Georgetown University
Health Policy Institute
CENTER FOR CHILDREN
AND FAMILIES

November 19, 2021

VIA ELECTRONIC SUBMISSION

Office of the Secretary
Department of Health and Human Services

Attention: RIN 0991-AC29, Department of Health and Human Services Good Guidance Practices

Dear Sir or Madam:

Thank you for the opportunity to comment on proposed regulation RIN 0991-AC29, which would repeal a final rule published on December 7, 2020, relating to "Department of Health and Human Services Good Guidance Practices." We write in strong support of the Department's proposal to repeal this unnecessary and ill-considered rule. This so-called "Good Guidance Practices" (GGP) rule is inconsistent with E.O. 14009, "Strengthening Medicaid and the Affordable Care Act;" promotes confusion among beneficiaries, state agencies, and other Medicaid stakeholders; and creates a central guidance repository that duplicates and undermines the guidance compilation maintained by the Center for Medicaid and CHIP Services.

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 GGP rule is inconsistent with E.O. 14009, "Strengthening Medicaid and the Affordable Care Act."

As the Department notes in the preamble, the Executive Order on which the GGP rule was based, E.O. 13891 (October 15, 2019), has been revoked. That in and of itself is sufficient grounds for repealing the GGP rule. Yet not only does the GGP rule lack a basis in law, it is inconsistent with E.O. 14009 (February 2, 2021), which directs the Secretary of HHS to "consider whether to suspend, revise, or rescind … policies or practices that may present unnecessary barriers to individual and families attempting to access Medicaid … coverage." The burdensome, one-size fits-all procedural requirements that the GGP rule imposes on CMS are the epitome of practices that "present unnecessary barriers to individuals and families" seeking Medicaid coverage.

Medicaid and CHIP are the source of health insurance coverage for 39 million children as of May 2021. 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 $775 billion (federal and state) Medicaid program that, as of May 2021 covered over 75 million Americans in 56 different states and territories, without the ability to use subregulatory guidance.

For example, CMS has used subregulatory guidance to help state Medicaid agencies, beneficiaries, applicants, and other stakeholders navigate the COVID-19 pandemic and the Afghan Evacuee crisis. On August 13, 2021, in order to help states plan for the enrollment actions states will need to take at the conclusion of the PHE and to minimize beneficiary burden, CMS issued RE: Updated Guidance Related to Planning for the Resumption of Normal State Medicaid, Children's Health Insurance Program (CHIP), and Basic Health Program (BHP) Operations Upon Conclusion of the COVID-19 Public Health Emergency (SHO #21-002). On August 30, to help states and providers understand the coverage policies for COVID-19 testing, CMS issued guidance to State Health Officials SHO# 21-003 RE: Medicaid and CHIP Coverage and Reimbursement of COVID-19 Testing under the American Rescue Plan Act of 2021. And on September 27, to assist states and refugee organizations in understanding the coverage options for Afghan evacuees, CMCS posted a Fact Sheet on Health Coverage Options for Afghan Evacuees, and updated it on November 1.

These important guidances were issued despite, not because of, the GGP rule. Its onerous procedural requirements—requiring a decision on what is a "guidance document" and what is a "significant guidance document," requiring the Secretary's approval of each "non-significant guidance document" that implicates "any policy matter of priority to the Secretary," requiring OIRA review and 30-day public notice and comment of all "significant guidance documents," etc. —did absolutely nothing to make the issuance of these guidances more efficient or more transparent.

The GGP rule unnecessarily promotes confusion and uncertainty about CMCS guidance among state agencies, beneficiaries, and other Medicaid stakeholders

The GGP rule requires that each "guidance document" that is not authorized by law to be binding must include the following language: "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under law." This legal boilerplate creates uncertainty about the subregulatory guidance on which it appears, undercutting the ability of CMS and state Medicaid agencies to

administer the program and, among other things, to respond effectively to rapidly evolving situations, such as the COVID-19 pandemic and the integration of Afghan evacuees.

For example, this boilerplate appears at the bottom of four of the five pages of the Fact Sheet on Health Coverage Options for Afghan Evacuees (updated November 1). The purpose of the Fact Sheet is to "provide clarity to the public regarding existing requirements under law." That is obvious; why is it necessary to say so? And what, other than creating uncertainty about the Fact Sheet, is accomplished by repeatedly stating that its contents "do not have the force and effect of law"? For example, in the context of discussing Afghan evacuees who are staying at DOD bases or in a designated medical hotel, the Fact Sheet on page 2 states, "Newborns born in the U.S. will be eligible for Medicaid, as U.S. citizens and if otherwise eligible. Unless the mother is enrolled in Medicaid for coverage of the baby's birth, an application will need to be filed on behalf of the newborn to apply for coverage." What does it mean to say, at the bottom of the same page, that this statement "does not have the force and effect of law"? Is the statement incorrect? Does an application not need to be filed on behalf of the newborn in this circumstance?

This boilerplate requirement also leads to unnecessary confusion on the part of state Medicaid agencies and other stakeholders about the relative legal standing of different guidance. For example, the boilerplate appears at the bottom of every page of SHO Letter #21-003 (August 30, 2021), relating to Medicaid reimbursement of testing of COVID-19. The boilerplate does not appear at all in SHO Letter #21-002 (August 13, 2021), relating to eligibility and enrollment procedures after the end of the PHE. Same type of guidance—a SHO Letter—and same month—August 2021. Why does the August 30 SHO tell its readers that it "does not have the force and effect of law," while the August 13 SHO does not? What are state Medicaid agencies and other stakeholders expected to make of this, especially since the boilerplate itself raises more questions than it answers?

The GGP rule creates a central guidance repository that unnecessarily duplicates the guidance compilation maintained by the Center for Medicaid and CHIP Services (CMCS).

The GGP rule requires the Department to maintain a guidance repository on its website at *www.hhs.gov/guidance* that contains or links all guidance documents in effect issued by any agency. It further deems any guidance document not in the repository to be rescinded, even if the document is posted on the website of a component agency and that agency has not, in fact, rescinded the document. This repository is unnecessary to the transparency of subregulatory guidance, duplicative of existing guidance compilations, and a waste of government resources.

In the case of Medicaid, this requirement is not only duplicative and unnecessary, but it also invites confusion when a document is inadvertently not included in the repository. CMCS maintains a fully text searchable website, Medicaid.gov, with a prominently displayed "Federal Policy Guidance" tab that contains all subregulatory guidance relating to Medicaid and CHIP. There is simply no reason to repost all CMCS guidance in a Departmental guidance repository, particularly if the accidental failure to post the document in the repository means that the guidance is deemed to be rescinded. If the purpose is transparency of Departmental subregulatory guidance across all components—a policy we strongly support—the most efficient solution is to provide a link to Medicaid.gov and similar websites of other components.

While we strongly support the Department's proposal to repeal the GGP rule in its entirety, including its requirement for a guidance repository, we have serious reservations about the Department's intention that the repository "remain active." We have been attempting to track Medicaid and CHIP guidance documents on the repository since it was established and have found this increasingly difficult. Specifically, the repository's keyword search function has changed in such a way as to make it essentially unusable. Rather than being able to filter out the documents in the repository by keyword and CMS, a user is taken to a separate page that looks like a sub-par search engine and does not produce useful results.

For example, a search for "Medicaid coverage for COVID-19 Treatment"—an issue of more than passing interest in the midst of the pandemic—yields 22 items, none of which is the October 22, 2021 State Health Official letter on this topic. In stark contrast, entering that same search term in "Federal Policy Guidance" on Medicaid.gov brings up the SHO letter as the first item. Without a reliable keyword search function, a user looking for a particular Medicaid guidance has to search through 3,808 pages of documents containing over 38,000 individual documents. No useful purpose is served by keeping a non-functional repository active when a functioning website is available; governmental resources are far better spent on improving the latter.

Summary

The GGP rule should be repealed. It is inconsistent with E.O. 14009, "Strengthening Medicaid and the Affordable Care Act." It creates confusion and uncertainty about CMCS guidance among state Medicaid agencies, beneficiaries, and other stakeholders. And it duplicates CMCS's existing website for making subregulatory guidance available to Medicaid and CHIP stakeholders and the public at large. In all three respects, it is not only unnecessary and wasteful of government resources; it also undercuts the ability of the Department and CMCS to efficiently and effectively administer the Medicaid program.

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,

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