HHS	CMS	Section 1135 Waiver.	N/A	Submission Flexibilities	Grant Flexibility on SPA Submission Deadline, Public Notice and Tribal Consultation.
305	HHS	CMS	Section 1135 Waiver.	N/A	HCBS Flexibilities	Temporarily Allow Beneficiaries to Relocate to Settings Not Meeting HCBS Settings Requirements. Temporarily Eliminate Requirement to Obtain Signatures on HCBS Person-Centered Service Plans.
306	HHS	CMS	Section 1135 Waiver.	N/A	Conflict of Interest Requirements	Waive Conflict of Interest Requirements for Case Management.
307	HHS	CMS	Section 1135 Waiver.	N/A	Provide Additional Benefits and services.	Allows states to add home delivered meals and other services including medical equipment and supplies to their Medicaid program.
308	HHS	CMS	Section 1135 Waiver.	N/A	Modify Licensure or Other Requirements for Wavier Services Settings	
309	HHS	CMS	Section 1135 Waiver.	N/A	Exceed Service Limitations or Requirements for Amount, Duration and Prior Authorization.	Suspend Medicaid fee-for-service prior authorization requirements. Section 1135(b)(1)(C) allows for a waiver or modification of pre-approval requirements if prior authorization processes are outlined in detail in the State Plan for particular benefits. Require fee-for-service providers to extend pre-existing authorizations through which a beneficiary has previously received prior authorization through the termination of the emergency declaration.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
310	HHS	CMS	Section 1135 Waiver.	N/A	Opportunities for Self Direction	This allows states to temporarily add or expand requirements for Medicaid self-direction during the PHE.
311	HHS	CMS	Section 1135 Waiver.	N/A	Increase the Cost Limits	Temporarily Increase the Cost Limits for Entry into the Waiver.
312	HHS	CMS	HCBS Appendix K Waiver.	N/A	Waive Visitors Settings Requirements.	Not comply with the HCBS settings requirement at 42 CFR 441.301(c)(4)(vi)(D) that individuals are able to have visitors of their choosing at any time, for settings added after March 17, 2014, to minimize the spread of infection during the COVID–19 pandemic.
313	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Reassessment and Reevaluation Extensions.	Allow an extension for reassessments and reevaluations for up to one year past the due date.
314	HHS	CMS	HCBS Appendix K Waiver.	N/A	Add Electronic Service Delivery	Add an electronic method of service delivery (*e.g.,* telephonic) allowing services to continue to be provided remotely in the home setting for: Case management; Personal care services that only require verbal cueing; In-home habilitation; Monthly monitoring (*i.e.,* in order to meet the reasonable indication of need for services requirement in 1915(c) waivers); Other [as described]:
315	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Virtual/Remote Evaluations, Assessments and Person-Centered Services Planning.	Allow the option to conduct evaluations, assessments, and person-centered service planning meetings virtually/remotely in lieu of face-to-face meetings.
316	HHS	CMS	HCBS Appendix K Waiver.	N/A	Add Electronic Method for Signing Required Documents.	Add an electronic method of signing off on required documents such as the person-centered service plan.
317	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Spouses and Parents of Minor Children to Provide Services.	Allow spouses and parents of minor children to provide personal care services.
318	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Family Member to Provide Services.	Allow a family member to be paid to render services to an individual.
319	HHS	CMS	HCBS Appendix K Waiver.	N/A	Modify Providers of Home-Delivered Meals.	Modify service providers for home-delivered meals to allow for additional providers, including non-traditional providers.
320	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Other Practitioners to Provide Services.	Allows states to apply for flexibilities like the ability to Allow Other Practitioners to Provide Services and Allow other practitioners in lieu of approved providers within the waiver.
321	HHS	CMS	HCBS Appendix K Waiver.	N/A	Waive Conflict of Interest Requirements for Case Management.	Case management entity qualifies under 42 CFR 441.301(c)(1)(vi) as the only willing and qualified entity.
322	HHS	CMS	HCBS Appendix K Waiver.	N/A	Modify Services	Allows for states to apply to provide additional services such as: Home-delivered meals, medical supplies, equipment and appliances (over and above that which is in the state plan), and assistive technology.
323	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Retainer Payments	Temporarily include retainer payments to address emergency related issues. States must describe the circumstances under which such payments are authorized and applicable limits on their duration. Retainer payments are available for habilitation and personal care only.]
324	HHS	CMS	HCBS Appendix K Waiver.	N/A	Changes to Participant Safeguards.	Postponing 372 Reporting Requirements. Temporarily modify incident reporting requirements, medication management or other participant safeguards to ensure individual health and welfare, and to account for emergency circumstances.
325	HHS	CMS	HCBS Appendix K Waiver.	N/A	Modify Person-Centered Planning Requirements.	Temporarily modify person-centered service plan development process and individual(s) responsible for person-centered service plan development, including qualifications. States must describe any modifications including qualifications of individuals responsible for service plan development, and address Participant Safeguards. Also include strategies to ensure that services are received as authorized.
326	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Payment in Institutional Settings.	Temporarily allow for payment for services for the purpose of supporting waiver participants in an acute care hospital or short-term institutional stay when necessary supports (including communication and intensive personal care) are not available in that setting, or when the individual requires those services for communication and behavioral stabilization, and such services are not covered in such settings.
327	HHS	CMS	HCBS Appendix K Waiver.	N/A	Allow Virtual LOC Determinations.	Temporarily modify processes for level of care evaluations or reevaluations (within regulatory requirements).
328	HHS	CMS	HCBS Appendix K Waiver.	N/A	Increase or Modify Payments Rates.	Temporarily increase payment rates. States provide an explanation for the increase; List the provider types, rates by service, and specify whether this change is based on a rate development method that is different from the current approved waiver. If the rate varies by provider, they list the rate by service and by provider.]
329	HHS	CMS	HCBS Appendix K Waiver.	N/A	Extend Dates for LOC Determinations.	Temporarily modify processes for level of care evaluations or reevaluations (within regulatory requirements.
330	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Adopt Optional COVID–19 Testing Group.	Furnishes medical assistance to the new optional group described at section 1902(a)(10)(A)(ii)(XXIII) and 1902(ss) of the Act providing coverage for uninsured individuals.
331	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Establish Residency for Individuals Temporarily Out of State Due to a Disaster.	Considers individuals who are evacuated from the state, who leave the state for medical reasons related to the disaster or public health emergency, or who are otherwise absent from the state due to the disaster or public health emergency and who intend to return to the state, to continue to be residents of the state under 42 CFR 435.403(j)(3).
332	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Extend PE to non-MAGI Populations.	Allow hospitals to make presumptive eligibility determinations for the following additional state plan populations, or for populations in an approved section 1115 demonstration, in accordance with section 1902(a)(47)(B) of the Act and 42 CFR 435.1110, provided that the agency has determined that the hospital is capable of making such determinations.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
333	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Extend the ROP for good faith effort.	Provides for an extension of the reasonable opportunity period for non-citizens declaring to be in a satisfactory immigration status, if the non-citizen is making a good faith effort to resolve any inconsistences or obtain any necessary documentation, or the agency is unable to complete the verification process within the 90-day reasonable opportunity period due to the disaster or public health emergency.
334	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Establish Income and Resource Disregards for non-MAGI Eligibility Groups.	Agency applies less restrictive financial methodologies to individuals excepted from financial methodologies based on modified adjusted gross income (MAGI).
335	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Designate Other Entities as a Qualified Entity for PE.	Agency designates itself as a qualified entity for purposes of making presumptive eligibility determinations described below in accordance with sections 1920, 1920A, 1920B, and 1920C of the Act and 42 CFR part 435 Subpart L. Also allow the agency to designate the following entities as qualified entities for purposes of making presumptive eligibility determinations or adds additional populations as described below in accordance with sections 1920, 1920A, 1920B, and 1920C of the Act and 42 CFR part 435 Subpart L.
336	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Adopt Continuous Eligibility for Children.	Agency adopts continuous eligibility for children regardless of changes in circumstances in accordance with section 1902(e)(12) of the Act and 42 CFR 435.926.
337	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Extend Residency to Individuals who May be Considered Residents of Other States.	Agency provides Medicaid coverage to the following individuals living in the state, who are non-residents.
338	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Extend the Redetermination Period for Non-MAGI Populations.	Agency conducts redeterminations of eligibility for individuals excepted from MAGI-based financial methodologies under 42 CFR 435.603(j) less frequently (but at least once every 12 months) in accordance with 42 CFR 435.916(b).
339	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Suspend Deductibles, Copayments, Coinsurance and other Cost Sharing Charges.	Agency suspends deductibles, copayments, coinsurance, and other cost sharing charges.
340	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Suspend Enrollment Fees, Premiums and Similar Charges.	Agency suspends enrollment fees, premiums and similar charges.
341	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Add a Variance to the Basic PETI Personal Needs Allowance.	State elects a new variance to the basic personal needs allowance for institutionalized individuals.
342	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Establish an Undue Hardship Waiver for Payment of Enrollment Fees, Premiums and Other Similar Charges.	Agency allows waiver of payment of the enrollment fee, premiums and similar charges for undue hardship.
343	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Adjust Covered Benefits	Give state flexibility to adjust or make changes to the covered benefits under their Medicaid program.
344	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Establish Preferred Drug List Exceptions.	Agency makes exceptions to their published Preferred Drug List if drug shortages occur.
345	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Extend Telehealth Utilization	Agency makes changes to telehealth utilization, which may be different than outlined in the state's approved state plan.
346	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Apply New or Adjusted Benefits to ABPs.	Applies new or adjusted benefits to ABPs.
347	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Compliance with Existing Requirements for New and Adjusted benefits.	Attest to compliance with existing benefit requirements.
348	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Expand Prior Authorization	Prior authorization for medications is expanded by automatic renewal without clinical review, or time/quantity extensions.
349	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Adjust Days' Supply or Quantity Limits.	Agency adjusts day supply or quantity limit for covered outpatient drugs, if current state plan pages have limits on the amount of medication dispensed.
350	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Add New Optional Benefits	Adds optional benefits in its state plan (include service descriptions, provider qualifications, and limitations on amount, duration or scope of the benefit).
351	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Add Temporary Supplemental Payment to the Professional Dispensing Fee.	Agency makes payment adjustment to the professional dispensing fee when additional costs are incurred by the providers for delivery.
352	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Miscellaneous Payment Changes.	Includes supplemental payments—Creating new targeted supplemental payments for hospitals, nursing facilities, and other providers types or modifying existing supplemental payments, such as to accelerate the timing of the payments or to allow for additional flexibility in qualification.
353	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Increase Payment Rates for Current State Plan Services.	Nursing facility rate increases or add-ons—Increases can be per diem dollar increases (ranging from $12 to $40 per day) or percentage increases (ranging from 4% to 30%). Some increases are across-the-board, while others are targeted to residents diagnosed with COVID–19. Other changes involve temporarily modifying existing rate setting methodologies (such as allowing additional costs to be considered), removing certain payment penalties, and setting payments for isolation centers. Telehealth payment—Removing existing state plan language restricting use of telehealth/telephonic delivery of services and paying for such services at either the same face-to-face state plan rates or alternative rates. Supplemental payments—Creating new targeted supplemental payments for hospitals, nursing facilities, and other providers types or modifying existing supplemental payments, such as to accelerate the timing of the payments or to allow for additional flexibility in qualification. Bed hold days—Increasing the number of inpatient facility bed hold days that the state will pay for or removing the limit altogether, subject to certain conditions, such as state pre-authorization for COVID–19-related leave of absences. Laboratory testing—Adding COVID–19 testing codes to state fee schedules and modifying payments of these codes to 100% of Medicare.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
						Hospital rate increases—Increasing hospital payment rates by a certain percentage, ranging from 5–12% increase for general hospital rates to targeting inpatient stays with COVID–19 diagnosis for 20% increase. Various provider rate increases or add-ons—Increasing rates across multiple provider/service types from 5 to 15% to providing increases to multiple provider types based on the hours worked by direct care workers, tiered based on the treatment of COVID–19 patients.
354	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Payments for Telehealth Services.	Removing existing state plan language restricting use of telehealth/telephonic delivery of services and paying for such services at either the same face-to-face state plan rates or alternative rates.
355	HHS	CMS	Medicaid Disaster Relief SPA.	N/A	Establish a Payment Methodology for New Covered Optional Benefits.	Establish payment methodology for newly covered benefits.
356	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Delay Renewal Processing and Deadlines.	At State discretion, requirements related to timely processing of renewals and/or deadlines for families to respond to renewal requests may be temporarily waived for CHIP beneficiaries who reside and/or work in a State or Federally declared disaster area.
357	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Delay Acting on Changes in Circumstance.	At State discretion, the waiting period policy will be temporarily suspended for CHIP applicants and current enrollees who reside and/or work in a State or Federally declared disaster area.
358	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Delay Application Processing	At State discretion, requirements related to timely processing of applications may be temporarily waived for CHIP applicants who reside and/or work in a State or Federally declared disaster area.
359	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Delay Tribal Consultation	To address the COVID–19 public health emergency, the State seeks a waiver under section 1135 of the Act to modify the tribal consultation process by shortening the number of days before submission of the SPA and/or conducting consultation after submission of the SPA.
360	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Waive Cost Sharing	At State discretion, cost sharing may be temporarily waived for CHIP applicants and/or existing beneficiaries who reside and/or work in a State or Federally declared disaster area.
361	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Waive Premiums/Enrollment Fees.	At State discretion, non-payment of premium or enrollment fees may be temporarily forgiven/waived for CHIP applicants and/or existing beneficiaries who reside and/or work in a State or Federally declared disaster area.
362	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Waive Premium Lock-Out Policy	At State discretion, the premium lock-out policy is temporarily suspended and coverage is available regardless of whether the family has paid their outstanding premium for existing beneficiaries who reside and/or work in a State or Federally declared disaster area.
363	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Extend the ROP for Good Faith Effort.	At State discretion, the agency may provide for an extension of the reasonable opportunity period for non-citizens declaring to be in a satisfactory immigration status, if the non-citizen is making a good faith effort to resolve any inconsistences or obtain any necessary documentation, or the agency is unable to complete the verification process within the 90-day reasonable opportunity period due to the State or Federally declared disaster or public health emergency.
364	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Institute More Frequent PE Periods.	At State discretion, the presumptive eligibility period will be extended to (insert State specific timeframe) for CHIP applicants and current enrollees who reside and/or work in a State or Federally declared disaster area.
365	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Extend Premium Deadlines	At State discretion, families may temporarily be given additional time to pay their premiums for existing beneficiaries who reside and/or work in a State or Federally declared disaster are a.
366	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Provide 12-Month Continuous Eligibility.	At State discretion, it may temporarily provide continuous eligibility to CHIP enrollees who reside and/or work in a State or Federally declared disaster area.
367	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Allow Phone Triage for Dental Services.	At State discretion, it may temporarily use a simplified application for CHIP enrollees who reside and/or work in a State or Federally declared disaster area.
368	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Provide Additional Benefits	At State discretion, requirements related to timely processing of renewals and/or deadlines for families to respond to renewal requests may be temporarily waived for CHIP beneficiaries who reside and/or work in a State or Federally declared disaster area.
369	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Waive Affordability Test and Private Insurance Lookback.	At State discretion, premiums or enrollment fees and co-payments may be temporarily waived for CHIP applicants and/or existing beneficiaries who reside and/or work in a State or Federally declared disaster area.
370	HHS	CMS	CHIP Disaster Relief SPA.	N/A	Add More Qualified Entities to Make PE Determinations.	At State discretion, non-payment of premium or enrollment fees may be temporarily forgiven/waived for CHIP applicants and/or existing beneficiaries who reside and/or work in a State or Federally declared disaster area.
371	HHS	CMS	Other regulatory action.	N/A	Payment and Grace Period Flexibilities Associated with the COVID–19 National Emergency.	Announces enforcement discretion to permit issuers that offer coverage through HealthCare.gov to extend premium payment deadlines and delay cancellation for non-payment of premiums.
372	HHS	CMS	Guidance	N/A	FAQs on Catastrophic Plan Coverage and COVID–19.	Announces enforcement discretion to permit issuers to amend their catastrophic plans to provide coverage without imposing cost-sharing requirements for COVID–19 related services before an enrollee meets the catastrophic plan's deductible.
373	HHS	CMS	Other regulatory action.	N/A	Postponement of 2019 Benefit year HHS-operated Risk Adjustment Data Validation (HHS–RADV).	Announces temporarily policy of relaxed enforcement to postpone issuer requirements related to the 2019 benefit year HHS–RADV process, delaying the timeline for release of 2019 benefit year HHS–RADV error rates, as well as the publication of 2019 benefit year HHS–RADV results to issuers.

ATTACHMENT A—Continued

Action	Agency	Sub-agency	Type of action	RIN (if applicable)	Title of action	Brief summary of action
374	HHS	CMS	Other regulatory action.	N/A	Risk Adjustment Telehealth and Telephone Services During COVID–19 FAQs.	Provides clarification that telephonic codes will be valid for 2020 benefit year risk adjustment data submissions for the HHS-operated risk adjustment program.
375	HHS	CMS	Other regulatory action.	N/A	Temporary Period of Relaxed Enforcement for Submitting the 2019 MLR Annual Reporting Form and Issuing MLR Rebates in Response to the COVID–19 Public Health Emergency.	Announces temporary policy of relaxed enforcement with respect to the regulatory timeframe for issuers to submit the 2019 MLR Annual Reporting Form and for issuers that elect to pay a portion or all of their estimated 2019 MLR rebates in the form of premium credits.
376	HHS	CMS	Other regulatory action.	N/A	Temporary Period of Relaxed Enforcement of Certain Timeframes Related to Group Market Requirements Under the Public Health Service Act in Response to the COVID–19 Outbreak.	The Departments of Labor and the Treasury released a joint **Federal Register** Notice providing relief from certain timing requirements under ERISA and the Code that affect private employer group health plans, and their participants and beneficiaries in response to the COVID–19 PHE. This guidance announces a temporary policy of relaxed enforcement to extend similar time frames otherwise applicable to non-Federal governmental group health plans and health insurance issuers offering coverage in connection with a group health plan, and their participants and beneficiaries.
377	HHS	CMS	Other regulatory action.	N/A	Temporary Policy on 2020 Premium Credits Associated with the COVID–19 Public Health Emergency.	Announces temporary policy of relaxed enforcement to allow health insurance issuers in the individual and small group markets to temporarily offer premium credits for 2020 coverage.
378	HHS	CMS	Other regulatory action.	N/A	TDL	On March 30 CMS suspended most Medicare Fee-For-Service (FFS) medical review because of the COVID–19 pandemic. This included pre-payment medical reviews conducted by Medicare Administrative Contractors (MACs) under the Targeted Probe and Educate program, and post-payment reviews conducted by the MACs, Supplemental Medical Review Contractor (SMRC) reviews and Recovery Audit Contractor (RAC).
379	HHS	CMS	Other regulatory action.		Prior Authorization for Certain DMEPOS items.	Effective March 29. 2020, certain claims processing requirements were paused for power mobility devices and pressure reducing support surfaces that required prior authorization. During this pause, claims for these items would not be denied for failing to obtain a provisional affirmation prior authorization decision. Additionally, CMS delayed the implementation of prior authorization for certain lower limb prosthetic codes. Prior to the COVID–19 PHE, CMS had announced that prior authorization for the specified LLPs would be required in California, Michigan, Pennsylvania, and Texas beginning May 11, 2020 and the remaining states beginning October 8, 2020.
380	HHS	CMS	Other regulatory action.		Opt-Out Physicians and Practitioners.	42 CFR 405.445. Allow opted-out physicians and non-physician practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.
381	HHS	CMS	Waiver		Medicaid Provider Enrollment Relief.	42 CFR 455.414, 42 CFR 455.432, 42 CFR 455.434, 42 CFR 455.460 42 CFR 455.436. Exercise 1135 waiver authority to allow providers to enroll and receive temporary Medicaid billing privileges using an abbreviated enrollment process; waive certain screening and enrollment requirements for temporary billing privileges established on all enrollment applications received on or after March 1, 2020 including collection of the application fee, site visits, and fingerprinting for ''moderate'' and ''high'' risk provider types; continue to require screening against HHS OIG exclusion list and Death Master File to ensure provider is not excluded or deceased; provided states with the ability to postpone all revalidation actions.
382	HHS	CMS	Waiver		Medicare Provider Medicare Provider Enrollment Relief: DME Suppliers 42 CFR 424.57.	Waive several DME supplier standards, including supplier standard 7 that requires facility access/maintaining a facility. Waive DME accreditation (at initial enrollment and re-accreditation requirement.

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