

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6079-N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2019

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

ACTION: Notice.

SUMMARY: This notice announces a \$586.00 calendar year (CY) 2019 application fee for institutional providers that are initially enrolling in the Medicare or Medicaid program or the Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid, or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2019 and on or before December 31, 2019.

DATES: This notice is applicable beginning on January 1, 2019.

FOR FURTHER INFORMATION CONTACT: Melissa Singer, (410) 786-0365.

SUPPLEMENTARY INFORMATION:

I. Background

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period titled "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers." This rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and CHIP provider enrollment processes. As provided in section 1866(j)(2)(C)(i) of the Social Security Act (the Act) and in 42 CFR 424.514, "institutional providers" that are initially enrolling in the Medicare or Medicaid programs or CHIP, revalidating their enrollment, or adding a new Medicare practice location are required to submit a fee with their enrollment application. An "institutional provider" for purposes of Medicare is defined at § 424.502 as "(a)ny provider or supplier that submits a paper Medicare enrollment application using the CMS-855A, CMS-855B (not including physician and non-physician practitioner organizations), CMS-855S, CMS-20134, or associated internet-based PECOS enrollment

application." As we explained in the February 2, 2011 final rule (76 FR 5914), in addition to the providers and suppliers subject to the application fee under Medicare, Medicaid-only and CHIP-only institutional providers would include nursing facilities, intermediate care facilities for persons with intellectual disabilities (ICF/IID), psychiatric residential treatment facilities, and may include other institutional provider types designated by a state in accordance with their approved state plan.

As indicated in § 424.514 and § 455.460, the application fee is not required for either of the following:

- A Medicare physician or non-physician practitioner submitting a CMS-855L.
- A prospective or revalidating Medicaid or CHIP provider—
 - ++ Who is an individual physician or non-physician practitioner; or
 - ++ That is enrolled in Title XVIII of the Act or another state's Title XIX or XXI plan and has paid the application fee to a Medicare contractor or another state.

II. Provisions of the Notice

A. CY 2018 Fee Amount

In the December 4, 2017 **Federal Register** (82 FR 57273), we published a notice announcing a fee amount for the period of January 1, 2018 through December 31, 2018 of \$569.00. This figure was calculated as follows:

- Section 1866(j)(2)(C)(i)(I) of the Act established a \$500 application fee for institutional providers in CY 2010.
- Consistent with section 1866(j)(2)(C)(i)(II) of the Act, § 424.514(d)(2) states that for CY 2011 and subsequent years, the preceding year's fee will be adjusted by the percentage change in the consumer price index (CPI) for all urban consumers (all items; United States city average, CPI-U) for the 12-month period ending on June 30 of the previous year.
 - The CPI-U increase for CY 2011 was 1.0 percent, based on data obtained from the Bureau of Labor Statistics (BLS). This resulted in an application fee amount for CY 2011 of \$505 (or \$500 × 1.01).
 - The CPI-U increase for the period of July 1, 2010 through June 30, 2011 was 3.54 percent, based on BLS data. This resulted in an application fee amount for CY 2012 of \$522.87 (or \$505 × 1.0354). In the February 2, 2011 final rule, we stated that if the adjustment sets the fee at an uneven dollar amount, we would round the fee to the nearest whole dollar amount. Accordingly, the application fee amount for CY 2012 was

rounded to the nearest whole dollar amount, or \$523.00.

- The CPI-U increase for the period of July 1, 2011 through June 30, 2012 was 1.664 percent, based on BLS data. This resulted in an application fee amount for CY 2013 of \$531.70 (\$523 × 1.01664). Rounding this figure to the nearest whole dollar amount resulted in a CY 2013 application fee amount of \$532.00.

- The CPI-U increase for the period of July 1, 2012 through June 30, 2013 was 1.8 percent, based on BLS data. This resulted in an application fee amount for CY 2014 of \$541.576 (\$532 × 1.018). Rounding this figure to the nearest whole dollar amount resulted in a CY 2014 application fee amount of \$542.00.

- The CPI-U increase for the period of July 1, 2013 through June 30, 2014 was 2.1 percent, based on BLS data. This resulted in an application fee amount for CY 2015 of \$553.382 (\$542 × 1.021). Rounding this figure to the nearest whole dollar amount resulted in a CY 2015 application fee amount of \$553.00.

- The CPI-U increase for the period of July 1, 2014 through June 30, 2015 was 0.2 percent, based on BLS data. This resulted in an application fee amount for CY 2016 of \$554.106 (\$553 × 1.002). Rounding this figure to the nearest whole dollar amount resulted in a CY 2016 application fee amount of \$554.00.

- The CPI-U increase for the period of July 1, 2015 through June 30, 2016 was

1.0 percent. This resulted in a CY 2017 application fee amount of \$559.56 (\$554 × 1.01). Rounding this figure to the nearest whole dollar amount resulted in a CY 2017 application fee amount of \$560.00.

- The CPI-U increase for the period of July 1, 2016 through June 30, 2017 was 1.6 percent. This resulted in a CY 2018 application fee amount of \$568.96 (\$560 × 1.016). Rounding this figure to the nearest whole dollar amount resulted in a CY 2018 application fee amount of \$569.00.

B. CY 2019 Fee Amount

Using BLS data, the CPU-U increase for the period of July 1, 2017 through June 30, 2018 was 2.9%. This results in a CY 2019 application fee amount of \$585.501 (\$569 × 1.029). As we must round this to the nearest whole dollar amount, the resultant application fee for CY 2019 is \$586.00.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995. However, it does reference previously approved information collections. The Forms CMS-855A, CMS-855B, and CMS-855I are approved under OMB control number 0938-0685; the Form CMS-855S is approved under OMB control number 0938-1056.

IV. Regulatory Impact Statement

A. Background

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). As explained in this section of the notice, we estimate that the total cost of the increase in the application fee will not exceed \$100 million. Therefore, this notice does not reach the \$100 million economic threshold and is not considered a major notice.

B. Costs

The costs associated with this notice involve the increase in the application fee amount that certain providers and suppliers must pay in CY 2019.

1. Estimates of Number of Affected Institutional Providers in December 4, 2017, 2016 Fee Notice

In the December 4, 2017 application fee notice, we estimated that based on CMS statistics—

- 3,800 newly enrolling Medicare institutional providers would be subject to and pay an application fee in CY 2018. The estimate of 3,800 newly enrolling Medicare institutional providers was corrected to 10,700 newly enrolling Medicare institutional providers in the January 3, 2018 correction notice (83 FR 381).
- 7,500 revalidating Medicare institutional providers would be subject to and pay an application fee in CY 2018.
- 9,000 newly enrolling Medicaid and CHIP providers would be subject to and pay an application fee in CY 2018.
- 21,000 revalidating Medicaid and CHIP providers would be subject to and pay an application fee in CY 2018.

2. CY 2019 Estimates

a. Medicare

Based on CMS data, we estimate that in CY 2019 approximately—

- 12,870 newly enrolling institutional providers will be subject to and pay an application fee; and
- 41,580 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 54,450 (12,870 newly enrolling + 41,580 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2019 of \$925,650 (or 54,450 x \$17 (or \$586 minus \$569)) from our CY 2018 projections and as previously described.

b. Medicaid and CHIP

Based on CMS and state statistics, we estimate that approximately 30,000 (9,000 newly enrolling + 21,000 revalidating) Medicaid and CHIP institutional providers will be subject to an application fee in CY 2019. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2019 of \$510,000 (or 30,000 x \$17 (or \$586 minus \$569)) from our CY 2018 projections and as previously described.

c. Total

Based on the foregoing, we estimate the total increase in the cost of the application fee requirement for Medicare, Medicaid, and CHIP providers and suppliers in CY 2019 to be \$1,435,650 (\$925,650 + \$510,000) from our CY 2018 projections.

The RFA requires agencies to analyze options for regulatory relief of small

businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$7.5 million to \$38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. As we stated in the RIA for the February 2, 2011 final rule with comment period (76 FR 5952), we do not believe that the application fee will have a significant impact on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold was approximately \$148 million. The Agency has determined that there will be minimal impact from the costs of this notice, as the threshold is not met under the UMRA.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this notice does not impose substantial direct costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs

and thus is not a regulatory action for the purposes of E.O. 13771.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: October 19, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4142]

Determination That REGITINE (Phentolamine Mesylate) Injection, 5 Milligrams/Vial, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means

that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT:

Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, *Stacy.Kane@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is generally known as the “Orange Book.” Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Applica-tion No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 008278.	REGITINE	Phentolamine Mesylate	5 milligrams (mg)/vial	Injectable; Injection	Novartis Pharma-ceuticals Corp.
NDA 011287.	KAYEXALATE	Sodium Polystyrene Sulfonate.	453.6 grams (g)/bottle ...	Powder; Oral, Rectal	Concordia Pharma-ceuticals, Inc.
NDA 011751.	PROLIXIN	Fluphenazine Hydro-chloride (HCl). Fluphenazine HCl	2.5 mg/milliliter (mL) 1 mg; 2.5 mg; 5 mg; 10 mg.	Injectable; Injection; Tablet; Oral	Bristol-Myers Squibb Co.
NDA 012249.	LIBRIUM	Chlordiazepoxide HCl ...	5 mg; 10 mg; 25 mg	Capsule; Oral	Valeant Pharmaceuticals North America, LLC.
NDA 016008.	PERMITIL	Fluphenazine HCl	5 mg/mL	Concentrate; Oral	Schering Corp., Sub-sidiary of Schering Plough, Corp.
NDA 016110.	PROLIXIN ENANTHATE	Fluphenazine Enanthate	25 mg/mL	Injectable; Injection	Bristol-Myers Squibb Co.
NDA 017007.	HEPARIN SODIUM	Heparin Sodium	1,000 units/mL; 2,500 units/mL; 5,000 units/mL; 7,500 units/mL; 10,000 units/mL; 15,000 units/mL; 20,000 units/mL; 5,000 units/0.5 mL;.	Injectable; Injection	West-Ward Pharma-ceuticals International, Ltd.
NDA 017105.	TRANXENE	Clorazepate Dipotassium.	3.75 mg; 7.5 mg; 15 mg	Tablet; Oral;	Recordati Rare Dis-eases, Inc.
	TRANXENE	Clorazepate Dipotassium.	3.75 mg; 7.5 mg; 15 mg	Capsule; Oral;	
	TRANXENE SD	Clorazepate Dipotassium.	11.25 mg; 22.5 mg	Tablet; Oral	
NDA 017488.	MODICON 21	Ethinyl Estradiol; Norethindrone.	0.035 mg; 0.5 mg	Tablet; Oral	Ortho-McNeil Pharma-ceutical, Inc.