



September 16, 2020

VIA ELECTRONIC SUBMISSION

Office of the Secretary
Department of Health and Human Services

Attention: RIN 0991-AC 17
Department of Health and Human Services Good Guidance Practices

Dear Sir or Madam:

Thank you for the opportunity to comment on proposed regulations RIN 0991-AC-17, "Department of Health and Human Services Good Guidance Practices." We believe that these proposed regulations should be withdrawn and reissued as explained below.

The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005 with a mission to expand and improve high-quality, affordable health coverage for America's children and families. As part of the McCourt School of Public Policy, Georgetown CCF conducts research, develops strategies, and offers solutions to improve the health of America's children and families, particularly those with low and moderate incomes. In particular, CCF examines policy development and implementation efforts related to Medicaid, the Children's Health Insurance Program (CHIP) and the Affordable Care Act.

The proposed regulations should be withdrawn and reissued with sufficient information to enable effective comment. The proposed regulations do little more than mirror the Executive Order pursuant to which they are issued, without explaining how the central term "guidance document" would apply in the context of Medicaid, CHIP, and the other programs administered by the Centers for Medicare & Medicaid Services (CMS). Without knowing what letters, memoranda, circulars, bulletins, advisories, preambles, slide decks, and other documents would be considered "guidance documents" and therefore subject to the new processes the proposed regulations would establish, it is impossible for us or other members of the public to comment effectively on the proposed changes.

In addition, the notice of the proposed regulations, 85 FR 51396 (August 20, 2020) allows only 27 days (including the Labor Day national holiday), and only 21 days from the date of publication of the notice of correction, 85 FR 52515 (August 26, 2020) for the public to comment. This is completely inadequate. Given the number of Americans covered by

Medicaid and CHIP, and the importance of administering these programs efficiently, upon reissuance of the proposed regulations, the Department should allow a minimum of 60 days (without an intervening National Holiday) for public comment.

The Notice of Proposed Rulemaking fails to explain how the proposed regulations would affect the administration of Medicaid and CHIP

Medicaid and CHIP are the source of health insurance coverage for 36 million children. How effectively the Department and the states administer these programs matters enormously to the health and well-being of these children. Since the beginnings of Medicaid over half a century ago, the Department has used subregulatory guidance to help it and the states administer the program. This guidance has taken many forms: State Medicaid Director Letters, State Health Official Letters, Informational Bulletins, Frequently Asked Questions, Fact Sheets, EPSDT Guide for States, Medicaid Drug Rebate Program Notices for Participating Drug Manufacturers, Managed Care Rate Development Guides, PERM Corrective Action Plan Template Instructions, Medicaid Enterprise Certification Toolkits, NCCI Manuals (Policy, Technical Assistance, Language Correspondence), and on and on. It is simply not possible for the CMS or the states to administer the \$650 billion (federal and state) Medicaid program that affects 67 million Americans in 56 different states and territories without the ability to use subregulatory guidance.

For example, on November 13, 2018, CMCS issued a letter to State Medicaid Directors (SMD #18-011) setting forth opportunities to design innovative service delivery systems for children (and adults) with serious emotional disturbance. On March 2, 2020, CMCS issued a letter to State Health Officials (SHO #20-002) relating to access to mental health and substance use disorder services for children and pregnant women in CHIP. And on November 19, 2019, CMCS issued an Informational Bulletin updating the Child Core Set measures for purposes of state reporting in 2020. State Medicaid and CHIP directors rely on SMDs, SHOs, and IBs like this in order to manage their programs for the benefit of children and families. Which, if any, of these would be subject to the new process described in the proposed regulations? The proposal is silent.

In its Rulemaking Analysis, the Department states that it “anticipates that the public, and in particular regulated parties, would benefit from greater efficiencies and more transparency in how the Department operates and regulates.” (85 FR at 51399) The implication is that the current use of subregulatory guidance in Medicaid and CHIP is inefficient and opaque. That is simply not the case. As evidenced by the three examples above, all of which were issued by the current Administration, CMCS generally issues subregulatory guidance when necessary for the efficient operation of the program by the state Medicaid and CHIP agencies, and it does so transparently. Each SMD, SHO, IB, etc., can be easily accessed through the “Federal Policy Guidance” tab on Medicaid.gov. When first published, each guidance is featured as “New and Notable.”

Executive Order 13891 of October 9, 2019 states that “it is the policy of the executive branch, to the extent consistent with applicable law, to require that agencies treat guidance documents as non-binding both in law and in practice, except as incorporated into a

contract....” (section 1). To this end, the EO directs each agency to “review its guidance documents and, consistent with applicable law, rescind those guidance documents that it determines should no longer be in effect.” Those guidance documents that remain in effect must be posted on an agency website established for this purpose which “shall note that guidance documents lack the force and effect of law, except as authorized by law or as incorporated into a contract.” (section 3(b)). Finally, the EO directs each agency to promulgate regulations that “set forth processes and procedures for issuing guidance documents.” (section 4). The EO was issued without notice and an opportunity for public comment.

The EO defines a “guidance document” as “an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulation, or technical issue, or an interpretation of a statute or regulation....” (section 2(b)). The regulations proposed by the Department repeat this definition (proposed 45 CFR 1.2). Neither the EO, nor the OMB implementing Memorandum M-20-02 (issued on October 31, 2019), nor the proposed regulations define the term “regulated party.” This term is obviously the lynchpin of a “guidance document;” the failure to define it makes informed public comment impossible.

There are numerous stakeholders in the Medicaid program: beneficiaries, state Medicaid agencies, delegated state agencies, providers, managed care plans, external quality review organizations, claims processing agents, management information system contractors, enrollment brokers, etc. Which of these is a “regulated party” such that the subregulatory guidance on which they currently rely would be treated as a “guidance document?”

This question is foundational: the proposed regulations require that all “guidance documents” either be rescinded or be posted in the proposed guidance repository?” Which “guidance documents” will not be included in the repository on November 16, and why? How will the “regulated parties” know?

Furthermore, the guidance repository will carry the caveat that it “lack[s] the force and effect of law, except as authorized by law or as specifically incorporated into a contract.” (proposed 45 CFR 1.4(a)((3)). What are affected stakeholders to make of this caveat? Should they conduct their own legal analysis as to whether the guidance is “authorized by law” continue to follow it, or not? More fundamentally, what is the justification for upending 55 years of Medicaid subregulatory guidance on November 16, 2020?

The failure of the Department to address, much less answer any of these questions in its August 20 notice (as corrected August 26) nullifies notice and comment.

The public comment period is completely inadequate

The Department published the proposed regulations on August 20. Six days later it published a notice of correction with multiple substantive revisions. Thus, the final version of the proposed regulations was not available to the public until August 26. The comments are due on September 16. This allows the public only 21 days to comment on the proposed

regulations. Neither the incorrect version of the proposed regulations published on August 20, nor the corrected version finally published on August 26, explains why an abbreviated comment period of less than 60 days is necessary. Moreover, as a practical matter, the abbreviated comment period was further because it encompassed Labor Day—a major National Holiday.

EO 13891 was issued October 15, 2019. On October 31, 2019, OMB issued Memorandum M-20-02 instructing all Executive Departments and Agencies as to how to implement EO 13891. The Memorandum notes that the EO requires each Department to establish, by February 28, 2020, a website that contains, or links to, all of the Department's guidance documents remaining in effect and post a notice in the Federal Register announcing the existence of the new guidance portal. The Memorandum further notes that the EO requires Departments to issue final implementing regulations by April 28, 2020.

Since the Department is already out of compliance with the EO, as implemented by the OMB Memorandum, by over six months (in the case of guidance portal) and four months (in the case of the regulations), we do not understand the need for the Department to truncate the public comment period to 21 days (including a National Holiday). We can appreciate that the Secretary declared a Public Health Emergency on January 31 and renewed the declaration on April 21 and again on July 23, and that during this emergency the Department needed to focus its resources on fighting the COVID-19 pandemic rather than implementing EO 13891. But the pandemic is still with us and shows no signs of receding. This is no time for the Department to finalize a regulation on a rushed basis that does not allow for meaningful public comment. If it took the Department at least 120 days longer than OMB instructed in order to publish the proposed regulations, surely the Department can give the public and the over 70 million people who rely on Medicaid for their health insurance the professional courtesy of a minimum 30-day comment period.

Summary

EO 13891 directs Executive Branch Departments to issue regulations to set forth processes and procedures for issuing guidance documents. We recognize that HHS must issue regulations in response to this directive. However, the August 20 notice, as corrected by the August 26 notice, does little more than repeat the language of EO 13891. Crucially, it does not explain what guidance documents issued by agencies within the HHS, including subregulatory guidance issued by the Center for Medicaid and CHIP Services (CMCS), would be affected. We urge the Department to withdraw the proposed regulations and reissue them with a full explanation of how they would affect the administration of Medicaid and CHIP so that we and other members of the public may understand the proposed regulations and comment effectively. In addition, upon reissuance, the Department should allow at least 60 days (without intervening National Holiday) for comment.

Thank you again for the opportunity to comment on the proposed rule. Please contact Andy Schneider at Andy.Schneider@georgetown.edu if you have any questions or if we can be of further assistance.

Respectfully submitted,

Joan Alker

Executive Director and Research Professor
Center for Children and Families
McCourt School of Public Policy
Georgetown University