

**Supporting Statement A for Paperwork Reduction Act Submissions
Temporary Extraordinary Circumstances Exception for Excepted Provider-Based
Departments**

(CMS-10730, OMB 0938-New)

Background

Section 603 of the Bipartisan Budget Act of 2015 (BBA 2015) (Pub. L. 114-74, enacted November 2, 2015) amended section 1833(t) of the Act by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments (OPD) of a provider on or after January 1, 2017 are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPSS and are instead paid “under the applicable payment system” under Medicare Part B if the requirements for payment are otherwise met.

In the CY 2017 OPSS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (81 FR 79720 through 79729), we established a number of policies to implement section 603 of the BBA 2015. Broadly, CMS finalized policies that define whether certain items and services furnished by a given off-campus provider-based department (PBD) may be considered excepted, and thus, continue to be paid under the OPSS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by excepted off-campus PBDs); and described the applicable payment system for non-excepted items and services (generally, the PFS).

In the CY 2017 OPSS/ASC final rule (81 FR 79704 through 79706), CMS also finalized a policy to allow excepted off-campus PBDs to relocate, temporarily or permanently, without loss of excepted status, for extraordinary circumstances outside of the hospital’s control, such as natural disasters, significant seismic building code requirements, or significant public health and public safety issues.

The interim final rule Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (RIN: 0938-AU32) includes a provision to temporarily adopt an expanded version of the extraordinary circumstances relocation policy during the COVID-19 PHE to include on-campus PBDs that relocate off-campus during the COVID-19 PHE for the purposes of addressing the COVID-19 pandemic.

As a result, hospitals that relocate on- or excepted off-campus PBDs to new off-campus locations in response to the COVID-19 PHE can seek an extraordinary circumstances exception under a new streamlined process. Hospitals seeking this exception must notify their CMS Regional Office by email of their hospital’s CCN; the address of the current PBD; the address(es) of the relocated PBD(s); the date which they began furnishing services at the new PBD(s); a brief justification for the relocation and the role of the relocation in the hospital’s response to COVID-19; and an attestation that the relocation is not inconsistent with their state’s emergency preparedness or pandemic plan.

A. Justification

1. Need and Legal Basis

Various sections of the Act and the Code of Federal Regulations define public health emergency, payment under the Hospital Outpatient Prospective Payment System (OPPS), what is considered an excepted on- or off-campus PBDs:

- 42 CFR 400.200 defines “public health emergency” which contains definitions that apply under the entirety of Chapter 400 of Title 42 of the CFR. The definition identifies the PHE determined to exist nationwide by the Secretary of Health and Human services under section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID-19.
- Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted on November 2, 2015, which amended section 1833(t) of the Act amended the OPPS statute at section 1833(t) by amending paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid “under the applicable payment system” under Medicare Part B if the requirements for such payment are otherwise met.
- The current criteria for provider-based status are located in the regulations at 42 CFR 413.65.
- In defining the term “off-campus outpatient department of a provider,” section 1833(t)(21)(B)(i) of the Act specifies that the term means a department of a provider (as defined at 42 CFR 413.65(a)(2) as that regulation was in effect on November 2, 2015, the date of enactment of Pub. L. 114–74) that is not located on the campus of such provider, or within the distance from a remote location of a hospital facility.
- Section 1833(t)(21)(B)(ii) of the Act excepts from the definition of “off-campus outpatient department of a provider,” for purposes of paragraphs (1)(B)(v) and (21)(B) of such section, an off-campus PBD that was billing under section 1833(t) with respect to covered OPD services furnished prior to the date of enactment of Public Law 114–74, that is, November 2, 2015.
- Definition of “campus” in § 413.65(a)(2) includes the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office (RO), to be part of the provider's campus.
- At 42 CFR 413.65(a)(2) remote location of a hospital is defined as “a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the

provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term ‘remote location of a hospital’ does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.’

2. Information Users

CMS will collect the necessary information from all hospitals that request temporary extraordinary circumstances exceptions for one or more on-campus or excepted off-campus provider-based departments during the COVID-19 PHE. CMS will use this information to review the hospitals’ justification for the relocation and the role of the relocation in the hospital’s response to COVID-19 to ensure efficient and legal use of Medicare program funds.

3. Use of Information Technology

If hospitals want to continue to bill under the OPPS (vs. the PFS), hospitals that relocate excepted on- or off-campus PBDs to off-campus locations in response to the COVID-19 PHE will be required to contact their CMS Regional Office by email to request a temporary extraordinary circumstances exception. Allowing hospitals to contact their CMS Regional Office by email facilitates use of information technology to reduce burden. 100% of applications would be submitted via email. This information is currently available for completion electronically and requires a signature from the respondent; however, a signature included in the body of the email is sufficient.

4. Duplication of Efforts

There is no duplicative information collection instrument or process.

5. Small Businesses

The request for a temporary extraordinary circumstances exception for relocating excepted PBDs is not completed by small businesses and therefore will not affect small businesses.

6. Less Frequent Collection

This request is voluntary. Hospitals can furnish services in relocated on- or excepted off-campus PBDs and be paid the PFS-equivalent rate. However, for purposes of responding to the PHE, we are allowing hospitals to request a temporary extraordinary circumstances exception for relocating excepted PBDs. This relocation request will allow hospitals to continue to bill under the OPPS for services furnished in relocated and excepted PBDs

during the PHE.

Without the relocation request, CMS does not have the ability to pay excepted PBDs that relocate as a result of the PHE under the OPPS. This change in payment system (OPPS vs. PFS) amounts to a payment reduction and could further negatively impact hospitals during the PHE. We anticipate that hospitals will only submit one relocation request, even though that request may be for multiple new PBD locations. The submission deadline could be delayed, but CMS has already afforded hospitals significant time to submit the request (120 days from when care is furnished). Giving hospitals additional time could create administrative complexity for CMS once the PHE ends and hospitals are expected to move their relocated PBDs back to their original location. We believe our approach, which a) provides hospitals with time to submit the request b) allows hospitals to submit the request through email, and c) reduces the amount of information that hospitals have to submit, maximizes the flexibility hospitals have during the PHE while not burdening them with new administrative requirements.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

We sought comment in the interim final rule titled “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” (CMS-5531-IFC), providing the public an opportunity to comment on these ICRs. The interim final rule published on May 8, 2020 (85 FR 27550).

9. Payments/Gifts to Respondents

There are gifts to respondents as the respondents are requesting a temporary extraordinary circumstances exception for relocating excepted PBDs during the COVID-19 PHE. The respondents are only requesting the exception. Once the exception is granted, CMS would pay the excepted PBDs that relocate as a result of the PHE under the OPPS, rather than the PFS.

10. Confidentiality

CMS will comply with all Privacy Act, Freedom of Information laws and regulations that apply to this collection. Specifically, we will comply with the Privacy Act of 1974 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to ensure that no personally identifiable information is released or compromised when excepted PBDs are submitting information to CMS. CMS will also follow the Department of Health and Human Services (DHHS) Privacy Act Regulations at 45 Code of Federal Regulations (C.F.R.) Part

5b.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature such as religious beliefs and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

We estimate that 450 hospitals will request the temporary extraordinary circumstances exception for one or more on-campus or excepted off-campus provider-based departments during the PHE. There are roughly 500 hospitals as identified by a unique CMS Certification Number (CCN) in the states of New York, New Jersey, Michigan, Washington, Massachusetts, and Louisiana. These states have some of the counties with the highest per-capita incidence of COVID-19, and we estimate that roughly 50% of the hospitals in those states will apply for an exception (roughly 250 hospitals) due to their need to relocate an on-campus or excepted off-campus provider-based department in response to the PHE. In the remaining states, we believe a smaller percent of hospitals in each state may also apply for the exception, resulting in a total of 450 hospitals.

We estimate that it will take each hospital 15 minutes to complete and submit the request to the CMS Regional Office. We believe that all hospitals will submit a maximum of one relocation request email (even though the request may include more than one location) and this request can include some of the same information (e.g., the same CCN, original provider-based department address, and justification) for multiple sites as deemed appropriate by the hospital. We believe a Medical and Health Services Manager will develop and submit the relocation request to the CMS Regional Office. These employees have an average hourly wage rate of \$55.35 based on the May 2019 Bureau of Labor and Statistics' Occupation Employment Statistics. (Citation: BLS code 11-9111, website for May 2019 data here: <https://www.bls.gov/oes/current/oes119111.htm>).

We estimate 450 total submissions (one per hospital) x 0.25 hours per submission = 113 total burden hours associated with this requirement and a total labor cost of \$6,257 (113 hours x \$55.37/hr).

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

We do not expect an annualized cost to the Federal government as we expect CMS Regional Office review of the requests to be part of federal employees' customary and usual business practices.

However, we estimate the following cost to the Federal government: Across the 10 regional offices (RO), we expect that one GS-13 employee at each RO would be responsible for receiving, reviewing and adjudicating the requests. We anticipate it will take 20 minutes to review each request. We estimate there will be approximately 45 responses per employee (450/10). Therefore, we estimate the following cost per employee is \$1,171.07 or \$11,710.71 total cost across all 10 ROs [1 employee x 45 responses/employee x .33 hr/response x \$78.861 (GS-13, step 1, base pay)].

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

The results from this data collection will not be published.

17. Expiration Date

CMS will post the expiration date along with the PRA Disclosure Statement on the CMS coronavirus waiver web site located here: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>. It is anticipated that this information collection is only needed for the duration of the COVID-19 public health emergency at which the collection will be formally discontinued.

18. Certification Statement

There are no exceptions to item 19 of OMB Form 83-1.