ANNUAL BURDEN ESTIMATES—Continued

| Instrument | Number of respondents (total over request period) | Number of responses per respondent (total over request period) | Average burden per response (in hours) | Total burden (in hours) | Annual burden (in hours) |
|---|---|---|---|---|---|
| Project Directors and Leaders Site Visit Discussion Guide (Instrument 2) | 60 | 1 | 2 | 120 | 60 |
| Staff Site Visit Discussion Guide (Instrument 3) | 108 | 1 | 1.5 | 162 | 81 |
| Nonprofit or Partner Organizations Site Visit Discussion Guide (Instrument 4) | 72 | 1 | 1 | 72 | 36 |

*Estimated Total Annual Burden Hours:* 189.

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the agency's functions, 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 information collection on respondents, including through using 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:** 42 U.S.C. 613, 42 U.S.C. 1397, 42 U.S.C. 711, and 42 U.S.C. 603(a)(2).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020–26248 Filed 11–27–20; 8:45 am]

**BILLING CODE 4184–09–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request; Healthy Marriage and Responsible Fatherhood Performance Measures and Additional Data Collection (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), Office of Family Assistance (OFA), has had administrative responsibility for federal funding of programs that strengthen families through healthy marriage and relationship education and responsible fatherhood programming since 2006 through the Healthy Marriage (HM) and Responsible Fatherhood (RF) Grant Programs. ACF required the 2015 cohort of HMRF grantees—which received 5-year grants in September 2015—to collect and report performance measures about program operations, services, and clients served (OMB #0970–0460). A performance measures data collection system called nFORM (Information, Family Outcomes, Reporting, and Management) was implemented with the 2015 cohort to improve the efficiency of data collection and reporting and the quality of data. This system allows for streamlined and standardized submission of grantee performance data through regular progress reports and supports grantee-led and federal research projects. ACF will continue performance measure and other data collection activities for the HMRF grant program with a new cohort of grantees who received 5-year awards in September 2020. ACF is requesting comment on a new data collection to support these activities with the 2020 HMRF grantee cohort. ACF has made changes to the previous cohort's data collection instruments and performance reports for use in the new cohort. This new grantee cohort is expected to begin collecting performance measure data and reporting to ACF in April 2021.

**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.* 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:* ACF proposes to collect a set of performance measures from all HMRF grantees. These measures collect standardized information in the following areas:

- Applicant characteristics;
- Program operations;
- Service delivery; and
- Participant outcomes:
  - Entrance survey, with five versions: (1) HM Program Entrance Survey for Adult-Focused Programs, (2) HM Program Entrance Survey for Youth-Focused Programs, (3) RF Program Entrance Survey for Community-Based Fathers, (4) RF Program Entrance Survey for Community-Based Mothers, and (5) RF Program Entrance Survey for Reentering Fathers.
  - Exit survey, with five versions: (1) HM Program Exit Survey for Adult-Focused Programs, (2) HM Program Exit Survey for Youth-Focused Programs, (3) RF Program Exit Survey for Community-Based Fathers, (4) RF Program Exit Survey for Community-Based Mothers, and (5) RF Program Exit Survey for Reentering Fathers.

The measures used by the 2015 grantee cohort were developed in 2014 after extensive review of the research literature and grantees' past measures. The performance measures, data collection instruments, and data collection system were revised in 2020 based on a targeted analysis of existing measures, feedback from key stakeholders, and discussions with ACF staff and the 2015 cohort of grantees.

ACF required the 2015 cohort of grantees to submit data on these standardized measures on a quarterly basis and proposes the same requirement for the 2020 cohort. In addition to the performance measures mentioned above, ACF proposes to repeat collection for these data submissions:

- Semi-annual Performance Progress Report (PPR), with two versions: (1) Performance Progress Report for HM

Programs, and (2) Performance Progress Report for RF Programs; and

• Quarterly Performance Report (QPR), with two versions: (1) Quarterly Performance Progress Report for HM Programs, and (2) Quarterly Performance Progress Report for RF Programs.

Grantees in the new cohort will also be required to engage in continuous quality improvement (CQI) planning and implementation using a proposed CQI plan template developed by ACF. The estimated burden for completing and updating this template is included in the table below.

*Respondents:* Respondents include HM and RF grantee staff and program applicants and participants (participants are called ''clients'').

ANNUAL BURDEN ESTIMATES

| Instrument | Respondent | Number of respondents (total over request period) | Annual number of respondents | Number of responses per respondent (total over request period) | Average burden per response (in hours) | Total burden (in hours) | Annual burden (in hours) |
|---|---|---|---|---|---|---|---|
| 1: Applicant Characteristics | Program applicants | 273,839 | 91,280 | 1 | 0.25 | 68,460 | 22,820 |
| | Program staff | 408 | 408 | 224 | 0.10 | 27,384 | 9,128 |
| 2: Program Operations | Program staff | 136 | 136 | 12 | 0.32 | 526.32 | 175.44 |
| 3: Service Delivery Data | Program staff | 2,040 | 2,040 | 126 | 0.50 | 128,706 | 42,902 |
| 4: Entrance and Exit Surveys | Program clients (entrance) | 257,409 | 85,803 | 1 | 0.42 | 108,111.78 | 36,037.26 |
| | Program clients (exit) | 169,965 | 56,655 | 1 | 0.42 | 71,385 | 23,795 |
| | Program staff (entrance and exit on paper). | 32 | 32 | 1,169 | 0.10 | 11,220 | 3,740 |
| 5: Semi-annual Performance Progress Report (PPR). | Program staff | 136 | 136 | 6 | 3 | 2,448 | 816 |
| 6: Quarterly Performance Report (QPR). | Program staff | 136 | 136 | 6 | 1 | 816 | 272 |
| 7: CQI Plan | Program staff | 136 | 136 | 3 | 4 | 1,632 | 544 |

*Estimated Total Annual Burden Hours:* 140,230.

*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:** Sec. 403. [42 U.S.C. 603].

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2020–26266 Filed 11–27–20; 8:45 am]

**BILLING CODE 4184–73–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–N–1337]**

### John Kapoor: Final Debarment Order

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring John Kapoor from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that John Kapoor was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. John Kapoor was given notice of the proposed permanent debarment and an opportunity to request a hearing to show why he should not be debarred. Mr. Kapoor, through counsel, submitted a letter to FDA, which commented on some of the factual circumstances surrounding the case. In the letter, he also stated that he did not intend to request a hearing nor, however, would he acquiesce to debarment. As of August 26, 2020 (30 days after receipt of the notice), Mr. Kapoor has not requested a hearing. His failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is applicable November 30, 2020.

**ADDRESSES:** Submit applications for special termination of debarment to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or *https://www.regulations.gov.*

**FOR FURTHER INFORMATION CONTACT:** Jaime Espinosa, (ELEM–4029) Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, *debarments@fda.hhs.gov,* 240–402–8743.

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On January 23, 2020, Mr. Kapoor was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after a jury verdict, to one count of Racketeering Conspiracy in violation of 18 U.S.C. 1962(d). The pattern of racketeering activity he was convicted of included engaging in multiple acts of mail fraud (18 U.S.C. 1341) and wire fraud (18 U.S.C. 1343).

The factual basis for this conviction is as follows: Mr. Kapoor was the founder and majority owner of Insys Therapeutics Inc. (Insys), a Delaware Corporation, with headquarters in Chandler, Arizona. In addition, he held executive management positions at Insys, including Executive Chairman of the Board of Directors and, for a time,