anticipated to cause adverse effects to human health or adverse environmental effects.” In contrast, EPCRA section 313(d)(2)(A) mandates that the EPA consider whether “a chemical is known to cause or can reasonably be anticipated to cause significant adverse acute health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries.” The contrast demonstrates that Congress intends to specifically require a risk assessment, it does so. It decided not to do so in CAA section 112(b)(3). The CAA is silent on the issue of noncancer hazards and quantitative cancer risk evaluation and does not explicitly prohibit the EPA from considering it when making a determination under CAA section 112(b)(3)(B). As previously explained in section II.C, the EPA also believes that in meeting its obligation under CAA section 112(b)(3)(B), the Administrator has discretion in forming her decision to either grant or deny a petition to add a substance to the CAA section 112(b)(1) HAP list. We believe this discretion would allow her, where appropriate, to consider risk evaluation of a substance in order to make the requisite determination as to whether a substance is “known to cause or may reasonably be anticipated to cause adverse effects to human health or adverse environmental effects,” under CAA section 112(b)(3)(B).

Thus, the EPA concludes that the petitioners have met the CAA section 112(b)(3)(A) requisite showing of adequate data by estimating nPB emissions and ambient concentrations that are likely to result beyond a facility’s fence line and providing adequate evidence of adverse health effects of nPB. Because the EPA is granting the petition for reasons stated above, the agency does not find it necessary to make determinations regarding other elements of the petition, such as a petitioner’s noncancer hazards and quantitative cancer risk evaluation, or whether nPB presents adverse environmental effects.

V. EPA’s Decision To Grant the Petitions

Based on the EPA’s evaluation of the petitions submitted by HSIA and NYSDEC, we conclude that the petitioners have provided sufficient information demonstrating the adverse health effects of nPB. The documented adverse health effects of nPB, which are based on established sound scientific principles, include carcinogenicity, reproductive toxicity, and neurotoxicity. The EPA also concludes that the petitioner’s assessment regarding estimates of potential ambient concentrations of nPB that are likely to result at a facility’s fence line and process emissions related information and chemical usage information representative of normal operating conditions are reasonable. The EPA concludes that there is adequate evidence to support a determination that nPB is an air pollutant and that emissions and ambient concentrations of nPB may reasonably be anticipated to cause adverse effects to human health. As mentioned above, we are seeking comments on all aspects of this notice, including EPA’s technical review of the HSIA and NYSDEC petitions, whether the criteria for listing have been met, and the agency’s rationale for the decision to grant these petitions.

VI. Statutory and Executive Order Review

Additional information about this Executive Order can be found at http://www.epa.gov/laws-regulations/laws-and-executive-orders.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review because it raises novel legal or policy issues. Any changes made in response to OMB recommendations have been documented in the docket. Accordingly, the EPA is issuing this draft notice announcing the decision to grant petitions to add nPB to the CAA section 112(b)(1) HAP list.

Gina McCarthy,
Administrator.

[FR Doc. 2017–00158 Filed 1–6–17; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[60Day–17–17IY]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS)

ACTION: Notice with comment period; withdrawal.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR) in the Department of Health and Human Services (HHS) announces the withdrawal of the notice published under the same title on December 30, 2016 for public comment.


FOR FURTHER INFORMATION CONTACT: Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.


ATSDR prematurely and inadvertently published this notice. The notice is being withdrawn immediately for public comment.

A new and corrected notice published on January 3, 2017 under the same title
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6059–N6]

Medicare, Medicaid, and Children’s Health Insurance Programs:
Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

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

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance providers and suppliers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. This extension also applies to the enrollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children’s Health Insurance Program in those states.


FOR FURTHER INFORMATION CONTACT: Steve Manning, (410) 786–1691. News media representatives must contact CMS’ Public Affairs Office at (202) 690–6145 or email them at press@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS’ Implementation of Temporary Enrollment Moratoria

Under the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) [collectively known as the Affordable Care Act], the Congress provided the Secretary with new tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). Section 6401(a) of the Affordable Care Act added a new section 1866(j)(7) to the Social Security Act (the Act) to provide that all of the Medicare provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In the February 2, 2011 Federal Register (76 FR 5862), CMS 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,” which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(iv), CMS, or CMS in consultation with the Department of Health and Human Services’ Office of Inspector General (HHS–OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular locations, or both. At § 424.570(a)(1)(ii), CMS stated that it would announce any temporary moratorium in a Federal Register document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(jj)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium; however the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied.

B. Moratoria in a Defined Geographic Location

Under the Patient Protection and Affordable Care Act, the Congress amended section 2107(e)(1) of the Act to provide that all of the Medicaid and CHIP programs are subject to moratoria on the enrollment of new Medicare, Medicaid or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Section 6401(b) of the Affordable Care Act added specific moratorium language applicable to Medicaid at section 1902(kk)(4) of the Act, requiring States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries’ access to care. Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to provide that all of the Medicaid provisions in sections 1902(a)(77) and 1902(kk) are also applicable to CHIP.

In a December 2012 Federal Register notice (78 FR 46339), we exercised this authority again in a notice published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded them to include enrollment of HHAs in Broward County, Florida; Harris County, Texas; and Wayne County, Michigan.

C. Moratoria in a Defined Geographic Location

In accordance with section 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium; however the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied.

D. Moratoria in a Defined Geographic Location

In the February 2, 2011 Federal Register (76 FR 5862), CMS 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,” which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under § 424.570(a)(2)(iv), CMS, or CMS in consultation with the Department of Health and Human Services’ Office of Inspector General (HHS–OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular locations, or both. At § 424.570(a)(1)(ii), CMS stated that it would announce any temporary moratorium in a Federal Register document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(jj)(7)(B) of the Act, there is no judicial review under sections 1869 and 1878 of the Act, or otherwise, of the decision to impose a temporary enrollment moratorium. A provider or supplier may use the existing appeal procedures at 42 CFR part 498 to administratively appeal a denial of billing privileges based on the imposition of a temporary moratorium; however the scope of any such appeal is limited solely to assessing whether the temporary moratorium applies to the provider or supplier appealing the denial. Under § 424.570(c), CMS denies the enrollment application of a provider or supplier if the provider or supplier is subject to a moratorium. If the provider or supplier was required to pay an application fee, the application fee will be refunded if the application was denied.

As noted in the preamble to the final rule with comment period implementing the moratorium authority (February 2, 2011, CMS–6026–FC (76 FR 5870)), home health agency subunits and branch locations are subject to the moratoria to the same extent as any other newly enrolling home health agency.

CMS has identified an error in the provider and beneficiary saturation data described in our July 31, 2013 Federal Register notice (78 FR 46339). We have subsequently revised the methodology by which we determine provider and beneficiary saturation. Following these revisions to the methodology, we simulated application of our current 2016 methodology to the 2013 data, and determined that the 2013 decision to impose the moratorium would not have been impacted had the revised methodology been applied. Provider and beneficiary saturation remains one of the criteria used to determine whether to implement a moratorium.