



Billing Code: 4160-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AA89

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties; Delay of Effective Date

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action temporarily delays for 60 days from the date of the memorandum the effective date of the final rule titled “340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation,” published in the January 5, 2017, Federal Register. This document announces that the effective date is delayed until March 21, 2017.

DATE: *Effective date:* This regulation is effective March 3, 2017. The effective date of the final rule published in the January 5, 2017, Federal Register (82 FR 1210), is delayed until March 21, 2017. *Compliance date:* HHS recognizes that the effective date falls in

the middle of a quarter. As such, HHS plans to begin enforcing the requirements of this final rule at the start of the next quarter, which begins April 1, 2017.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTAL INFORMATION: The January 20, 2017 memorandum from the Assistant to the President and Chief of Staff, titled “Regulatory Freeze Pending Review,” published in the Federal Register on January 24, 2017 (82 FR 8346) instructed federal agencies to delay the effective date of rules published in the Federal Register, but which have not yet taken effect, for a period of 60 days from the date of the memorandum. The final rule sets forth the calculation of the 340B ceiling price and application of civil monetary penalties (CMPs). The effective date of that rule, which would have been March 6, 2017, is now March 21, 2017. The temporary delay in the effective date of this final rule is necessary to give Department officials the opportunity for further review and consideration of new regulations, consistent with the Assistant to the President and Chief of Staff’s memorandum.

Dated: February 23, 2017.

James Macrae,
Acting Administrator,
Health Resources and Services Administration.

Approved: March 1, 2017.

Thomas E. Price
Secretary,
Department of Health and Human Services.

[FR Doc. 2017-04337 Filed: 3/2/2017 11:15 am; Publication Date: 3/6/2017]