

11. Memorandum to File entitled, "CVM's review of documents Phibro submitted to Docket No. FDA-2021-N-1326 and presentation at the March 10, 2022 Part 15 Hearing" (October 30, 2023).
12. Memorandum to File entitled, "CVM review of comments on the Zhang Article that Phibro references in the document submitted to the Part 15 Hearing docket under cover letter dated June 9, 2022, and entitled, 'Phibro Animal Health Corporation's Reply to the January 6, 2022 'CVM Response to Phibro Animal Health Corporation's September 18, 2020 Comments on CVM's July 20, 2020 Proposed Order to Revoke the Regulatory Method for Carbadox''" (October 30, 2023).
13. Zhang, J., W. Qu, Z. Wang, and Y. Pan, "Metabolism and Tissue Depletion of Carbadox in Swine, Broilers, and Rats," *ACS Agricultural Science & Technology* 2022 2(3), 477–485. Abstract is available at <https://pubs.acs.org/doi/abs/10.1021/acsagscitech.1c00260>.

Dated: November 1, 2023.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms, OMB No. 0915-0126—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than December 7, 2023.

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 Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, Joella Roland, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners—45 CFR Part 60 Regulations and Forms, OMB No. 0915-0126—Revision.

Abstract: This is a request for a revision of OMB approval of the information collection contained in regulations found in 45 CFR part 60 governing the National Practitioner Data Bank (NPDB) and the forms to be used in registering with, reporting information to, and requesting information from the NPDB. Administrative forms are also included to aid in monitoring compliance with federal reporting and querying requirements. Responsibility for NPDB implementation and operation resides in HRSA's Bureau of Health Workforce.

The intent of the NPDB is to improve the quality of health care by encouraging entities such as hospitals, state licensing boards, professional societies, and other eligible entities¹ providing health care services to identify and discipline those who engage in unprofessional behavior, and to restrict the ability of incompetent health care practitioners, providers, or suppliers to move from state to state

¹ "Other eligible entities" that participate in the NPDB are defined in the provisions of Title IV, Section 1921, Section 1128E, and implementing regulations. In addition, a few federal agencies also participate with the NPDB through federal memorandums of understanding. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity. Each eligible entity must certify its eligibility in order to report to the NPDB, query the NPDB, or both. Information from the NPDB is available only to those entities specified as eligible in the statutes and regulations. Not all entities have the same reporting requirements or level of query access.

without disclosure or discovery of previous damaging or incompetent performance. It also serves as a fraud and abuse clearinghouse for the reporting and disclosing of certain final adverse actions taken against health care practitioners, providers, or suppliers by health plans, federal agencies, and state agencies (excluding settlements in which no findings of liability have been made). Users of the NPDB include reporters (entities that are required to submit reports) and queriers (entities and individuals that are authorized to request information).

The reporting forms, request for information forms (query forms), and administrative forms (used to monitor compliance) are accessed, completed, and submitted to the NPDB electronically through the NPDB website at <https://www.npdb.hrsa.gov/>. All reporting and querying is performed through the secure portal of this website. This revision proposes changes to improve navigation through the secure portal.

A 60-day notice published in the **Federal Register** on August 22, 2023, vol. 88, No. 161; pp. 57118–120. There were no public comments.

Need and Proposed Use of the Information: The NPDB acts primarily as a flagging system; its principal purpose is to facilitate comprehensive review of practitioners' professional credentials and background. Information is collected from, and disseminated to, eligible entities (entities that are entitled to query and/or report to the NPDB as authorized in Title 45 CFR part 60 of the Code of Federal Regulations) on the following: (1) medical malpractice payments, (2) licensure actions taken by Boards of Medical Examiners, (3) state licensure and certification actions, (4) federal licensure and certification actions, (5) negative actions or findings taken by peer review organizations or private accreditation entities, (6) adverse actions taken against clinical privileges, (7) federal or state criminal convictions related to the delivery of a health care item or service, (8) civil judgments related to the delivery of a health care item or service, (9) exclusions from participation in federal or state health care programs, and (10) other adjudicated actions or decisions. It is intended for NPDB information to be considered with other relevant information in evaluating credentials of health care practitioners, providers, and suppliers.

Likely Respondents: Eligible entities or individuals that are entitled to query and/or report to the NPDB as authorized in regulations found at 45 CFR part 60.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize

technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search

data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
§ 60.6: Reporting errors, omissions, revisions or whether an action is on appeal.	Correction, Revision-to-Action, Void, Notice of Appeal (manual).	8,897	1	8,897	.2500	2,225
	Correction, Revision-to-Action, Void, Notice of Appeal (automated).	14,982	1	14,982	.0003	5
§ 60.7: Reporting medical malpractice payments.	Medical Malpractice Payment (manual).	11,080	1	11,080	.7500	8,310
	Medical Malpractice Payment (automated).	447	1	447	.0003	1
§ 60.8: Reporting licensure actions taken by Boards of Medical Examiners.	State Licensure or Certification (manual).	13,996	1	13,996	.7500	10,497
§ 60.9: Reporting licensure and certification actions taken by States.	State Licensure or Certification (automated).	14,636	1	14,636	.0003	5
§ 60.10: Reporting Federal licensure and certification actions.	DEA/Federal Licensure	555	1	555	.7500	417
§ 60.11: Reporting negative actions or findings taken by peer review organizations or private accreditation entities.	Peer Review Organization	10	1	10	.7500	8
	Accreditation	10	1	10	.7500	8
§ 60.12: Reporting adverse actions taken against clinical privileges.	Title IV Clinical Privileges Actions.	782	1	782	.7500	587
	Professional Society	27	1	27	.7500	21
§ 60.13: Reporting Federal or State criminal convictions related to the delivery of a health care item or service.	Criminal Conviction (Guilty Plea or Trial) (manual).	979	1	979	.7500	735
	Criminal Conviction (Guilty Plea or Trial) (automated).	406	1	406	.0003	1
	Deferred Conviction or Pre-Trial Diversion.	60	1	60	.7500	45
	Nolo Contendere (no contest plea).	75	1	75	.7500	57
	Injunction	10	1	10	.7500	8
§ 60.14: Reporting civil judgments related to the delivery of a health care item or service.	Civil Judgment	6	1	6	.7500	5
§ 60.15: Reporting exclusions from participation in Federal or State health care programs.	Exclusion or Debarment (manual).	1,287	1	1,287	.7500	966
	Exclusion or Debarment (automated).	2,610	1	2,610	.0003	1
§ 60.16: Reporting other adjudicated actions or decisions.	Government Administrative (manual).	1,367	1	1,367	.7500	1,026
	Government Administrative (automated).	632	1	632	.0003	1
	Health Plan Action	391	1	391	.7500	294

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Regulation citation	Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours (rounded up)
§ 60.17 Information which hospitals must request from the National Practitioner Data Bank.	One-Time Query for an Individual (manual).	1,790,355	1	1,790,355	.0800	143,229
§ 60.18 Requesting Information from the NPDB.	One-Time Query for an Individual (automated).	3,945,360	1	3,945,360	.0003	1,184
	One-Time Query for an Organization (manual).	77,095	1	77,095	.0800	6,168
	One-Time Query for an Organization (automated)	33,993	1	33,993	.0003	11
	Self-Query on an Individual	223,589	1	223,589	.4200	93,908
	Self-Query on an Organization.	879	1	879	.4200	370
	Continuous Query (manual)	1,030,917	1	1,030,917	.0800	82,474
	Continuous Query (automated).	900,661	1	900,661	.0003	271
§ 60.21: How to dispute the accuracy of NPDB information.	Subject Statement and Dispute.	4,015	1	4,015	.7500	3,012
	Request for Dispute Resolution.	83	1	83	8.0000	664
Administrative	Entity Registration (Initial) ..	3,252	1	3,252	1.0000	3,252
	Entity Registration (Renewal & Update).	12,990	1	12,990	.2500	3,248
	State Licensing Board Data Request.	87	1	87	10.5000	914
	State Licensing Board Attestation.	360	1	360	1.0000	360
	Authorized Agent Attestation.	171	1	171	1.0000	171
	Health Center Attestation ...	724	1	724	1.0000	724
	Hospital Attestation	3,238	1	3,238	1.0000	3,238
	Medical Malpractice Payer, Peer Review Organization, or Private Accreditation Organization Attestation.	267	1	267	1.0000	267
	Other Eligible Entity Attestation.	4,790	1	4,790	1.0000	4,790
	Corrective Action Plan (Entity).	10	1	10	.0800	1
	Reconciling Missing Actions	1,371	1	1,371	.0800	110
	Agent Registration (Initial) ..	78	1	78	1.0000	78
	Agent Registration (Renewal & Update).	318	1	318	.0800	26
	Electronic Funds Transfer Authorization.	734	1	734	.0800	59
	Authorized Agent Designation.	183	1	183	.2500	46
	Account Discrepancy	4	1	4	.2500	1
	New Administrator Request	215	1	215	.0800	18
	Purchase Query Credits	5,590	1	5,590	.0800	448
	Education Request	10	1	10	.0800	1
	Account Balance Transfer ..	10	1	10	.0800	1
	Missing Report From Query Form.	10	1	10	.0800	1
	TOTAL	8,114,604	8,114,604	374,268

Maria G. Button,

Director, Executive Secretariat.

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