

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Law enforcement officers	phone call for recruitment & informed consent.	60	1	30/60	30
Law enforcement officers	Initial meeting	60	1	15/60	15
Law enforcement officers	Knowledge survey	60	2	5/60	10
Law enforcement officers	Epworth Sleepiness Scale	60	2	1/60	2
Law enforcement officers	Pittsburgh Sleep Quality Index	60	2	2/60	4
Law enforcement officers	Demographics and work experience	60	1	2/60	2
Law enforcement officers	Sleep diary	60	42	2/60	84
Law enforcement officers	Online training	60	1	150/60	150
Law enforcement officers	Feedback about Training, Barriers, and Influential People.	60	1	5/60	5
Law enforcement officers	Changes in Behaviors after Training	60	1	2/60	2
Law enforcement officers	Actigraph fitting and return	60	3	10/60	30
Total	334

Jeffrey M. Zirger,
*Lead, Information Collection Review Office,
 Office of Scientific Integrity, Office of Science,
 Centers for Disease Control and Prevention.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3386-CN]

Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program; Correction

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

ACTION: Final notice; correction.

SUMMARY: This document corrects a technical error that appeared in the final notice published in the **Federal Register** on September 28, 2020 entitled “Medicare Program; Approval of Application by The Compliance Team for Initial CMS-Approval of Its Home Infusion Therapy Accreditation Program.”

DATES: This correction is effective September 28, 2020.

FOR FURTHER INFORMATION CONTACT: Christina Mister-Ward, (410) 786-2441. Shannon Freeland, (410) 786-4348. Lillian Williams, (410) 786-8636.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 2020-21260 of September 28, 2020 (85 FR 60799-60800), there was a technical error that is identified

and corrected in this correcting document. The provision in this correction document is effective as if it had been included in the document published September 28, 2020. Accordingly, the correction is effective September 28, 2020.

II. Summary of Error

On page 60799, in the **DATES** section of the notice, the phrase “takes effect October 1, 2020 through October 1, 2024” should be replaced with the phrase “September 28, 2020-September 28, 2024.”

III. Correction of Error

In the **Federal Register** of September 28, 2020, in FR Doc. 2020-21260, on page 60799, in the 2nd column, in the **DATES** section, the phrase “takes effect October 1, 2020 through October 1, 2024” is corrected to read “September 28, 2020-September 28, 2024.”

Dated: September 28, 2020.

Wilma M. Robinson,

Deputy Executive Secretary to the Department, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-1517]

The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “The Use of Physiologically Based Pharmacokinetic Analyses—Biopharmaceutics Applications for Oral Drug Product Development, Manufacturing Changes, and Controls.” This guidance provides general recommendations regarding the development, evaluation, and use of physiologically based pharmacokinetic (PBPK) analyses for biopharmaceutics applications employed by sponsors of investigational new drug applications, new drug applications, or abbreviated new drug applications, and supplements to these applications, for oral drug product development, manufacturing changes, and controls. The guidance covers how to develop, evaluate, and apply PBPK models for biopharmaceutics-related uses, such as establishing clinically relevant dissolution specifications and quality risk assessment for postapproval manufacturing changes.