



Forthcoming Health Care Regulations

Wednesday, April 17, 2019

Overview

This brief is part of the **WSC Regulatory Report** series, which lists and evaluates forthcoming federal health care regulations. The information below is based on an analysis of the most recent Department of Health and Human Services' (HHS) Regulatory Agenda (published November 11, 2018), the Office of Information and Regulatory Affairs (OIRA) Unified Agenda, and other Office of Management and Budget (OMB) documents.

The rules are divided into two sections: those that have been reviewed by OIRA and returned to the agency (but have not yet been published in the Federal Register); and those rules that are currently undergoing OIRA review. In either case, the HHS Secretary has the sole authority to determine whether and when the regulation is ultimately published in the Federal Register.

Note that this list is limited to certain non-annual, provider-focused health industry rules – i.e., it does not include the annually-published payment policy updates and is generally limited to rules that apply to providers, health systems, and insurance carriers. While certain drug pricing rules are included, the list generally omits industry-specific FDA regulations.

For more information on these rules or any other federal health care regulations, please contact Ross K. Airington, Director of Health Policy, at info@wscdc.com.

About OIRA Review

Executive Order 12866, "Regulatory Planning and Review," issued by President Clinton on September 30, 1993, establishes and governs the process under which the Office of Management and Budget (OMB) Office of Information and Regulatory Affairs (OIRA) reviews agency draft and proposed final regulatory actions. The OIRA review process seeks to ensure that agencies, to the extent permitted by law, comply with the regulatory principles stated in the Executive Order and that the President's policies and priorities are reflected in agency rules.

The period for OIRA review is limited to 90 days; there is no minimum period for review. Under the Executive Order, the review period may be extended indefinitely by the head of the rulemaking agency; alternatively, the OMB Director may extend the review period on a one-time basis for no more than 30 days.

The description and abstract of the draft regulations undergoing OIRA review are provided by Federal agencies directly through bi-annual submissions of the Unified Agenda, which are published descriptions

of each agency's upcoming regulatory actions. If the information about an individual rule is blank (or "not yet available"), it is because the agency did not provide such descriptive information in its Unified Agenda entries.

About Legal Deadlines

Generally speaking, section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that Medicare final rules be published within three years of a proposed or interim final rule. Rules may be, and usually are, published well before the three-year deadline.

Forthcoming Health Care Regulations

OIRA Review Complete; Not Yet Published

Title: Medicaid, Revisions to State Medicaid Fraud Control Unit Rules

Stage: Final Rule

Agency: HHS Office of Inspector General (OIG)

Date Review Completed: 3/15/2019

Description: The proposed regulation sought to amend the regulation governing the State Medicaid Fraud Control Units. MFCUs or Units to incorporate statutory changes affecting the MFCUs as well as policy and practice changes that have occurred since the regulation was initially issued in 1978. This final action would respond to public comments on the rule.

Currently Under OIRA Review

Title: Revision of Requirements for Long-Term Care Facilities: Arbitration Agreements (CMS-3342-F)

Stage: Final Rule

Agency: CMS

Received by OMB: 1/30/2019

Legal Deadline (if applicable): 6/8/2020

Description: This final rule revises the requirements that Long-Term Care (LTC) facilities must meet to participate in the Medicare and Medicaid programs. Specifically, it removes provisions prohibiting binding pre-dispute arbitration and strengthens requirements regarding the transparency of arbitration agreements in LTC facilities. This rule supports the resident's right to make informed choices about important aspects of his or her healthcare. In addition, this rule is consistent with [CMS'] approach to eliminating unnecessary burden on providers.

Title: Programs of All-Inclusive Care for the Elderly (PACE) Update (CMS-4168-F)

Stage: Final Rule

Agency: CMS

Received by OMB: 3/5/2019

Legal Deadline (if applicable): 8/16/2019

Description: This final rule updates the PACE regulations published on December 8, 2006. This rule improves the quality of the existing regulations, provides operational flexibility and modifications, and removes redundancies and outdated information. These updates are intended to ensure the health and safety of PACE participants.

Title: Medicaid Provider Payment Reassignment (CMS-2413-F)

Stage: Final Rule

Agency: CMS

Received by OMB: 3/15/2019

Description: This final rule would amend regulations to limit exceptions to provider payments under the Medicaid program.

Title: Regulation to Require Drug Pricing Transparency (CMS-4187-F)

Stage: Final Rule

Agency: CMS

Received by OMB: 3/18/2019

Description: This proposed rule would revise the Federal Health Insurance Programs for the Aged and Disabled by amending the Medicare Parts A, B, C and D programs, as well as the Medicaid program, to require drug pricing transparency.

Title: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses (CMS-4180-F)

Stage: Final Rule

Agency: CMS

Received by OMB: 4/3/2019

Description: Not yet available.

Title: Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3347-P)

Stage: Proposed Rule

Agency: CMS

Received by OMB: 11/8/2018

Description: This proposed rule would reform the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs, that CMS has identified as unnecessary, obsolete, or excessively burdensome on facilities. This rule would increase the ability of healthcare professionals to devote resources to improving resident care by eliminating or reducing requirements that impede quality care or that divert resources away from providing high quality care.

Title: Program Integrity Enhancements to the Provider Enrollment Process (CMS-6058-F)

Stage: Final Rule

Agency: CMS

Received by OMB: 12/3/2018

Description: This final rule implements statutory provisions that furnish the agency with additional authority to deny or revoke a provider's or supplier's Medicare enrollment in certain specified circumstances. It also requires that to order, certify, refer, or prescribe any Part A or B service, item, or drug, a physician or, when permitted, an eligible professional must be enrolled in Medicare in an approved status or have validly opted out of the Medicare program.

Title: Methods for Assuring Access to Covered Medicaid Services--Rescission (CMS-2406-P2)

Stage: Proposed Rule

Agency: CMS

Received by OMB: 12/12/2018

Description: This proposed rule would rescind all or part of the March 2018 proposed rule that provides an exception to the requirements for documenting Medicaid fee-for-service access to care for States with high managed care penetration rates. The proposed rule also set a threshold for rate reductions and restructuring that are not subject to the analysis, monitoring, and public processes required for larger reductions. At this point it remains unclear which parts of the proposed rule would be changed.

Title: Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

Stage: Final Rule

Agency: HHS Office of Civil Rights (OCR)

Received by OMB: 1/17/2019

Description: This final rule would enforce and implement health care conscience and associated anti-discrimination statutes that protect health care providers and patients in these areas as prescribed by Congress: (1) conscience protections related to abortion, sterilization, and certain other health services to participants in programs and their personnel funded by the Department; (2) conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion; (3) protections from discrimination for health care entities and individuals who object to furthering or participating in abortion under programs funded by the Department's yearly appropriations acts; (4) conscience protections under the Patient Protection and Affordable Care Act related to assisted suicide, individual mandate, and other matters of conscience; (5) conscience protections for objections to counseling and referral for certain services in Medicaid or Medicare Advantage; (6) conscience protections related to the performance of advanced directives; (7) conscience protections related to Global Health Programs to the extent administered by the Secretary; (8) exemptions from compulsory health care or services generally and under specific programs for hearing screenings, occupational illness testing, vaccination, and mental health treatment; and (9) protections for religious nonmedical health care.

Title: Nondiscrimination in Health Programs or Activities

Stage: Proposed Rule

Agency: HHS Office of Civil Rights (OCR)

Received by OMB: 4/13/2018

Description: This proposed rule implements Section 1557 of the Patient Protection and Affordable Care Act (PPACA), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability under any health program or activity receiving Federal financial assistance, or under any program or activity that is administered by the Department of Health and Human Services or by an entity established under title I of the PPACA. The proposed rule applies the enforcement mechanisms provided for and available under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), the Age Discrimination Act of 1975 (42 U.S.C. 6101 et seq.), and Section 504 of the Rehabilitation Act (29 U.S.C. 794).

Title: Confidential Communications

Stage: Proposed Rule

Agency: SAMHSA

Received by OMB: 2/8/2019

Description: This proposed rule will revise the 2017 final 42 CFR Part 2 rule to clarify language in Section 2.63(a)(2). The goal of this rule is to reduce confusion about when crimes not committed by a patient may be subject to investigations.

Title: Veterans Care Agreements

Stage: Interim Final Rule

Agency: Department of Veterans Affairs

Received by OMB: 3/12/2019

Description: The Department of Veterans Affairs (VA) intends to add new regulations to title 38 Code of Federal Regulations to implement section 102 of the VA MISSION Act (Public Law 115-182) to establish the use of Veterans Care Agreements (VCAs) to procure care in the community for eligible Veterans.