

vulnerabilities are identified and resolved.

**Authority:** 44 U.S.C. 3101.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, 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 22, 2020.

**Lynette Wilson,**

*Federal Register, Centers for Medicare & Medicaid Services.*

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**BILLING CODE 4120-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; OPRE Data Collection for Supporting Youth To Be Successful in Life (SYSIL) (New Collection)**

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF) is requesting approval from the Office of Management and Budget (OMB) for a new data collection. The Supporting Youth to be Successful in Life study

(SYSIL) will build evidence on how to end homelessness among youth and young adults with experience in the child welfare system by continuing work with an organization who conducted foundational work as part of the Youth At-Risk of Homelessness project (OMB Control Number: 0970-0445). SYSIL will provide important information to the field by designing and conducting a federally led evaluation of a comprehensive service model for youth at risk of homelessness.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

**SUPPLEMENTARY INFORMATION:** *Description:* The SYSIL evaluation includes an implementation study and an impact study, which will use a rigorous quasi-experimental design that includes a comparison group. This new

information collection request includes the baseline and follow-up survey instruments for the impact study (a single instrument administered four times), and discussion guides for interviews and focus groups and the Working Alliance Inventory (WAI) for the implementation study. The data collected from the baseline and follow-up surveys will be used to describe the characteristics of the study sample of youth, develop models for estimating program impacts, and determine program effectiveness by comparing outcomes between youth in the treatment (youth receiving the Pathways program) and control groups. Data from the interviews and focus groups will provide a detailed understanding of program implementation. The study will also use administrative data from the child welfare system, homelessness management information system, and program providers. Administrative data will be used in its existing format and does not impose any new information collection or recordkeeping requirements on respondents.

*Respondents:* The baseline and follow-up surveys will be administered to youth in the treatment group (youth receiving the Pathways program) and youth in the control group who consent to participate in the study. Interviews will be conducted with program leadership and staff. Focus groups will be conducted with a subset of youth who are participating in the study. The WAI will be completed by Pathways youth and their caseworkers.

**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)
SYSIL Youth Survey—Baseline survey .....	700	1	.5	350	117
SYSIL Youth Survey—Follow-up survey 1 (6 months) .....	630	1	.5	315	105
SYSIL Youth Survey—Follow-up survey 2 (12 months) .....	595	1	.5	298	99
SYSIL Youth Survey—Follow-up survey 3 (24 months) .....	372	1	.5	186	62
Interview guide for Pathways sites (treatment sites) .....	30	1	1.5	45	15
Interview guide for comparison sites .....	30	1	1.5	45	15
Focus group discussion guide for Pathways youth (treatment youth) .....	50	1	1.5	75	25
Focus group discussion guide for comparison youth .....	50	1	1.5	75	25
Working Alliance Inventory for Pathways youth .....	400	1	.08	32	11
Working Alliance Inventory for Pathways case workers .....	40	10	.08	32	11

*Estimated Total Annual Burden Hours:* 485.

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper

performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility,

and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information

technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Authority:** Section 105(b)(5) of the Child Abuse Prevention and Treatment Act (CAPTA) of 1978 (42 U.S.C. 5106(b)(5)), as amended by the CAPTA Reauthorization Act of 2010 (Pub. L. 111–320).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020–28886 Filed 12–29–20; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–D–1804]

#### Product Labeling for Laparoscopic Power Morcellators; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled “Product Labeling for Laparoscopic Power Morcellators.” This guidance updates recommended “Contraindications” and “Warnings” information to be included in product labeling to reflect the state of the science and available technology regarding use of laparoscopic power morcellators (LPMs). These labeling recommendations are intended to enhance, but not replace, the physician-patient discussion of the benefits and risks of use of LPMs that uniquely pertain to individual patients.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 30, 2020.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2014–D–1804 for “Product Labeling for Laparoscopic Power Morcellators.” 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 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Product Labeling for Laparoscopic Power Morcellators” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Veronica Price, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2659, Silver Spring, MD 20993–0002, 301–796–6538.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Following issuance of the 2014 guidance document entitled “Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators,” FDA has continued to consider new scientific information and the input of stakeholders. Additional scientific information is available that stratifies the risks of an undetected uterine cancer in women with presumed fibroids based on age.

FDA also considered scientific information pertaining to the risk of spreading benign uterine tissue beyond the uterus during gynecologic surgeries