Every year the Centers for Medicare & Medicaid Services (CMS) publishes numerous regulations that influence health care delivery and are important to clinicians, health care organizations, suppliers, and beneficiaries across the US. The regulations strive to create transparent rules for more than 17 different types of health care organizations and suppliers to participate in and get paid by Medicare. Understanding stakeholder perspectives is critical to developing the policies established in these rules. This article describes processes that CMS uses to develop regulations, in particular, the requirements for participating in the program; reviews the tools available to CMS during times of emergency; and highlights the opportunity for interested persons or groups to help shape the direction of health care.

Regulations establishing requirements for participation in the Medicare program, a subset of the greater body of regulations developed by CMS, are complex. These regulations often tackle challenging issues for which there are divergent viewpoints, evolving data, and no perfect answer. Tasked with creating policies through notice and comment rulemaking, CMS must consider multiple competing priorities and perspectives and the available scientific evidence and data. A recent example is the Organ Procurement Organizations Final Rule issued in December 2020. The final rule revised these organizations’ conditions for coverage to increase organ donation and transplantation rates by replacing current outcome measures with new ones designed to be transparent, reliable, and objective, and by increasing competition for open donation service areas. The proposed rule, published in December 2019, received more than 800 public comments that CMS considered when finalizing the rule. Divergent views across stakeholders underscored the delicate balance CMS needed to achieve in the final rule.

The CMS has the flexibility to respond to national, state, and local disasters, such as hurricanes, wildfires, and the COVID-19 pandemic. The US Congress established emergency authorities that allow CMS to modify regulatory requirements quickly when it finds “good cause” that the notice and comment rulemaking process before adoption of a rule would be “impracticable, unnecessary, or contrary to the public interest.” During the pandemic, CMS used this authority to create flexibilities, which facilitated a focus on delivering safe and effective care to patients.

The most recent example of CMS using its emergency rulemaking authority is the 2020 response to the COVID-19 Public Health Emergency (PHE). To address urgent nationwide needs, CMS issued several Interim Final Rules with Comment Period (IFCs) and many waivers. The IFCs follow a different process from notice and comment rulemaking because of the need to rapidly implement regulations in emergency situations. Several IFCs were needed to address the public health crisis associated with the rapid transmission and virulence of SARS-CoV-2. Given the circumstances, CMS established or modified requirements that went into effect immediately, such as expanding the number of telehealth services available to Medicare beneficiaries to support them safely in their homes.

In addition, CMS has the authority to waive certain statutory and regulatory standards during the pandemic or in other local, regional, and national public health emergencies. When the President declares a disaster or emergency, or the Secretary of the US Department of Health and Human Services declares a public health emergency, the Secretary is authorized to take actions under Section 1135 of the Social Security Act, including temporarily waiving or modifying certain Medicare, Medicaid, and Children’s Health Insurance Program requirements.
Waivers may be issued to a specific organization or as blanket waivers when the Secretary determines that similarly situated organizations, such as all hospitals, in the emergency area need relief from certain CMS requirements to ensure sufficient health care services and supplies are available to meet the needs of beneficiaries. This authority has been used during the COVID-19 PHE to grant flexibility as health care organizations coped with the PHE. Examples include waivers to augment the health care workforce by allowing health care professionals to work to the top of their license and by allowing temporary expansion sites of care. While the flexibilities created by waiver generally cease when the emergency ends, their use creates opportunities for all stakeholders to engage with CMS and to contribute feedback to inform future action.

To permanently adopt any changes that were implemented through an IFC or allowed by an 1135 waiver, if doing so is permissible by law, CMS is required to go through the notice and comment rulemaking process. With an IFC, this means reviewing the public comments received in response to the IFC and developing and issuing a final rule that responds to these comments. To permanently incorporate a flexibility that was initially provided by a waiver and is not otherwise prohibited by law, CMS must also complete notice and comment rulemaking. First, CMS develops and publishes a proposed rule that outlines the standards it wants to establish or revise; then CMS must obtain public comment on the proposal and develop and publish a final rule that responds to those comments, thereby putting the final requirements into effect. The comment period for a proposed rule is the public’s opportunity to provide input on CMS regulatory proposals.

When CMS reviews existing regulations or temporary regulatory flexibilities to potentially make them permanent, it considers current evidence and standards for safe and effective service delivery and opportunities to remove policies that may not reflect current practice. This responsibility—to hold health care organizations accountable for keeping beneficiaries safe—is taken very seriously by CMS, while also endeavoring to minimize burden.

When a regulation is proposed, it is published in the Federal Register, which affords an opportunity for public input on the proposal’s provisions. All comments are welcomed by CMS, including simple ones in support or opposition to a proposed regulation. It also strongly encourages detailed comments that provide more extensive discussions of pros, cons, alternatives, implications, and challenges associated with implementation and relevant evidence, including anecdotal information and detailed analyses. Comments that explain a proposal’s unintended consequences, suggest alternatives to the proposal, explain why an alternative may work better, or present other data that CMS should consider are often extremely helpful. After the comment period closes, CMS decides whether and how to finalize the proposals. All of the comments, evidence, and information provided by stakeholders is reviewed by CMS as part of its decision-making process. Finalized requirements and responses to comments are also published in the Federal Register as a final rule and become part of the official rules governing Medicare.

The CMS strives to establish requirements that promote quality and safety at a national level while allowing innovation. Rulemaking and other flexibilities can serve as a valuable lever during a public health crisis to relieve pressure within the health care system and equip health care organizations with the agility needed to promote patient safety and quality outcomes. Commenting on proposed regulations is a key opportunity for interested persons or groups to help shape the direction of Medicare and other federal health programs.
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REFERENCES


