

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed updates to the currently approved information collection project: “*Medical Expenditure Panel Survey (MEPS) Household Component*.”

DATES: Comments on this notice must be received by July 1, 2019.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by emails at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection. This request is for an update to the previously submitted and OMB-approved clearance for the data collections of the Household and Medical Provider Components of the Medical Expenditure Panel Survey (MEPS). The previous OMB clearance request for the MEPS was approved November, 2018, with an expiration date of November 30, 2021. We propose updating the MEPS –HC by (1) adding a self-administered questionnaire focusing on mental health, (2) collecting a health insurance cost-sharing document and (3) implementing a pilot study to evaluate the potential effectiveness of including a sample of NHIS nonrespondents in future MEPS panels as a strategy to improve the overall MEPS response rate.

Medical Expenditure Panel Survey (MEPS) Household Component and the MEPS Medical Provider Component

- **Household Component:** A sample of households participating in the National Health Interview Survey (NHIS) in the prior calendar year are interviewed 5 times over a 2 and one half (2.5) year period. These 5 interviews yield two years of information on use of, and expenditures for, health care, sources of payment for that health care, insurance status, employment, health status and health care quality.

- **Medical Provider Component:** The MEPS-MPC collects information from medical and financial records maintained by hospitals, physicians, pharmacies and home health agencies named as sources of care by household respondents.

- **Insurance Component (MEPS-IC):** The MEPS-IC collects information on establishment characteristics, insurance offerings and premiums from employers. The MEPS-IC is conducted by the Census Bureau for AHRQ and is cleared separately.

The MEPS is a multi-purpose survey. In addition to collecting data to yield annual estimates for a variety of measures related to health care use and expenditures, MEPS also provides estimates of measures related to health status, consumer assessment of health care, health insurance coverage, demographic characteristics, employment and access to health care indicators. Estimates can be provided for individuals, families and population subgroups of interest. Data obtained in this study are used to provide, among others, the following national estimates:

- Annual estimates of health care use and expenditures for persons and families
- annual estimates of sources of payment for health care utilizations, including public programs such as Medicare and Medicaid, private insurance, and out of pocket payments
- annual estimates of health care use, expenditures and sources of payment of persons and families by type of utilization including inpatient stay, ambulatory care, home health, dental care and prescribed medications
- the number and characteristics of the population eligible for public programs including the use of services and expenditures of the population(s) eligible for benefits under Medicare and Medicaid
- the number, characteristics, and use of services and expenditures of persons and families with various forms of insurance

- annual estimates of consumer satisfaction with health care, and indicators of health care quality for key conditions
- annual estimates to track disparities in health care use and access

In addition to national estimates, data collected in this ongoing longitudinal study are used to study the determinants of the use of services and expenditures, and changes in the access to and the provision of health care in relation to:

- Socio-economic and demographic factors such as employment or income
- the health status and satisfaction with health care of individuals and families
- the health needs and circumstances of specific subpopulation groups such as the elderly and children

To meet the need for national data on health care use, access, cost and quality, MEPS-HC collects information on:

- Access to care and barriers to receiving needed care
- satisfaction with usual providers
- health status and limitations in activities
- medical conditions for which health care was used
- use, expense and payment (as well as insurance status of person receiving care) for health services

Given the twin problems of nonresponse and response error of some household reported data, information is collected directly from medical providers in the MEPS-MPC to improve the accuracy of expenditure estimates derived from the MEPS-HC. Because of their greater level of precision and detail, we also use MEPS-MPC data as the main source of imputations of missing expenditure data. Thus, the MEPS-MPC is designed to satisfy the following analytical objectives:

- Serve as source data for household reported events with missing expenditure information
- Serve as an imputation source to reduce the level of bias in survey estimates of medical expenditures due to item nonresponse and less complete and less accurate household data
- Serve as the primary data source for expenditure estimates of medical care provided by separately billing doctors in hospitals, emergency rooms, and outpatient departments, Medicaid recipients and expenditure estimates for pharmacies
- Allow for an examination of the level of agreement in reported expenditures from household respondents and medical providers

Data from the MEPS, both the HC and MPC components, are intended for a number of annual reports produced by AHRQ, including the National Healthcare Quality and Disparities Report.

This study is being conducted by AHRQ through its contractors, Westat and RTI International, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the cost and use of health care services and with respect to health statistics and surveys. 42 U.S.C. 299a(a)(3) and (8); 42 U.S.C. 299b-2.

Method of Collection

To achieve the goals of the MEPS-HC the following data collections are implemented:

1. **Household Component Core Instrument.** The core instrument collects data about persons in sample households. Topical areas asked in each round of interviewing include priority condition enumeration, health status, health care utilization including prescribed medicines, expenses and payments, employment, and health insurance. Other topical areas that are asked only once a year include access to care, income, assets, satisfaction with providers, and children's health. While many of the questions are asked about the entire reporting unit (RU), which is typically a family, only one person normally provides this information. All sections of the current core instrument are available on the AHRQ website at http://meps.ahrq.gov/mepsweb/survey_comp/survey_questionnaires.jsp.

2. **Adult Self-Administered Questionnaire.** A brief self-administered questionnaire (SAQ) is used to collect self-reported (rather than through household proxy) health opinions and satisfaction with health care, and information on health status, preventive care and health care quality measures for adults 18 and older.

3. **Diabetes Care SAQ.** A brief self-administered paper-and-pencil questionnaire on the quality of diabetes care is administered once a year (during rounds 3 and 5) to persons identified as having diabetes. Included are questions about the number of times the respondent reported having a hemoglobin A1c blood test, whether the respondent reported having his or her feet checked for sores or irritations, whether the respondent reported having an eye exam in which the pupils were dilated, the last time the respondent had his or her blood cholesterol checked and whether the diabetes has caused kidney or eye problems. Respondents are also

asked if their diabetes is being treated with diet, oral medications or insulin.

4. **Authorization forms for the MEPS-MPC Provider and Pharmacy Survey.** We ask respondents for authorization to obtain supplemental information from their medical providers (hospitals, physicians, home health agencies and institutions) and pharmacies.

5. **MEPS Validation Interview.** Each interviewer is required to have at least 15 percent of his/her caseload validated to insure that the computer assisted personal interview (CAPI) questionnaire content was asked appropriately and procedures followed, for example, the use of show cards. Validation flags are set programmatically for cases pre-selected by data processing staff before each round of interviewing. Home office and field management may also request that other cases be validated throughout the field period. When an interviewer fails a validation their work is subject to 100 percent validation. Additionally, any case completed in less than 30 minutes is validated. A validation abstract form containing selected data collected in the CAPI interview is generated and used by the validator to guide the validation interview.

Proposed HC Additions

6. **Mental Health SAQ.** MEPS will include a new self-administered questionnaire for spring of 2020 data collection targeting the adult (age 18 and over) population. The questionnaire includes questions addressing issues in regards to an individual's mental health and mental health treatment including mental health status, access to care, barriers to care, experiences with care, and use of peer support and other services. AHRQ worked with several experts in the mental health field to develop this self-administered questionnaire and used their expertise to take advantage of already tested and widely accepted measures in the SAQ.

7. **Health Insurance Cost Sharing Collection.** AHRQ is seeking to enhance data collection practices in the 2020 fielding of the MEPS-HC to collect more detailed health insurance cost-sharing information from respondents with current private insurance, Medicare Advantage, or Medicare Part D Prescription Drug plans. Specifically, we will ask respondents to provide a document for themselves and family members that includes information on plan deductibles, out-of-pocket maximums and other cost sharing details for specific services. An example of the type of document we propose to collect is the Summary of Benefits and Coverage (SBC). AHRQ worked with experts on a feasibility study to identify

the best methods for collecting these types of documents in a way that would minimize respondent burden (OMB approval 0935-0124).

8. **Pilot Test on Sampling NHIS Nonrespondents.** This test will be conducted on a relatively small sample of households in a few selected primary sampling units (PSUs) in the 2020 spring data collection cycle. The sample households for this test will be drawn from nonrespondents to the 2019 NHIS (which are not currently part of the MEPS frame) and only the MEPS Round 1 interview will be administered. The purpose of the test is to evaluate the potential effectiveness of including a sample of NHIS nonrespondents in future MEPS panels to mitigate the impact of declining NHIS response rates on the overall MEPS response rate. The general trend of declining response rates for household surveys is problematic and this evaluation is designed to explore an avenue to stop further declines and potentially improve the overall MEPS response rate.

To achieve the goal of the MEPS-MPC the following data collections are implemented. No updates to the MEPS-MPC are being requested:

1. **MPC Contact Guide/Screening Call.** An initial screening call is placed to determine the type of facility, whether the practice or facility is in scope for the MEPS-MPC, the appropriate MEPS-MPC respondent and some details about the organization and availability of medical records and billing at the practice/facility. All hospitals, physician offices, home health agencies, institutions and pharmacies are screened by telephone. A unique screening instrument is used for each of these seven provider types in the MEPS-MPC, except for the two home care provider types which use the same screening form.

2. **Home Care Provider Questionnaire for Health Care Providers.** This questionnaire is used to collect data from home health care agencies which provide medical care services to household respondents. Information collected includes type of personnel providing care, hours or visits provided per month, and the charges and payments for services received. Some HMOs may be included in this provider type.

3. **Home Care Provider Questionnaire for Non-Health Care Providers.** This questionnaire is used to collect information about services provided in the home by non-health care workers to household respondents because of a medical condition; for example, cleaning or yard work, transportation, shopping, or child care.

4. Medical Event Questionnaire for Office-Based Providers. This questionnaire is for office-based physicians, including doctors of medicine (MDs) and osteopathy (DOs), as well as providers practicing under the direction or supervision of an MD or DO (e.g., physician assistants and nurse practitioners working in clinics). Providers of care in private offices as well as staff model HMOs are included.

5. Medical Event Questionnaire for Separately Billing Doctors. This questionnaire collects information from physicians identified by hospitals (during the Hospital Event data collection) as providing care to sampled persons during the course of inpatient, outpatient department or emergency room care, but who bill separately from the hospital.

6. Hospital Event Questionnaire. This questionnaire is used to collect information about hospital events, including inpatient stays, outpatient department, and emergency room visits. Hospital data are collected not only from the billing department, but from medical records and administrative records departments as well. Medical records departments are contacted to determine the names of all the doctors who treated the patient during a stay or visit. In many cases, the hospital administrative office also has to be contacted to determine whether the doctors identified by medical records billed separately from the hospital; doctors that do bill separately from the hospital will be contacted as part of the Medical Event Questionnaire for Separately Billing Doctors. HMOs are included in this provider type.

7. Institutions Event Questionnaire. This questionnaire is used to collect information about institution events, including nursing homes, rehabilitation facilities and skilled nursing facilities. Institution data are collected not only from the billing department, but from medical records and administrative records departments as well. Medical records departments are contacted to determine the names of all the doctors who treated the patient during a stay. In many cases, the institution's administrative office also has to be contacted to determine whether the doctors identified by medical records billed separately from the institution itself. Some HMOs may be included in this provider type.

8. Pharmacy Data Collection Questionnaire. This questionnaire

requests the National Drug Code (NDC) and when that is not available the prescription name, strength and form as well as the date prescription was filled, payments by source, the quantity, and person for whom the prescription was filled. When the NDC is available, we do not ask for prescription name, strength or form because that information is embedded in the NDC; this reduces burden on the respondent. Most pharmacies have the requested information available in electronic format and respond by providing a computer generated printout of the patient's prescription information. If the computerized form is unavailable, the pharmacy can report their data to a telephone interviewer. Pharmacies are also able to provide a CD-ROM with the requested information if that is preferred. HMOs are included in this provider type.

Dentists, optometrists, psychologists, podiatrists, chiropractors, and others not providing care under the supervision of a MD or DO are considered out of scope for the MEPS-MPC.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the MEPS-HC and the MEPS-MPC.

The MEPS-HC Core Interview will be completed by 13,338 * (see note below Exhibit 1) "family level" respondents, also referred to as RU respondents. Since the MEPS-HC consists of 5 rounds of interviewing covering a full two years of data, the annual average number of responses per respondent is 2.5 responses per year. The MEPS-HC core requires an average response time of 92 minutes to administer. The Adult Female SAQ (PSAQ) and Adult SAQ (SAQ) will be completed once a year by each female person in the RU that is 18 years old and older, an estimated 12,984 persons. The Adult Male SAQ (PSAQ) and Adult SAQ (SAQ) will be completed once a year by each male person in the RU that is 18 years old and older, an estimated 11,985 persons. The Adult SAQs each require an average of 7 minutes to complete. The Mental Health SAQ will be completed during Round 1, Panel 25; Round 3, Panel 24; Round 5, Panel 23 interviews by each person in the RU that is 18 years old and older, an estimated 24,969 persons, and takes about 7 minutes to complete. The Diabetes care SAQ will be completed once a year by each person

in the RU identified as having diabetes, an estimated 2,072 persons, and takes about 3 minutes to complete. The 12,804 RUs in the MEPS-HC will complete an average of 5.4 forms, which require about 3 minutes each to complete. The authorization form for the MEPS-MPC Pharmacy Survey will be completed once for each pharmacy for any RU member who has obtained a prescription medication. RUs will complete an average of 3.1 forms, which take about 3 minutes to complete. The Health Insurance Cost Sharing collection will be completed during Round 1, Panel 25 and Round 3, Panel 24 by each RU with a current private health insurance plan, a Medicare Advantage plan, or a Medicare Part D plan. An estimated 5,835 respondents will locate and provide cost-sharing documentation for an average of 1.3 plans per eligible RU. This activity will require 45 minutes to complete for each plan. About one third of all interviewed RUs will complete a validation interview as part of the MEPS-HC quality control, which takes an average of 5 minutes to complete. The total annual burden hours for the MEPS-HC are estimated to be 68,772 hours.

All medical providers and pharmacies included in the MEPS-MPC will receive a screening call and the MEPS-MPC uses 7 different questionnaires; 6 for medical providers and 1 for pharmacies. Each questionnaire is relatively short and requires 2 to 13 minutes to complete. The total annual burden hours for the MEPS-MPC are estimated to be 17,388 hours. The total annual burden for the MEPS-HC and MPC is estimated to be 86,160 hours.

The total estimated annual burden hours for the MEPS has increased from 77,666 hours in the previous clearance to 86,160 hours in this clearance request, an increase of 2,913 hours due to the addition of the Mental Health SAQ, 5,689 hours due to the health insurance cost sharing collection, and 230 hours due to the pilot test on sampling NHIS nonrespondents.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this information collection. The annual cost burden for the MEPS-HC is estimated to be \$1,673,909; the annual cost burden for the MEPS-MPC is estimated to be \$298,580. The total annual cost burden for the MEPS-HC and MPC is estimated to be \$1,972,489.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
MEPS-HC				
MEPS-HC Core Interview	13,338	2.5	92/60	51,129
Adult Female SAQ (PSAQ)—Years 2019 and 2021; Adult SAQ (SAQ)—Year 2020	12,984	1	7/60	1,515
Adult Male SAQ (PSAQ)—Years 2019 and 2021; Adult SAQ (SAQ)—Year 2020	11,985	1	7/60	1,398
Diabetes care SAQ	2,072	1	3/60	104
Mental Health SAQ—Year 2020	24,969	1	7/60	2,913
Authorization form for the MEPS-MPC Provider Survey	12,804	5.4	3/60	3,457
Authorization form for the MEPS-MPC Pharmacy Survey	12,804	3.1	3/60	1,985
Health Insurance Cost Sharing Collection—2020	5,835	1.3	45/60	5,689
MEPS-HC Validation Interview	4,225	1	5/60	352
Pilot Test on Sampling NHIS Nonrespondents—2020	150	1	92/60	230
Subtotal for the MEPS-HC	102,366	na	na	68,772
MEPS-MPC				
MPC Contact Guide/Screening Call **	36,598	1	2/60	1,220
Home care for health care providers questionnaire	635	1.53	9/60	146
Home care for non-health care providers questionnaire	11	1	11/60	2
Office-based providers questionnaire	11,210	1.65	10/60	3,083
Separately billing doctors questionnaire	12,397	3.46	13/60	9,294
Hospitals questionnaire	5,310	3.26	9/60	2,597
Institutions (non-hospital) questionnaire	116	2.05	9/60	36
Pharmacies questionnaire	6,919	2.92	3/60	1,010
Subtotal for the MEPS-MPC	73,196	na	na	17,388
Grand Total	175, 562	na	na	86,160

* While the expected number of responding units for the annual estimates is 12,804, it is necessary to adjust for survey attrition of initial respondents by a factor of 0.96 (13,338=12,804/0.96).

** There are 6 different contact guides; one for office based, separately billing doctor, hospital, institution, and pharmacy provider types, and the two home care provider types, which use the same contact guide.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
MEPS-HC				
MEPS-HC Core Interview	13,338	51,129	\$24.34	\$1,244,480
Adult Female SAQ (PSAQ)—Years 2019 and 2021; Adult SAQ (SAQ)—Year 2020	12,984	1,515	*24.34	36,875
Adult Male SAQ (PSAQ)—Years 2019 and 2021; Adult SAQ (SAQ)—Year 2020	11,985	1,398	*24.34	34,027
Diabetes care SAQ	2,072	104	*24.34	2,531
Mental Health SAQ—Year 2020	24,969	2,913	*24.34	70,902
Authorization forms for the MEPS-MPC Provider Survey	12,804	3,457	*24.34	84,143
Authorization form for the MEPS-MPC Pharmacy Survey	12,804	1,985	*24.34	48,315
Health Insurance Cost Sharing Collection—2020	5,835	5,689	*24.34	138,470
MEPS-HC Validation Interview	4,225	352	*24.34	8,568
Pilot Test on Sampling NHIS Nonrespondents—2020	150	230	*24.34	5,598
Subtotal for the MEPS-HC	102,366	68,800	na	1,673,909
MEPS-MPC				
MPC Contact Guide/Screening Call	36,598	1,220	**17.25	21,045
Home care for health care providers questionnaire	635	146	**17.25	2,519
Home care for non-health care providers questionnaire	11	2	**17.25	35
Office-based providers questionnaire	11,210	3,083	**17.25	53,182
Separately billing doctors questionnaire	12,397	9,294	**17.25	160,322
Hospitals questionnaire	5,310	2,597	**17.25	44,798
Institutions (non-hospital) questionnaire	116	36	**17.25	621
Pharmacies questionnaire	6,919	1,010	***15.90	16,059
Subtotal for the MEPS-MPC	73,196	17,388	na	298,580
Grand Total	175, 562	na	1,972,489

* Mean hourly wage for All Occupations (00–0000).

** Mean hourly wage for Medical Secretaries (43–6013).

*** Mean hourly wage for Pharmacy Technicians (29–2052).

Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Gopal Khanna,

Director.

[FR Doc. 2019–08765 Filed 4–30–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the estimated reporting, recordkeeping, and third-party disclosure burden associated with the Mammography Quality Standards Act requirements.

DATES: Submit either electronic or written comments on the collection of information by July 1, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 1, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 1, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–0134 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- **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 submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the