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July 25, 2016

The Honorable Lamar Alexander  
Chairman  
The Honorable Patty Murray  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Frank Pallone, Jr.  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Subject: *Department of Health and Human Services: Medication Assisted Treatment for Opioid Use Disorders*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services (HHS) entitled “Medication Assisted Treatment for Opioid Use Disorders” (RIN: 0930-AA22). We received the rule on July 7, 2016. It was published in the *Federal Register* as a final rule on July 8, 2016. 81 Fed. Reg. 44,712.

The final rule increases access to medication-assisted treatment (MAT) with buprenorphine and the combination buprenorphine/naloxone (hereinafter referred to as buprenorphine) in the office-based setting as authorized under the United States Code. Section 303(g)(2) of the Controlled Substances Act (CSA) allows individual practitioners to dispense or prescribe Schedule III, IV, or V controlled substances that have been approved by the Food and Drug Administration (FDA). Section 303(g)(2)(B)(iii) of CSA allows qualified practitioners who file an initial notification of intent (NOI) to treat a maximum of 30 patients at a time. After 1 year, the practitioner may file a second NOI indicating his/her intent to treat up to 100 patients at a time. This final rule will expand access to MAT by allowing eligible practitioners to request approval to treat up to 275 patients under section 303(g)(2) of CSA. The final rule also includes requirements to ensure that patients receive the full array of services that comprise evidence-based MAT and minimize the risk that the medications provided for treatment are misused or diverted.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This final rule has a stated effective date of August 8, 2016. The rule was received by GAO on July 7, 2016, and was published in the

*Federal Register* on July 8, 2016. Therefore, the final rule does not have the required 60-day delay in its effective date.

Enclosed is our assessment of HHS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. With the exception of the 60-day delay in effective date, our review of the procedural steps taken indicates that HHS complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer  
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas  
Regulations Coordinator  
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE  
ISSUED BY THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
ENTITLED  
"MEDICATION ASSISTED TREATMENT  
FOR OPIOID USE DISORDERS"  
(RIN: 0930-AA22)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS) conducted an analysis of the costs and benefits over the first 5 years of the final rule. According to HHS, the final rule's impacts will take place over a long period of time. HHS expects the existence of the waiver to treat up to 275 patients will increase the desirability of waivers to treat 30 and 100 patients. HHS states that this implies that more practitioners will work toward fulfilling the requirements associated with receiving these waivers. Further, according to HHS, this might make practitioners early in their career more likely to choose addiction medicine or addiction psychiatry as their specialty. HHS suggests that all of this implies that the final rule will have a growing impact on capacity to prescribe buprenorphine as time passes. Since the lack of capacity to treat patients using buprenorphine is a barrier to its utilization, HHS states that the final rule will lead to growing increases in the utilization of buprenorphine, and growing increases in the associated positive health and economic effects.

HHS included a table summarizing the costs and benefits over the first 5 years of the final rule. The quantified benefits at the present value, over 5 years, by a 3 percent discount rate (in millions of 2014 dollars) is estimated to be \$8,935, and the 7 percent discount rate (in millions of 2014 dollars) is estimated to be \$8,228. The quantified benefits at an annualized value, over 5 years, by a 3 percent discount rate (in millions of 2014 dollars) is estimated to be \$1,894, and the 7 percent discount rate (in millions of 2014 dollars) is estimated to be \$1,875. The quantified costs at the present value, over 5 years by a 3 percent discount rate (in millions of 2014 dollars) is estimated to be \$1,109, and the 7 percent discount rate (in millions of 2014 dollars) is estimated to be \$1,022. The quantified costs at an annualized value, over 5 years, by a 3 percent discount rate (in millions of 2014 dollars) is estimated to be \$235, and the 7 percent discount rate in millions of 2014 dollars) is estimated to be \$233. HHS stated that the total estimated benefits of the changes are sensitive to assumptions regarding the number of practitioners who will seek a waiver to treat up to 275 patients as a result of the final rule, the number of individuals who will receive medication-assisted treatment (MAT) as a result of the final rule, the average per-person health benefits associated with this additional treatment, and the dollar value of these health improvements. HHS also included an additional summary table of low, high, and primary benefit and cost estimates which incorporated this sensitivity analysis.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

HHS considers a rule to have a significant economic impact on a substantial number of small entities if at least 5 percent of small entities experience an impact of more than 3 percent of revenue. HHS states that it anticipates that the final rule will not have a significant economic impact on a substantial number of small entities.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

HHS states that section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$146 million, using the most current (2015) implicit price deflator for the gross domestic product. HHS states that it expects this final rule to result in expenditures that would exceed this amount.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 et seq.

On March 30, 2016, HHS issued a notice of proposed rulemaking (NPRM), entitled, “Medication Assisted Treatment for Opioid Use Disorders” in the *Federal Register*, and invited comment on the proposed rule. 81 Fed. Reg. 17,639. The comment period ended on May 31, 2016. HHS received 498 comments on the proposed rule. Comments came from a variety of stakeholders, including, but not limited to: individuals who currently prescribe buprenorphine and other health care professionals, such as nurse practitioners and pharmacists; health care policymakers; national organizations representing providers and public health agencies; and individuals who self-identified as current buprenorphine patients. According to HHS, a number of comments came from individuals who were part of a mass mail campaign organized by a national organization representing substance use disorder treatment specialists. HHS responded to the comments in the final rule.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

According to HHS, the notice of proposed rulemaking called for new collections of information under PRA. The final rule calls for most of the same collections of information as the NPRM. HHS identified and described the types of information applicants and waived practitioners must collect and report and provided an estimate of the total annual burden. The categories of information collection are:

- approval for a patient limit of 275, requires practitioners to meet all of the requirements specified;
- a Diversion Control Plan, which requires creating and maintaining a diversion control plan that practitioners must attest to (but are not required to submit to HHS) before they are approved to treat at the higher limit;
- renewal, which requires a practitioner renewing his or her approval for the higher patient limit to submit a renewal Request for Patient Limit Increase in accordance with the procedures outlined at least 90 days before the expiration of the approval term;
- Patient Notice, which requires that practitioners who do not submit a renewal Request for Patient Limit Increase or whose renewal request is denied will be required to notify all patients above the 100 patient limit that the practitioner will no longer be able to provide MAT services using covered medications and make every effort to transfer patients to other addiction treatment; and

- Emergency Provisions, which describes the process for practitioners with a current waiver to prescribe up to 100 patients, and who are not otherwise eligible to treat up to 275 patients, to request a temporary increase to treat up to 275 patients in order to address emergency situations.

Annual burden estimates for these requirements were summarized in the table in the final rule. The total estimated number of respondents is 2,394, the total estimated burden in hours is 4,598, and the total wage cost in dollars is \$50,398. HHS states that the OMB Control Number for these information collection requirements is: 0930-03XX.

#### Statutory authorization for the rule

The final rule was promulgated under the authority of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. § 823(g)(2)), specifically, section 303(g)(2)(B)(iii) (21 U.S.C. § 823(g)(2)(B)(iii)).

#### Executive Order No. 12,866 (Regulatory Planning and Review)

HHS expects that this final rule will have an annual effect on the economy of \$100 million or more in at least 1 year and therefore is a significant regulatory action as defined by Executive Order 12,866.

#### Executive Order No. 13,132 (Federalism)

HHS determined that the final rule does not contain policies that would have substantial direct effects on the states, on the relationship between the federal government and the states, or on the distribution of power and responsibilities among the various levels of government. According to HHS, the changes in the rule represent the federal government regulating its own program. Accordingly, HHS concluded that the final rule does not contain policies that have federalism implications as defined in the Federalism Order and, consequently, a federalism summary impact statement is not required.