II. Advisory Committee Membership Roster

On November 23, 2021, HHS published a Notice of Charter and Invitation for Member Nominations in the **Federal Register** for the GAPB Advisory Committee (86 FR 66565 through 66566). HHS received a total of 52 complete member nominations from the public by December 13, 2021. The nominees were evaluated by the Departments for alignment with the membership categories required under Section 117 of the No Surprises Act, their professional qualifications, recognition by the ground ambulance and emergency medical services community, years of relevant experience, experience with State or Federal committees on related issues, and expertise in subject matter to be addressed by the committee. The Departments also considered membership balance as required by FACA, and as appropriate to address health equity issues pertaining to ground ambulance consumer balance billing, and ground ambulance services in underserved communities.

The 17 Members of the GAPB Advisory Committee are:

- Asbel Montes—Committee Chairperson; Additional Representative determined necessary and appropriate by the Secretaries
- Ali Khawar—Secretary of Labor's Designee
- Thomas West—Secretary of Treasury's Designee
- Rogelyn McLean—Secretary of Health and Human Services' Designee
- Gamunu Wijetunge—Department of Transportation—National Highway Traffic Safety Administration
- Suzanne Prentiss—State Insurance Regulators
- Adam Beck—Health Insurance Providers
- Patricia Kelmar—Consumer Advocacy Groups
- Gary Wingrove—Patient Advocacy Groups
- Ayobami Ogunsola—State and Local Governments
- Ritu Sahni—Physician specializing in emergency, trauma, cardiac, or stroke
- Peter Lawrence—State Emergency Medical Services Officials
- Shawn Baird—Emergency Medical Technicians, Paramedics, and Other Emergency Medical Services Personnel
- Edward Van Horne—Representative of Various Segments of the Ground Ambulance Industry
- Regina Godette-Crawford—Representative of Various Segments of the Ground Ambulance Industry
- Rhonda Holden—Representative of Various Segments of the Ground Ambulance Industry
- Loren Adler—Additional Representative determined necessary and appropriate by the Secretaries

The GAPB Committee Roster will also be posted on the GAPB website at: *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.*

III. Meeting Agenda

The first meeting of the GAPB Advisory Committee will occur on January 17 and 18, 2023. During this meeting, the Committee will gather background information on the No Surprises Act, the ground ambulance industry, insurance and billing practices, and consumer issues such as disclosure of fees and balance billing, prior to discussing potential subcommittees and focus areas. The agenda will cover the following topics:

- No Surprises Act overview
- Overview of the ground ambulance industry
- Insurance and ground ambulance payment systems
- Ground ambulance billing practices
- Disclosure of charges to consumers, separation of charges and cost shifting
- Impact of balance billing on consumers and current consumer protections
- Balance billing prevention, including potential legislative and regulatory options

A more detailed agenda and materials will be made available approximately 2 days before the meeting on the GAPB website (listed above).

IV. Public Participation

This meeting will be open to the public. Attendance may be limited due to virtual meeting constraints. Interested parties are encouraged to register as far in advance of the meeting as possible. To register for the meeting, please visit: *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.* CMS is committed to providing equal access to this meeting for all participants and to ensuring Section 508 compliance. Closed captioning will be provided. If you need alternative formats or services because of a disability, such as sign language interpreter or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

V. Submitting Written Comments

Members of the public may submit written comments on subject matter under committee deliberation prior to the webinar via email to *gapbadvisorycommittee@cms.hhs.gov.* Comments must be submitted via email no later than January 3, 2023. During the virtual meeting, members of the public will have the opportunity to submit comments through the chat feature of the webinar platform. These comments will be compiled for future consideration by the committee.

V. Viewing Documents

You may view the documents discussed in this notice at *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.*

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: December 12, 2022.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2022–27263 Filed 12–13–22; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget (OMB) Review; Culture of Continuous Learning Project: Case Study of a Breakthrough Series Collaborative for Improving Child Care and Head Start Quality (New Collection)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Child and Families (ACF) is proposing an information collection activity for the Culture of Continuous Learning Project (CCL). The goal of the project is to assess the feasibility of implementing continuous quality improvement methods in early care and education (ECE) programs and systems to support the use and

sustainability of evidence-based practices.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. You can also obtain copies of the proposed collection of information by emailing *OPREinfocollection@acf.hhs.gov.* Identify all emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The CCL project is proposing a new information collection activity to assess the feasibility of implementing continuous quality improvement methods in ECE programs and systems to support the use and sustainability of evidence-based practices. Three Breakthrough Series Collaboratives (BSCs), a specific quality improvement model designed to support the implementation of continuous quality improvement methods in organizations, will be implemented in Head Start and child care settings. The BSC methodology has been studied extensively in health care and other fields but has limited evidence as an effective quality improvement methodology in the early childhood field. The findings will be of broad interest to ECE programs as well as training and technical assistance providers and researchers, all of whom are interested in improving the quality of services young children receive.

Head Start and child care programs that voluntarily participate in the BSCs will be asked to complete a number of tools designed to facilitate implementation of the BSC. The implementation of the BSCs will be evaluated using a case study design that will involve focus groups, interviews, surveys, and classroom observations. To fully capture participants' experiences in the BSCs, the implementation and evaluation instruments are designed to engage respondents one to three times during a thirty six-month period, depending on the instrument. The goal of the case study is to document the factors that contribute to the feasibility of BSC implementation within a state quality improvement system (*e.g.,* a state quality rating and improvement system) and/or a regional professional development or technical assistance system (*e.g.,* a region within a state, or a cross-state region such as Head Start regional technical assistance areas) such that we can refine hypotheses and study measures which will be useful in the design of an evaluation for a future study of BSCs in ECE systems. The case study will also help determine what additional capacity ECE systems may need to adopt the BSC methodology and offer it within their system at a larger scale.

Respondents: Up to 45 ECE programs will be invited to complete an application to participate in a BSC and up to five people per program will be involved in completing the application. Up to eight programs will be selected to participate in one of three BSCs, for a total of up to 24 programs. Within each program, up to seven individuals (*e.g.,* directors, lead teachers, assistant teachers, teacher aides, parents, curriculum specialists, etc.) will participate in the implementation of the BSC, meaning that up to 168 individuals will participate. Respondents will also include additional teachers (up to 114), program staff (up to 96), and parents (up to 2,136) located at participating Head Start and child care programs where a BSC is implemented but who are not members of the BSC Team.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
BSC Implementation Instruments					
Instrument 1: BSC Selection Application Questionnaire	225	1	1.5	338	113
Instrument 2: Pre-Work Assignment: Data Collection Planning Worksheet	48	1	2	96	32
Instrument 3: Plan, Do, Study, Act (PDSA)Form & Tracker	168	34	0.25	1,428	476
Instrument 4: Monthly Metrics	48	8	1.5	576	192
Instrument 5: Implementation Discussion Forum Prompts	168	34	0.25	1,428	476
Instrument 6: Learning Session Feedback Form	168	4	0.25	168	56
Instrument 7: Action Planning Form	168	4	0.25	168	56
Instrument 8: BSC Overall Feedback Form	168	1	0.25	42	14
Instrument 9: Organizational Self-Assessment	168	5	1.5	1,260	420
BSC Evaluation Instruments					
Instrument 10: Key Informant Interviews with BSC Faculty Members Affiliated with the States/Regions Discussion Guide	9	1	1	9	3
Instrument 11: BSC Implementation Staff and Faculty Focus Group Discussion Guide	30	2	1.5	90	30
Instrument 12: BSC Implementation Staff and Faculty Background Survey	30	1	0.17	5	2
Instrument 13: Key Informant Interviews with BSC Center Administrators Discussion Guide	24	2	1	48	16

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Instrument 14: BSC Teachers and Support Staff Focus Group Discussion Guide	120	2	1.5	360	120
Instrument 15: BSC Parent Focus Group Discussion Guide	24	2	1.5	72	24
Instrument 16: Individual BSC Teams Focus Group Discussion Guide	168	2	1.5	504	168
Instrument 17a: Administrator Surveys	24	3	0.5	36	12
Instrument 17b: Teacher Surveys	240	3	0.5	360	120
Instrument 17c: Other Center Staff Surveys	96	3	0.5	144	48
Instrument 17di: Non-BSC Parent Surveys	2136	2	0.25	1068	356
Instrument 17dii: BSC Parent Surveys	24	3	0.5	36	12
Instrument 18: Classroom Observations	48	3	0.33	48	16
Instrument 19: Administrative Data Survey	24	4	0.25	24	8

Estimated Total Annual Burden Hours: 2,770.

Authority: Head Start Act 640 [42 U.S.C. 9835] and 649 [42 U.S.C. 9844]; appropriated by the Continuing Appropriations Act of 2019. Child Care and Development Block Grant Act of 1990 as amended by the CCDBG Act of 2014 (Public Law 113186).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–27241 Filed 12–15–22; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0710]

Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection; Draft Guidance for Industry, Revision 1; 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 entitled, ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection.'' The FDA Reauthorization Act of 2017 (FDARA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) so that, as is the case with a drug, a device is deemed to be adulterated if the owner, operator, or agent of the factory, warehouse, or establishment at which the device is manufactured, processed, packed, or held delays, denies, or limits an FDA inspection. This draft guidance describes, for both drugs and now devices, the types of behaviors (actions, inactions, and circumstances) that the FDA considers to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection. Once finalized, this draft guidance is intended to supersede the October 2014 FDA final guidance for industry entitled, ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection.'' However, until this draft guidance is finalized, the October 2014 FDA guidance remains in effect until it is withdrawn and will continue to reflect FDA's current thinking on this issue. FDA is particularly interested in comments on the inclusion of devices to the October 2014 guidance.

DATES: Submit either electronic or written comments on the draft guidance by February 14, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–0710 for ''Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper