recommendations in the draft guidance, these establishments could submit a single process form that covers all container sizes of a product. Thus, the estimated number of annual voluntary process filings is 2,725 process filings (2,251 products/892 establishments x 540 establishments x 2 = 2,725.4 process filings, rounded to 2,725). On average, we calculate that the annual frequency of reporting would be 5 process filings (2,725 process filings/540 establishments = 5.04, rounded to 5). For the purpose of this analysis, we use the rounded number of process filings (i.e., 5) and, thus, calculate that the estimated recurring reporting burden for submission of Form 2541a is 2,700 process filings rather than 2,725 process filings (540 establishments x 5 process filings per establishment = 2,700 process filings), resulting in an annual reporting burden of 891 hours (2,700 process filings x 0.33 hours/process filing = 891 hours). Table 2 of this document includes the estimated one-time and recurring reporting burden for establishments that voluntarily submit process filings for foods that they conclude are acid foods or fermented foods that are not also acidified foods.

We also estimate that all 3,000 establishments that process foods that they conclude are acid foods or fermented foods that are not also acidified foods and voluntarily register their establishments will submit a total of 30,000 process filings in the first year—i.e., twice as many process filings as would be submitted, on average, by any given establishment on an annual basis (2 x 5 process filings/establishment on an annual basis x 3,000 establishments = 30,000 process filings), resulting in a one-time reporting burden of 9,900 hours (30,000 process filings x 0.33 hours/establishment = 9,900 hours). Table 2 of this document includes the estimated one-time reporting burden for establishments that voluntarily submit process filings for fermented foods and/or acid foods.

TABLE 2.—ESTIMATED ONE-TIME AND RECURRING REPORTING BURDEN[1]

Activity	No. of Reporters	Annual Frequency per Reporter	Total Annual Records	Hours per Record	Total Hours
Registration (Form FDA 2541)[2]	2,250	1	2,250	0.17	383
Registration (Form FDA 2541)	180	1	180	0.17	31
Process filing (Form FDA 2541a)[2]	3,000	10	30,000	0.33	9,900
Process filing (Form FDA 2541a)	540	5	2,700	0.33	891
Total one-time burden					10,283
Total recurring burden					922

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time reporting burden.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov* or at *http://www.fda.gov/FoodGuidances*.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to Web site after this document publishes in the **Federal Register**.)

1. Codex Alimentarius Commission, Recommended International Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods CAC/RCP 23–1979, Rev. 2 (1993), Available at *http://www.codexalimentarius.net/download/standards/24/CXP_023e.pdf*, Accessed and printed on June 17, 2008.

Dated: September 21, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24089 Filed 9–24–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1820–NC]

Medicare and Medicaid Programs; Announcement of an Application from a Hospital Requesting Waiver for Organ Procurement Service Area

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

ACTION: Notice with comment period.

SUMMARY: A hospital has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated Organ Procurement Organization (OPO). The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 26, 2010.

ADDRESSES: In commenting, please refer to file code CMS–1820–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1820–NC, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Department of Health and Human Services, Attention: CMS–1820–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Mark A. Horney, (410) 786–4554.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Organ Procurement Organizations (OPOs) are not-for-profit organizations that are responsible for the procurement, preservation, and transport of transplantable organs to transplant centers throughout the country. Qualified OPOs are designated by the Centers for Medicare & Medicaid Services (CMS) to recover or procure organs in CMS-defined exclusive geographic service areas, pursuant to section 371(b)(1) of the Public Health Service Act (42 U.S.C. 273(b)(1) and our regulations at 42 CFR 486.306. Once an OPO has been designated for an area, hospitals in that area that participate in Medicare and Medicaid are required to work with that OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR § 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every participating hospital must have an agreement to identify potential donors only with its designated OPO.

However, section 1138(a)(2)(A) of the Act provides that a hospital may obtain a waiver of the above requirements from the Secretary under certain specified conditions. A waiver allows the hospital to have an agreement with an OPO other than the one initially designated by CMS, if the hospital meets certain conditions specified in section 1138(a)(2)(A) of the Act. In addition, the Secretary may review additional criteria described in section 1138(a)(2)(B) of the Act to evaluate the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that in granting a waiver, the Secretary must determine that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider, among other factors: (1) Cost-effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. Under section 1138(a)(2)(D) of the Act, the Secretary is required to publish a notice of any waiver application received from a hospital within 30 days of receiving the application, and to offer interested parties an opportunity to comment in writing during the 60-day period beginning on the publication date in the **Federal Register**.

The criteria that the Secretary uses to evaluate the waiver in these cases are the same as those described above under sections 1138(a)(2)(A) and (B) of the Act and have been incorporated into the regulations at § 486.308(e) and (f).

II. Waiver Request Procedures

In October 1995, we issued a Program Memorandum (Transmittal No. A–95–11) detailing the waiver process and discussing the information hospitals must provide in requesting a waiver. We indicated that upon receipt of a waiver request, we would publish a **Federal Register** notice to solicit public comments, as required by section 1138(a)(2)(D) of the Act.

According to these requirements, we will review the request and comments received. During the review process, we may consult on an as-needed basis with the Health Resources and Services

Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request additional clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Requests

As permitted by § 486.308(e), the following hospital has requested a waiver in order to enter into an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located: War Memorial Hospital (Medicare provider number 51–1309), of Berkeley Springs, West Virginia, is requesting a waiver to work with:

LifeNet Health, 1864 Concert Drive, Virginia Beach, VA 23453.

The Hospital's Designated OPO is:

Center for Organ Recovery and Education, RIDC Park, 204 Sigma Drive, Pittsburgh, PA 15238.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance, and Program No. 93.778, Medical Assistance Program)

Dated: *September 21, 2010.*

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–24100 Filed 9–24–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1825–NC]

Medicare and Medicaid Programs; Announcement of Application from Hospital Requesting Waiver for Organ Procurement Service Area

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

ACTION: Notice with comment period.

SUMMARY: A hospital has requested a waiver of statutory requirements that would otherwise require the hospital to enter into an agreement with its designated Organ Procurement Organization (OPO). The request was made in accordance with section 1138(a)(2) of the Social Security Act (the Act). This notice requests comments from OPOs and the general public for our consideration in determining whether we should grant the requested waiver.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on November 26, 2010.

ADDRESSES: In commenting, please refer to file code CMS–1825–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–1825–NC, P.O. Box 8010, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Department of Health and Human Services, *Attention:* CMS–1825–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to one of the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

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I. Background

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