

Dated: July 21, 2017.

**Demetrios L. Kouzoukas,**

*Principal Deputy Administrator and Director,  
Center for Medicare.*

Approved: September 7, 2017.

**Thomas E. Price,**

*Secretary, Department of Health and Human  
Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 511

[CMS-1670-WN]

RIN 0938-AS85

#### Medicare Program; Part B Drug Payment Model; Withdrawal

**AGENCY:** Centers for Medicare &  
Medicaid Services (CMS), HHS.

**ACTION:** Withdrawal of proposed rule.

**SUMMARY:** This document withdraws a proposed rule that was published in the **Federal Register** on March 11, 2016. The proposed rule discussed our proposal to implement a new Medicare payment model under section 1115A of the Social Security Act (the Act).

**DATES:** As of October 4, 2017, the proposed rule published March 11, 2016, at 81 FR 13230, is withdrawn.

**FOR FURTHER INFORMATION CONTACT:** Rasheeda Johnson, (410) 786-3434.

**SUPPLEMENTARY INFORMATION:** On March 11, 2016, we published a proposed rule in the **Federal Register** entitled “Medicare Program; Part B Drug Payment Model” (81 FR 13230). The rule proposed the Part B Drug Payment Model as a two-phase model that would test whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. In the first phase, CMS would test a change to the 6 percent add-on to Average Sales Price (ASP) that is used to make drug payments under Part B such that the add-on would be 2.5 percent plus a flat fee (in a budget neutral manner). In the second phase, we would implement a collection of value-based purchasing tools similar to those employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. We proposed to operate the model for 5 years; phase I would begin in the fall of

2016 (no earlier than 60 days after the rule was finalized), and phase II would begin no sooner than January 1, 2017. The proposed goal was to have both phases of the model in full operation during the last 3 years of the proposed 5-year duration to fully evaluate changes and collect sufficient data.

We received 1,350 timely public comments in response to the March 11, 2016, proposed rule. Some commenters signaled their support for the proposed rule, however, a number of commenters expressed concerns about the proposed model. As we worked to address these concerns, the complexity of the issues related to the proposed model design and the desire to increase stakeholder input led us to the decision to withdraw the March 11, 2016 proposed rule. Moving forward, we want to ensure agency flexibility in re-examining these important issues and exploring new options and alternatives with stakeholders as we develop potential payment models that support innovative approaches to improve quality, accessibility, and affordability, reduce Medicare program expenditures, and empower patients and doctors to make decisions about their health care.

Accordingly, the proposed rule published March 11, 2016, at 81 FR 13230, is withdrawn.

Dated: July 17, 2017.

**Seema Verma,**

*Administrator, Centers for Medicare &  
Medicaid Services.*

Dated: August 25, 2017.

**Thomas E. Price,**

*Secretary, Department of Health and Human  
Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 45 CFR Parts 160 and 162

[CMS-0037-WN]

#### Administrative Simplification: Certification of Compliance for Health Plans; Withdrawal

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Withdrawal of proposed rule.

**SUMMARY:** This document withdraws the January 2, 2014, proposed rule that would have required a controlling health plan (CHP) to submit information and documentation demonstrating that it is compliant with certain standards and operating rules adopted by the

Secretary of Health and Human Services (the Secretary) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This proposed rule would have also established penalty fees for a CHP that failed to comply with the certification of compliance requirements.

**DATES:** As of October 4, 2017, the proposed rule published January 2, 2014, at 79 FR 298, is withdrawn.

#### FOR FURTHER INFORMATION CONTACT:

Geanelle G. Herring, (410) 786-4466.

**SUPPLEMENTARY INFORMATION:** In the January 2, 2014, **Federal Register** (79 FR 298), we published the proposed rule titled “Administrative Simplification: Certification of Compliance for Health Plans” which would have required controlling health plans (CHPs) to submit certain information and documentation that demonstrated compliance with the standards and operating rules adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for three electronic transactions: Eligibility for a health plan, health care claim status, and health care electronic funds transfers (EFT) and remittance advice. The proposed rule would have also established penalty fees for a CHP that failed to comply with the certification of compliance requirements.

We received approximately 72 public comments in response to the January 2, 2014 proposed rule. In light of the issues raised in the public comments received, we have decided to withdraw the January 2014 proposed rule in order to re-examine the issues and explore options and alternatives to comply with the statutory requirements. We note that the Secretary has established regulations pertaining to compliance with, and enforcement of, HIPAA Administrative Simplification standards and operating rules. The withdrawal of this proposed rule does not remove the requirements for covered entities to comply with any of those regulations codified at 45 CFR parts 160 and 162.

Accordingly, the proposed rule published January 2, 2014, at 79 FR 298, is withdrawn.

Dated: August 18, 2017.

**Seema Verma,**

*Administrator, Centers for Medicare &  
Medicaid Services.*

Dated: August 30, 2017.

**Thomas E. Price,**

*Secretary, Department of Health and Human  
Services.*

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