ISSUE BRIEF
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Regulatory Changes to Medicare in Response to COVID-19

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ABSTRACT

ISSUE: The COVID-19 pandemic prompted Congress and the Trump administration to rapidly waive or change existing Medicare regulations, providing unprecedented flexibility to help health care providers, Medicare Advantage plans, and Part D plans respond to the public health emergency.

GOALS: Track and categorize these regulatory changes, describe the benefits and risks of the changes, and describe the possible effects on the Medicare program if the temporary policies are made permanent.

METHODS: Analysis of COVID-19-related legislative, regulatory, and subregulatory changes to existing Medicare regulations issued January 1, 2020, through July 24, 2020.

KEY FINDINGS: Congress and the administration modified 212 policies. The majority of changes addressed Medicare's conditions of participation for health care providers (55) and hospital regulation and financing (60). About two-thirds of the policies were implemented under 1135 waiver authority (137), and most are expected to expire in the future (203).

CONCLUSION: Many important, long-standing beneficiary protections and controls to reduce inappropriate Medicare spending have been temporarily waived by extensive regulatory changes. Any changes considered for extension should be studied to assess their long-term benefits and potential consequences. The effects of these policies should also be studied to determine what actions should be immediately taken to respond to future public health emergencies.

TOPLINES

- The COVID-19 pandemic prompted Congress and the Trump administration to make unprecedented changes to existing Medicare regulations.
- Policymakers and stakeholders need to carefully weigh the benefits and unintended consequences of changes to Medicare with respect to Medicare spending, patients' access to care, and providers' ability to provide high-quality care.

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INTRODUCTION

As the COVID-19 pandemic started to spread, Congress and the Trump administration responded with a series of legislative, regulatory, and subregulatory changes to the Medicare program that were designed to provide relief from certain Medicare rules in order to assist health care providers, Medicare Advantage organizations, and Part D plans in responding to the pandemic. Some of these changes waived conditions of Medicare participation to enable patients to be treated in alternative care settings. Other changes permitted physicians and other providers to receive Medicare reimbursements for telemedicine services.

Between January 1 and July 24, 2020, over 200 Medicare legislative and regulatory changes were made in response to COVID-19 (Exhibit 1). In addition, the Centers for Medicare & Medicaid Services (CMS) has issued subregulatory guidance on a near-weekly basis during this time to provide additional flexibility to providers and Medicare plans.

KEY COVID-19-RELATED CHANGES

Medicare reimbursement for telehealth is temporarily permitted for more types of clinicians and services, including:

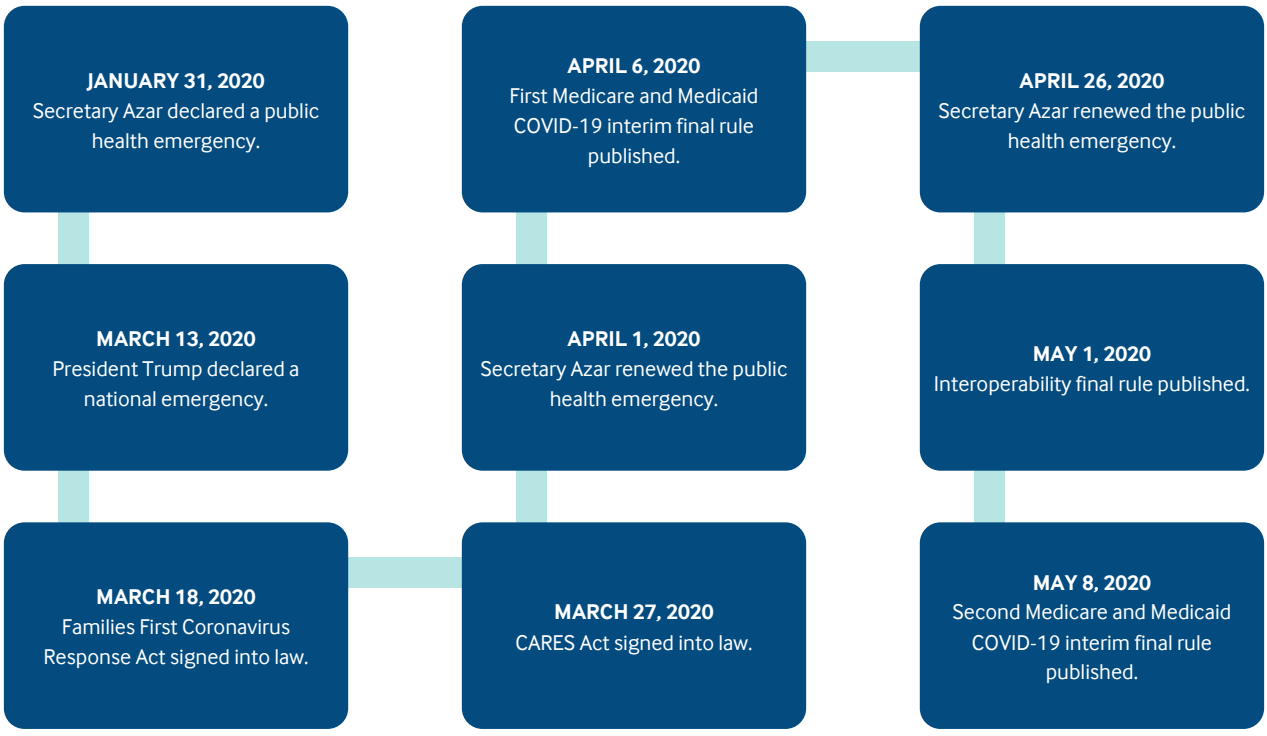
- Telephone visits
- Physician supervision services
- Urban and rural areas
- New sites, including patients' homes.

Hospitals can temporarily provide services in alternative care sites, including:

- Other health care facilities
- Expansion sites (such as hotels or community facilities)
- Patients' homes (for some services).

Licensed providers can temporarily provide services outside of their state of enrollment.

Exhibit 1. Timeline of Major Medicare COVID-19-Related Legislative and Regulatory Changes



HHS'S AND CMS'S REGULATORY AUTHORITY

Section 1135 of the Social Security Act (SSA) is the foundation of the Department of Health and Human Services' (HHS's) legal authority for responding to public health emergencies.[1] Section 1135 waivers require both a declaration of national emergency or disaster by the president and a public health emergency determination by the HHS secretary.[2] President Trump declared a national emergency on March 13, 2020, effective March 1, 2020.[3] HHS Secretary Azar declared a public health emergency on January 31, 2020, effective January 27, 2020.[4]

Under SSA Section 1135, the Secretary can temporarily waive or modify certain Medicare, Medicaid, Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA) requirements.[5] The Secretary cannot waive Medicare coverage or payment rules, but some of the permitted waivers or modifications may have an indirect effect on the application of Medicare fee-for-service coverage or payment rules.[6]

In addition to the 1135 waivers, HHS and the Centers for Medicare and Medicaid Services (CMS) exercised 1812(f) and 1877(g) waivers and agency authority to waive or modify policy or procedural norms (for example, expediting enrollment applications, adjusting timelines or requirements for Innovation Center models). [7] CMS has also announced that the agency will exercise its discretion to refrain temporarily from enforcing certain regulatory requirements during the emergency.

CMS also released two interim final rules with comment periods to make policy and regulatory revisions to the Medicare program (and other programs) in response to the COVID-19 public health emergency (Exhibit 1).

Health Management Associates (HMA) catalogued the array of COVID-19-related regulatory changes during this time period and categorized them according to their characteristics, including types of providers and plans affected, effective date, and expected duration. This information is available in the companion policy tracker, which will be periodically updated.

KEY FINDINGS

Our analysis found that actions taken by Congress and the administration in response to the COVID-19 pandemic affected virtually all types of health care providers and health plans that participate in the Medicare program (Exhibit 2). To date, efforts have been concentrated on hospital providers, accounting for 60 of the 212 policy actions.

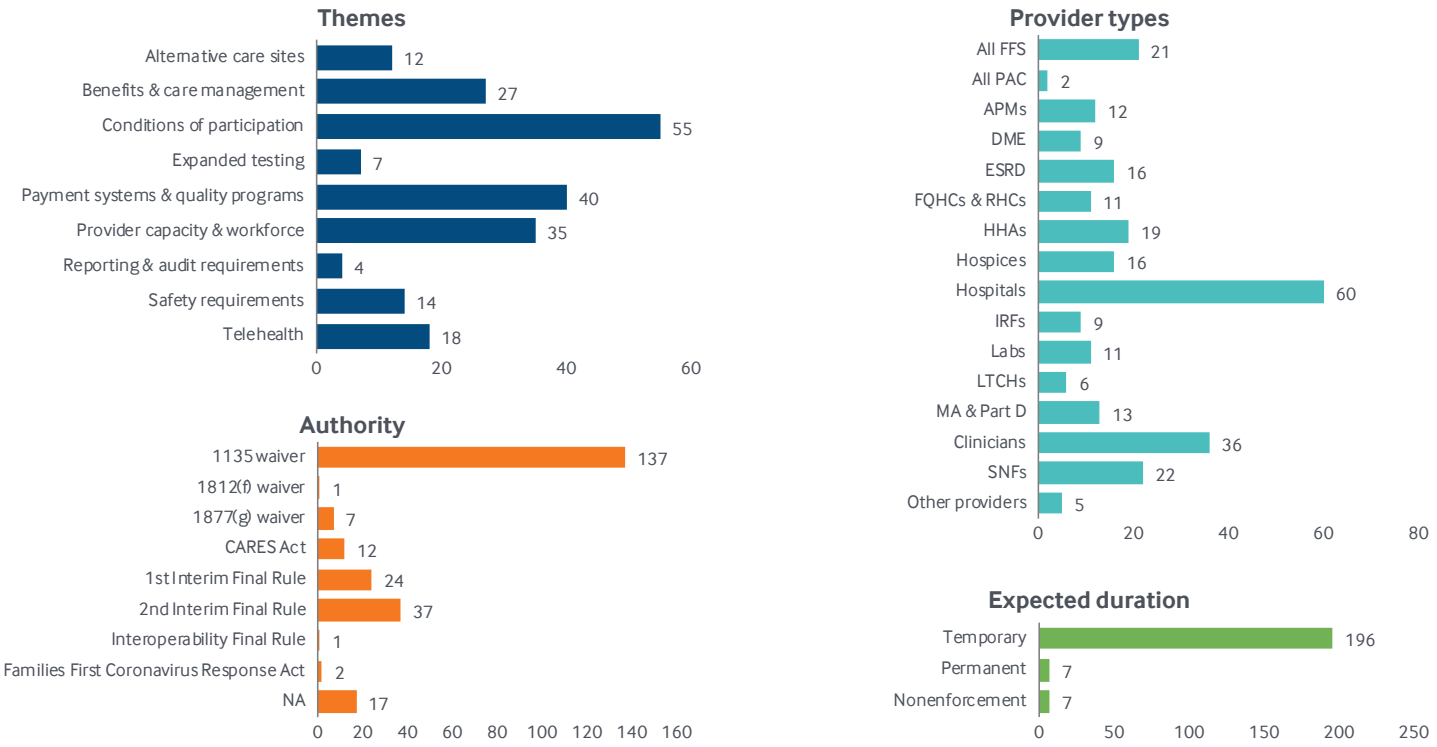
We organized the policies into nine themes. According to our categorization, actions taken by Congress and the administration primarily addressed conditions of participation requirements for Medicare providers (55). The next most common themes were payment systems and quality programs (40) and provider capacity and workforce (35).

Nearly all these policy actions (203) are currently expected to be temporary (Exhibit 2), absent further Congressional or administration action. Seven of the actions were not direct changes to or waivers of regulations; instead CMS indicated that, for a limited time, it would not enforce the existing regulations.

Most policies (145) were implemented through HHS's various waiver authorities (Exhibit 2). CMS implemented 61 changes through two interim final rules with comment periods.

Most, but not all, of the changes included an indication of the effective date and end date. Most of the changes (179) went into effect sometime during March and many (130) are expected to be in effect through the duration of the public health emergency.[8]

Exhibit 2. Characteristics of COVID-19-Related Regulatory Changes



Note: There were 212 total regulatory changes. The number of changes by provider type and authority is greater than the total number of regulatory changes because each change could affect more than one type of provider and be included in more than one change action. "Nonenforcement" changes are those where CMS indicated that the agency was not changing existing regulations but would temporarily cease to enforce the regulations.

*Abbreviations (alphabetical order): alternative payment model (APM), durable medical equipment (DME), end-stage renal disease (ESRD), federal qualified health centers (FQHCs), fee-for-service (FFS), home health agency (HHA), inpatient rehabilitation facility (IRF), long-term care hospital (LTCH), Medicare Advantage (MA), post-acute care (PAC), rural health clinic (RHC), and skilled nursing facility (SNF).

DISCUSSION

Since the COVID-19-related changes have been in effect for several months, key questions include:

1. How were the regulatory changes designed to help the health care system respond to the current public health emergency?
2. What are the potential positive and negative impacts of these regulatory changes on Medicare beneficiaries' access to care?
3. What was the purpose of the existing, pre-COVID Medicare regulations?
4. If the temporary COVID-19-related regulatory changes become permanent, how can the public have meaningful input on the potential positive and negative consequences?

The nine themes that HMA assigned to each of the regulatory changes help to address the first question. In general, the regulatory changes were designed to assist health care systems in testing and treating a surge of COVID-19 patients and in enabling health care providers to continue treating Medicare patients under social distancing requirements. With more than 200 individual regulatory changes, there is a wide range of specific intended benefits (Exhibit 3).

Most changes to Medicare regulations bring both potential positive and negative impacts for Medicare beneficiaries and the health care systems that provide care to them. In response to the second question, Exhibit 3 highlights some potential positive and negative impacts for Medicare beneficiaries. For example, even highly necessary and appropriate changes, like increased COVID-19 testing, come with potential drawbacks for

Exhibit 3. Summary of COVID-19-Related Regulatory Change Themes

Theme	Purpose of existing regulations	Intended benefit of changes	Potential impact on beneficiaries
Alternative care sites	Set payment rates and clinical requirements for different facility types based on their unique features	Ensure capacity to handle a potential surge of COVID-19 patients through temporary expansion sites	**Pro:** Provides more choice in sites to access care **Con:** Patients may not know facility and may be surprised by billing and cost-sharing rates
Benefits and care management	Ensure that beneficiaries have access to certain items and services and quality of care from Medicare providers, facilities, and plans	Cover new services, modify requirements for services, remove prior authorization requirements, and ease requirements for patient assessments and care plans	**Pro:** Easier access is given to prescription drugs and testing **Con:** Some patient rights are curtailed, and there is a risk of reduced quality of care
Conditions of participation	Define facility types by characteristics and ensure that providers comply with measures to protect patients and program spending	Ease or waive requirements providers must meet to participate in Medicare	**Pro:** Access to providers is maintained or expanded **Con:** Increases risk of reduced quality and risk of fraud, waste, and abuse
Expanded testing	Not applicable	Enable more COVID-19 testing at more locations	**Pro:** Provides more access to testing **Con:** Increases risk of surprise billing and cost sharing
Payment systems and quality programs	Ensure that Medicare pays providers appropriately; deters fraud, abuse, and overuse; and incentivizes payment systems to reward value	Waive some payment system and quality requirements to maintain or increase provider payments	**Pro:** Maintained or expanded access to providers **Con:** Increases risk of reduced quality of care and higher cost-sharing
Provider capacity and workforce	Limit the provision of some services to certain types of providers	Remove scope-of-practice and other barriers for clinicians to treat patients	**Pro:** Maintained or expanded access to providers **Con:** Increases risk of reduced quality of care
Reporting and audit requirements	Collect information to improve Medicare program and deter fraud, abuse, and overuse	Limit collection of some information and pause audit activity	**Pro:** New reporting will yield more information **Con:** Reporting cuts will yield less information
Safety requirements	Protect patients from serious harm (for example, fires, health care–acquired infections)	Temporarily suspend some safety requirements to reduce provider responsibility and facility traffic	**Pro:** Provides potential for facilities to focus more on COVID-19 **Con:** Increases risks to patient safety
Telehealth	Limit use of telehealth to services that may be better suited to the technology and deter fraud, abuse, and overuse	Increase use of telehealth for clinicians to provide services and supervision	**Pro:** Maintained or expanded provider access; no exposure to risk of COVID-19 infection **Con:** Increases potential of reduced quality, surprise billing, and cost-sharing

Note: This table summarizes characteristics that are generally shared across changes within each theme category. For more information on individual changes, see the companion policy tracker.

beneficiaries, such as the risk of surprise billing and high cost-sharing amounts.

As to the third question, Exhibit 3 indicates that existing Medicare regulations that have been temporarily or permanently waived by COVID-19-related changes fulfill critical public policy purposes for the program, such as:

- ensuring that beneficiaries have access to certain items and services
- ensuring that providers comply with measures to protect patients
- deterring fraud, abuse, and overuse
- protecting patients from serious harm.

It is also important to note that Medicare regulations, under normal circumstances, go into effect only after going through an established notice-and-comment rulemaking process, which enables stakeholders to raise questions and provide input that the agency can use to determine the best course of action. HHS and CMS may waive or modify this process if they can demonstrate good cause, such as public emergencies.

While the majority of COVID-19-related regulatory changes were declared to be temporary when they were announced, the administration has indicated plans to make some permanent.[9] Changes that have proved popular with providers and patients are likely candidates, such as expanded reimbursement for telemedicine services. Stakeholders have expressed eagerness to learn which changes may become permanent, and the administration has taken actions to gather input on these decisions. On June 23, 2020, CMS announced the creation of a new division in the agency, the Office of Burden Reduction and Health Informatics, which is tasked with continuing "to explore innovative ways to address regulatory reform and burden reduction."[10]

It may be necessary to let certain temporary waivers expire, possibly even before conclusion of the public health emergency if the continued threat of possible patient harm outweighs the potential benefits of the policy waiver, such as reducing the overall number of people coming through health care facilities. For example, policymakers may need to significantly limit the duration of the waivers related to on-time preventive maintenance of dialysis machines and scheduled fire inspections.

To answer the fourth question, it will be essential to make use of the unique opportunity presented by the temporary policy changes to study their impact, especially any unintended consequences. These analyses should compare the trade-offs in positive and negative consequences for beneficiaries (including populations such as dual-eligibles), providers, and taxpayers. The analytic results, along with stakeholder comments, should be part of regular notice-and-comment rulemaking to determine which regulatory changes should be made permanent.

CONCLUSION

In response to the COVID-19 public health emergency, Congress and the Trump administration made an unprecedented number of legislative, regulatory, and subregulatory changes to the Medicare program. While these policy actions were designed to address urgent concerns — protecting beneficiaries' access to care through use of alternative care settings and Medicare-reimbursed telemedicine services, as well as supporting provider and health plan responses through temporary relief from certain requirements — the actions come with the risk of negative outcomes. Those risks include trading the important, long-standing beneficiary protections and Medicare spending controls included in the original regulations for policies that may, on balance, prove less preferable.

As the COVID-19 pandemic continues, policymakers and stakeholders should carefully assess both the benefits and unintended consequences of these policy actions for patients' access to care and the ability of providers to provide high-quality care. The analyses and stakeholder input should inform the regular notice-and-comment rulemaking process to ensure that any permanent regulatory changes improve the Medicare program. In addition, the effects of these policies should be carefully studied to help determine the best way to prepare for future public health emergencies.

HOW THIS STUDY WAS CONDUCTED

Health Management Associates reviewed the COVID-19-related legislative, regulatory, and subregulatory changes to the Medicare program that occurred between January 1, 2020, and July 24, 2020. We catalogued these changes and categorized them according to their characteristics, including types of providers and plans affected, effective date, and expected duration. This information is available in the companion policy tracker.

NOTES

1. "Public Health Emergency: Legal Authority," U.S. Department of Health and Human Services, September 18, 2019; "Public Health Emergency: Waiver or Modification of Requirements Under Section 1135 of the Social Security Act," U.S. Department of Health and Human Services, March 13, 2020.

2. "Emergency Authority and Immunity Toolkit: Waiver Authority in National Emergencies," Association of State and Territorial Health Officials, May 2013.

3. National emergencies remain in effect for one year unless ended sooner by Congress or the administration.

4. Public health emergencies remain in effect for 90 days. The HHS Secretary most recently renewed the public health emergency on July 23, 2020, effective July 25, 2020. https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx

5. Association of State and Territorial Health Officials, "Emergency Authority and Immunity Toolkit: Waiver Authority in National Emergencies."

6. Centers for Medicare and Medicaid Services, *Medicare Fee-for-Service: Additional Emergency and Disaster-Related Policies and Procedures That May Be Implemented Only with a § 1135 Waiver*, (CMS, March 15, 2019).

7. Centers for Medicare and Medicaid Services, "Coronavirus Waivers & Flexibilities," July 15, 2020; Centers for Medicare and Medicaid Services, "Physician Self-Referral: Spotlight," July 20, 2020; Centers for Medicare and Medicaid Services, "Waivers & Flexibilities," January 17, 2020; Centers for Medicare and Medicaid Services, "Medicare Fee-for-Service: Emergency-Related Policies and Procedures That May Be Implemented Without § 1135 Waivers," March 15, 2019.

8. There were instances where the same change was associated with different effective dates. For example, one end date was indicated in the Coronavirus Aid, Relief, and Economic Security (CARES) Act and another in the interim final rule with comment period.

9. Jessica Kim Cohen, "CMS to Use 'Glide Path' When Removing COVID-19 Waivers," *Modern Healthcare*, June 8, 2020. On August 3, 2020, CMS issued a proposed physician fee schedule rule that solicits comments on extending or making permanent several of the temporary Medicare changes made in response to COVID-19, including telehealth, scope of practice, direct supervision, medical record sign-off, and other provisions.

10. Centers for Medicare and Medicaid Services, "CMS Unveils Major Organizational Change to Reduce Provider and Clinician Burden and Improve Patient Outcomes," June 23, 2020.

ABOUT THE AUTHORS

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