

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Food Safety and Applied Nutrition (CFSAN), including its Office of the Center Director (OCD), has modified their organizational structure. The new organizational structure was approved by the Deputy Secretary of Health and Human Services and effective on November 24, 2021.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD 20705-4304, 301-796-3843.

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect FDA's reorganization of CFSAN to elevate its OCD's International Affairs Staff to the Office of International Engagement.

The primary purpose of this reorganization is to establish the Office of International Engagement (OIE) within CFSAN. With the establishment of OIE, the current structure of the International Affairs Staff (IAS) (currently under OCD) would dissolve and its resources and functions absorbed into OIE. OIE (currently IAS) would maintain its current roles and responsibilities as the Center's focal point for engaging in international activities.

The establishment of the proposed OIE aligns with broader organizational initiatives and priorities due to the establishment of the Office of Global Policy and Strategy (OGPS) and the Associate Commissioner for Imported Food Safety in the Office of Food Policy and Response (OFPR). OIE (currently IAS) has primary responsibility for the Center's coordination of international

engagement for all its mission areas and coordinates with OGPS and OFPR daily. The establishment of OIE will streamline and improve work processes for better effectiveness and efficiency. All OIE work activities cut across Foods program offices and agency lines and requires central coordination and support, and OIE, by having more prominence as an Office in the Center, will enhance this effort. Additionally, the efficiencies gained by the reorganization aligns with HHS Strategic Goal 5: Promote Effective and Efficient Management and Stewardship; Strategic Objective 5.1: Ensure responsible financial management and Strategic Objective 5.2: Manage human capital to achieve the HHS mission.

The Food and Drug Administration's Center for Food Safety and Applied Nutrition's Office of the Center Director and Office of International Engagement has been restructured as follows:

DCEA. ORGANIZATION. The Center for Food Safety and Applied Nutrition's, Office of the Center Director is headed by the Center Director and includes the following:

Office of the Center Director (DCEA)

DCEO. ORGANIZATION. The Center for Food Safety and Applied Nutrition's, Office International Engagement is headed by the Director, Office of International Engagement, and includes the following:

Public Health and Trade Staff (DCEO1)
Regulatory Cooperation and Partnerships Staff (DCEO2)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA's Staff Manual Guide (SMG). Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>.
Authority: 44 U.S.C. 3101.

Dated: October 22, 2021.

Andrea Palm,

Deputy Secretary of Health and Human Services.

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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: Modification of the National Practitioner Data Bank Code Lists

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

ACTION: Request for public comment on the National Practitioner Data Bank's (NPDB) Basis for action code lists for licensure and certification actions.

SUMMARY: HRSA, a sub-agency of the Department of Health and Human Services, is announcing a change in the NPDB Basis for Action Code Lists for Federal Licensure, and State Licensure or Certification Actions to individuals and entities authorized to report and request information from the NPDB. These changes will contain updated codes and code use guidance applicable to organizations submitting Federal Licensure, or State Licensure or Certification Actions. The code modifications and guidance are intended to provide improved report accuracy and promote a better understanding of the use and application of the basis of action codes available for report submission. The modifications are based in part upon recommendations made through a collaborative effort with NPDB industry partners: the Federation of State Boards of Physical Therapy, the National Council of State Boards of Nursing, the Federation of State Medical Boards, the Association of State and Provincial Psychology Boards, the National Board for Certification in Occupational Therapy, the Association of Social Work Boards, and the National Association of Boards of Pharmacy. Basis for Action codes help to accurately describe the basis for licensure actions reported. Basis for Action codes have no impact on the licensure action reported or the applicability of NPDB reporting criteria. New, modified, and retired codes have no impact on historical reporting. The coding of previously submitted reports will remain unchanged.

DATES: Submit comments no later than February 2, 2022.

ADDRESSES: Written and/or electronic comments should be submitted to NPDBPolicy@hrsa.gov by February 2, 2022.

FOR FURTHER INFORMATION CONTACT: David Loewenstein, Director, Division of Practitioner Data Bank, Bureau of Health Workforce, HRSA, (301) 443-2300, NPDBPolicy@hrsa.gov.

SUPPLEMENTARY INFORMATION: The current published NPDB Code Lists are

available on the NPDB website: <https://www.npdb.hrsa.gov/hcorg/codes.jsp>.

The NPDB is authorized by the Health Care Quality Improvement Act of 1986 (the Act), Title IV of Public Law 99-660, as amended (42 U.S.C. 11101 *et seq.*). Further, two additional statutes expanded the scope of the NPDB—Section 1921 of the Social Security Act,

as amended (42 U.S.C. 1396r-2) and Section 1128E of the Social Security Act, as amended (42 U.S.C. 1320a-7e). Information collected under the Section 1128E authority was consolidated within the NPDB pursuant to Section 6403 of the Affordable Care Act, Public Law 111-148; this consolidation became effective on May 6, 2013.

PROPOSED NPDB CODE LISTS MODIFICATIONS

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
Non-Compliance With Requirements						
48	44	U	Default on Health Education Loan or Scholarship Obligations.	Fails to meet health education loan or scholarship obligations.	Explanation: Use only if your state has this requirement.
48	35	U	Drug Screening Violation.	Fails a drug screening test	Examples: <ul style="list-style-type: none"> • Failure of a required drug screen or failure to comply with the requested drug screen; • Sample is adulterated, invalid or substituted; • Failure of a drug screen for employment.
48	A2	U	Failure to Comply With Continuing Education or Competency Requirements.	Fails to meet the continuing education or competency requirements for renewal or reinstatement.	Examples: <ul style="list-style-type: none"> • Failure to complete state requirements; • If the licensee falsified meeting the requirements, then also use Code E3.
48	31	M	Failure to Comply With Health and Safety Requirements.	Failure to comply with health and safety requirements or state health code.	Fails to comply with federal, state, local, or institutional safety requirements or state health codes.	Examples: <ul style="list-style-type: none"> • Failure to meet required health tests or inoculations. DO NOT use for: <ul style="list-style-type: none"> • Violation of infection control, sterile technique, and isolation requirements; instead use Code 17.
48	23	U	Failure to Cooperate With Board Investigation.	Interferes with an investigation or disciplinary proceeding by withholding information, deliberate misrepresentation of facts or attempts to suppress evidence.	Examples: <ul style="list-style-type: none"> • Failure to respond or to respond adequately to board investigation requests; • Failure to cooperate with the board as a witness to an investigation.
48	50	M	Failure to Maintain Adequate or Accurate Records.	Failure to Maintain or Provide Adequate or Accurate Medical Records, Financial Records or Other Required Information.	Fails to meet documentation requirements for maintaining patient care, financial or other records.	Example: <ul style="list-style-type: none"> • Failure to provide adequate documentation of treatment/care in the medical record.
48	45	R	Failure to Maintain Records or Provide Medical, Financial or Other Required Information.	Redundant code, use code 50.	
48	A3	R	Failure to Meet Licensing Board Reporting Requirements.	Use code A1.	

PROPOSED NPDB CODE LISTS MODIFICATIONS—Continued

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
48	A1	M	Failure to Meet the Initial Requirements of a License.	Failure to Meet Licensure Requirements/Licensing Board Reporting Requirements.	Fails to meet board specified licensing requirements or provide requested/required information. NOTE: Do not report or include threshold criteria: the accepted minimum licensure requirements that are universally applied without decision or exception. Examples include academic degrees, criminality, certifications, or training hours or requirements.	Examples: <ul style="list-style-type: none"> • Failure to meet board requirements other than threshold licensure requirements; • Failure to provide information required by the board (e.g., criminal conviction, loss of job due to unprofessional conduct, disciplinary action in another jurisdiction, change of address etc.); • Failure to report any renewal and reinstatement requirements; • Failure to report another health care professional as required by mandatory reporting obligations. DO NOT use for: <ul style="list-style-type: none"> • Failure to meet threshold criteria: the accepted minimum licensure requirements that are universally applied without decision or exception. Examples include academic degrees, criminality, certifications, or training hours or requirements; • Continuing Competency requirements; instead use Code A2; • Obtaining a license but failing to disclose required information on the application; instead use Code E4.
48	37	M	Failure to Pay Child Support/Delinquent Child Support.	Failure to Pay or Delinquent with Child Support.	Fails to meet child support responsibilities	Explanation: Use only if your state has this requirement.
48	39	M	License Revocation, Suspension or Other Disciplinary Action Taken by a Federal, State or Local Licensing Authority.	Disciplinary Action Taken by another Federal, State or Local Licensing Authority.	Grounds for action are based on action(s) taken by another state licensing, federal, or other authority.	Examples: <ul style="list-style-type: none"> • A licensee is licensed in another jurisdiction and has final disciplinary action by that authority. DO NOT use for: <ul style="list-style-type: none"> • Your own jurisdiction's disciplinary action.
48	29	U	Practicing Beyond the Scope of Practice.	Provides care not permitted under the terms of a license or within the licensee's level of education, training, knowledge, skills, experience, or demonstrated competency.	Examples: <ul style="list-style-type: none"> • Performing practice interventions, whether advanced or not, without required license, certification or training; • Failure to work with adequate/required supervision. DO NOT use for: <ul style="list-style-type: none"> • Substandard or Inadequate Care for incompetence issues; instead use Code F6; • Negligence for not exercising reasonable judgement; instead use Code 13.
48	24	U	Practicing With an Expired License.	Fails to renew license and continues to practice.	Example: <ul style="list-style-type: none"> • Failure to renew license intentionally or unintentionally and continues to practice. DO NOT use for: <ul style="list-style-type: none"> • A new graduate who fails the exam and continues to practice under a temporary license which expired on getting exam results; instead use Code A4; • Someone who has had their license revoked and continues to practice; instead use Code A4.
48	25	R	Practicing Without a License.	Redundant code, use code A4.	
48	A4	U	Practicing Without a Valid License.	Practices without obtaining the proper authorization.	Examples: <ul style="list-style-type: none"> • Failure to cease practice after a temporary license or permit has expired; • Applicant or licensee practices after passing the exam but before licensing authority has issued license. DO NOT use for: <ul style="list-style-type: none"> • Someone whose license has expired; instead use Code 24.

PROPOSED NPDB CODE LISTS MODIFICATIONS—Continued

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
48	A6	U	Violation of Federal or State Statutes, Regulations or Rules.	Violation of federal or state statutes, regulations or rules not associated with the practice act.	Examples: <ul style="list-style-type: none"> • Failure to meet alimony responsibilities; • Failure to report abuse or other federal or state requirement. DO NOT use for: <ul style="list-style-type: none"> • Violations of the state practice act; • Failure to meet child support; instead use Code 37.
48	36	U	Violation of Federal or State Tax Code.	Fails to meet federal or state tax code responsibilities.	Example: <ul style="list-style-type: none"> • Failure to meet federal or state tax code responsibilities. Explanation: <ul style="list-style-type: none"> • Use with appropriate criminal conviction or adjudication code if applicable.
48	84	R	Violation of State Health Code.	Redundant code, use code 31.	
48	A5	U	Violation of or Failure to Comply With Licensing Board Order.	Fails to comply with a specific board order.	Example: <ul style="list-style-type: none"> • Failure to meet terms of a board order.

Criminal Conviction or Adjudication

49	19	U	Criminal Conviction	Convicted of a felony or misdemeanor crime.	Example: <ul style="list-style-type: none"> • Convicted of a felony or misdemeanor crime. Explanation: <ul style="list-style-type: none"> • Use this code along with the appropriate code to describe the underlying violation of law; • If there is no appropriate code, describe the criminal conviction in the narrative.
49	18	U	Deferred Adjudication.	Plea that avoids criminal conviction by meeting certain probationary requirements.	Explanation: <ul style="list-style-type: none"> • Deferred adjudication involves probation, treatment programs, and/or some type of community supervision; • Use this code along with the appropriate code to describe the underlying violation of law; • If there is no appropriate code, describe the violation in the narrative.
49	B1	U	Nolo Contendere Plea.	Plea of no contest, same consequence as a guilty plea.	
49	I1	U	Diverted Conviction	Pre-trial sentencing that avoids criminal conviction by completing a court ordered intervention program.	Explanation: <ul style="list-style-type: none"> • Pretrial sentencing includes participating in a treatment or rehabilitation program; • Use this code along with the appropriate code to describe the underlying violation of law; • If there is no appropriate code, describe the violation in the narrative.

Confidentiality, Consent or Disclosure Violations

50	C3	U	Breach of Confidentiality.	Releases or obtains patient information without appropriate authorization.	Example: <ul style="list-style-type: none"> • Releasing or obtaining patient information without appropriate authorization.
50	C2	U	Failure to Comply With Patient Consultation Requirements.	Fails to meet requirements for consultation with other health care providers or refer when appropriate.	Examples: <ul style="list-style-type: none"> • Failure to consult with or refer to an appropriate licensee when care is beyond the licensee's level of training, skill, expertise or license; • Failure to keep a referring source informed of the patient's progress.
50	C1	U	Failure to Obtain Informed Consent.	Fails to meet informed consent requirements.	Examples: <ul style="list-style-type: none"> • Failure to explain procedures and possible complications; • Failure to obtain permission of the patient to evaluate and treat; as well as failure to obtain parental permission for a minor.

PROPOSED NPDB CODE LISTS MODIFICATIONS—Continued

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
Misconduct or Abuse						
51	D4	U	Abusive Conduct Toward Staff.	Engages in the maltreatment of a colleague or employee which can include mental, physical and/or verbal abuse.	Example: <ul style="list-style-type: none"> Engaging in the maltreatment of a colleague or employee (i.e. mental, physical and/or verbal abuse). DO NOT use for: <ul style="list-style-type: none"> Sexual abuse; instead use Code D1.
51	D7	M	Conduct Evidencing Ethical Unfitness.	Conduct Evidencing Ethical or Moral Unfitness.	Engages in conduct that is unethical or violates the ethical code of conduct.	Examples: <ul style="list-style-type: none"> Failure to respect the beliefs and values of patient without prejudice; Failure to protect or disregards the rights, health, safety of the patient.
51	D6	R	Conduct Evidencing Moral Unfitness.	Use Code D7.	
51	71	U	Conflict of Interest	Fails to disclose information that presents a conflict of interest.	Examples: <ul style="list-style-type: none"> Failure to disclose ownership; Failure to provide freedom of choice.
51	D5	U	Disruptive Conduct	Engages in conduct which interferes with or disrupts normal operations in the patient care setting or workplace.	Example: <ul style="list-style-type: none"> Interferes with or disrupts normal operations in the patient care setting or workplace. DO NOT use for: <ul style="list-style-type: none"> Patient abuse; instead use Code 14.
51	D3	U	Exploiting a Patient for Financial Gain.	Exploits a professional relationship with a patient to benefit financially beyond that which is reasonable for the provision of treatment.	Examples: <ul style="list-style-type: none"> Takes advantage of the patient relationship by selling products that are not needed for treatment or could be obtained for a lower price; Takes advantage of the patient relationship by inviting them into business opportunities. DO NOT use for: <ul style="list-style-type: none"> Excessive or fraudulent billing; instead use Code 55.
51	16	U	Misappropriation of Patient Property or Other Property.	Uses a patient's or coworker's property or the property of a facility without approval or permission.	Example: <ul style="list-style-type: none"> Using or taking a patient's or coworker's property or the property of a facility without approval or permission. Explanation: <ul style="list-style-type: none"> Also use Code 19 Criminal Conviction if there has been a criminal conviction. DO NOT use for: <ul style="list-style-type: none"> Diverting medications from a patient; instead use Code H6.
51	D2	M	Non-Sexual Dual Relationship or Boundary Violation.	Non-Sexual Boundary Violation.	Engages in a non-sexual relationship, behavior or boundary violation that involves exploitation or coercion of a patient or former patient and contains harmful or potentially harmful elements.	Examples: <ul style="list-style-type: none"> Excessive personal disclosure, secrecy, reversal of roles or actions that meet the needs of the licensee (borrowing money); Non-sexual relationship with a patient's significant other.
51	14	U	Patient Abuse	Engages in the maltreatment of a patient which can include mental, physical and/or verbal abuse.	Example: <ul style="list-style-type: none"> Mental, physical and/or verbal abuse of a patient. DO NOT use for: <ul style="list-style-type: none"> Sexual abuse or sexual assault; instead use Code D1.
51	D1	U	Sexual Misconduct	Engages in behavior that exploits the practitioner-patient relationship in a sexual way, or engages in workplace sexual harassment such as unwelcome sexual advances or conduct of a sexual nature which interferes with the performance of another person's job or creates an intimidating, hostile, or offensive work environment.	Examples: <ul style="list-style-type: none"> Sexual exploitation of a patient; Workplace sexual harassment; Sexual Assault; Sexual Abuse.
51	D8	R	Other Unprofessional Conduct, Specify.	Redundant code, covered by other categories, or use code 99.	

PROPOSED NPDB CODE LISTS MODIFICATIONS—Continued

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
Fraud, Deception, or Misrepresentation						
52	E6	U	Failure to Disclose	Fails to disclose information that is required by the board.	Examples: <ul style="list-style-type: none"> • Failure to disclose criminal or disciplinary history on a license application; • Failure to disclose revenues generated from selling equipment or other financial relationships, etc.
52	E3	U	Filing False Reports or Falsifying Records.	Fabricates patient, medical, health, employee, or other records.	Examples: <ul style="list-style-type: none"> • Failure to provide accurate patient, medical, health, employee, or other records; • Documenting treatment that did not occur. Explanation: Use this code in conjunction with A2 Failure to Comply with Continuing Education or Competency Requirements for falsifying licensee continuing education or competence records. DO NOT use for: <ul style="list-style-type: none"> • False billing for care/treatment; instead use Code 56.
52	5	R	Fraud—Unspecified	Redundant code, covered by other fraud codes.	
52	E4	U	Fraud, Deceit or Material Omission in Obtaining License or Credentials.	Provides false, altered or omitting documents and information when applying for licensure.	Examples: <ul style="list-style-type: none"> • Provides false documentation in licensure application materials (transcript, letters, etc.); • Failure to disclose prior disciplinary action or criminal conviction on application; • Falsifies testing materials (cheating, trafficking, etc.).
52	55	M	Improper or Abusive Billing Practices.	Improper Billing Practices.	Knowingly or intentionally bills improperly	Examples: <ul style="list-style-type: none"> • Knowingly uses incorrect treatment or billing codes; • Charges unreasonable fees; • Intentionally overbills. DO NOT use for: <ul style="list-style-type: none"> • Conviction of insurance fraud; instead use Code E1.
52	E1	U	Insurance Fraud (Medicare, Medicaid or Other Insurance).	Convicted of Medicare, Medicaid or other insurance fraud.	Examples: <ul style="list-style-type: none"> • Convicted of Medicare, Medicaid or other insurance fraud. Explanation: <ul style="list-style-type: none"> • Use in conjunction with Code 19 Criminal Conviction.
52	E5	U	Misleading, False or Deceptive Advertising or Marketing.	Uses misleading, false or deceptive advertising or marketing related to services, treatment, procedures or care.	Example: <ul style="list-style-type: none"> • False or misleading advertising related to license. DO NOT use for: <ul style="list-style-type: none"> • Failure to correctly identify credentials; instead use Code 81.
52	81	U	Misrepresentation of Credentials.	Fails to properly identify oneself with regards to education, training, knowledge, experience, or skills.	Example: <ul style="list-style-type: none"> • Failure to properly identify education, training, knowledge, experience, or skills.
52	E2	U	Providing or Ordering Unnecessary Tests or Services.	Orders or provides unnecessary tests, procedures, treatment or services.	Examples: <ul style="list-style-type: none"> • Overutilization of tests/services; • Providing unnecessary treatment.
52	56	U	Submitting False Claims.	Requests reimbursement for services that did not occur or does not reflect the actual treatment provided.	Example: <ul style="list-style-type: none"> • Intentionally billing for interventions/care that did not occur. DO NOT use for: <ul style="list-style-type: none"> • Conviction for insurance fraud; instead use Code E1; • Documenting treatments/care that did not occur or falsifying patient records; instead use Code E3.
Unsafe Practice or Substandard Care						
53	F8	U	Failure to Consult or Delay in Seeking Consultation With Supervisor/Proctor.	Fails to provide or delaying proper consultation with supervisor or proctor.	Example: <ul style="list-style-type: none"> • Failure to consult with or report to a supervisor/ordering health care provider/proctor.

PROPOSED NPDB CODE LISTS MODIFICATIONS—Continued

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
53	53	R	Failure to Provide Medically Reasonable and/or Necessary Items or Services.	Redundant code, use code 13.	
53	F1	M	Immediate Threat to Health or Safety.	Immediate Threat to Public.	Presents an immediate risk to health or safety; Board uses emergency measures to remove a practitioner from practice.	Examples: • Emergency or summary suspension of a license. Explanation: • Use in combination with a code that best describes the violation.
53	17	U	Inadequate or Improper Infection Control Practices.	Fails to conform to recognized standards or orders for infection control.	Example: • Failure to follow policies or procedures for infection control, sterile technique or isolation requirements. DO NOT use for: • Failure to comply with federal, state, local or institutional safety requirements or state health codes; instead use Code 31.
53	FA	U	Inappropriate Refusal to Treat.	Refuses to treat a patient due to religious, moral or other reasons.	Example: • Refusal to treat a patient due to religious, moral or other reasons.
53	11	R	Incompetence	Redundant code, use F1 or F6.	
53	12	R	Malpractice	Redundant code, use specific reason associated with malpractice.	
53	13	U	Negligence	Fails to exercise the skill, care and learning expected of a reasonably prudent health care provider.	Example: • Failure to exercise reasonable judgment. DO NOT use for: • Competence issue; instead use Code F6.
53	F9	U	Patient Abandonment.	Terminates care without adequate notice of the professional relationship between a health care provider and a patient/client at a time when the patient needs further care.	Example: • Deserts or neglects a patient with whom there is an established provider-patient relationship without making reasonable arrangements for the continuation of care and without reasonable notice.
53	15	R	Patient Neglect	Redundant code, use 13.	
53	F6	M	Substandard or Inadequate Care.	Substandard Care or Inadequate Skill Level.	Fails to meet clinical standards of practice, unable to practice competently or practicing with insufficient skill.	Example: • Failure to provide competent care. DO NOT use for: • Practicing beyond level of training; instead use Code 29.
53	F7	R	Substandard or Inadequate Skill Level.	Redundant code, use code F6.	
53	F5	R	Unable to Practice Safely.	Redundant code, use code F2, F3, or F4.	
53	F2	M	Unable to Practice Safely by Reason of Alcohol or Other Substance Abuse.	Unable to Practice Safely by Reason of Substance Use.	Unable to practice safely by reason of substance use.	Example: • Failure/inability to practice safely by reason of substance use.
53	F4	M	Unable to Practice Safely by Reason of Physical Illness or Impairment.	Unable to Practice Safely by Reason of Physical Impairment.	Unable to practice safely by reason of physical impairment.	Example: • Failure/inability to practice safely by reason of physical impairment.
53	F3	M	Unable to Practice Safely by Reason of Psychological Impairment or Mental Disorder.	Unable to Practice Safely by Reason of Psychological Impairment.	Unable to practice safely by reason of psychological impairment.	Example: • Failure/inability to practice safely by reason of psychological impairment.
53	To be determined.	N	N/A	Incorrect Site Procedure.	Procedure performed on the wrong side or site of the body, wrong surgical procedure performed.	Example: • Performing an invasive procedure on wrong side of the body; • Performing a non-invasive procedure on the wrong side of the body, i.e. taking blood pressure on the side of an arteriovenous fistula.

PROPOSED NPDB CODE LISTS MODIFICATIONS—Continued

Table	Code	Status	Current code description	New/modified code description	Guideline or explanation of status change	Code use examples and explanations
53	To be determined.	N	N/A	Foreign Body Retained Inappropriately in a Patient.	Leaves an item(s) inside a patient after a procedure that should not be there.	Example: <ul style="list-style-type: none"> Retained foreign body refers to any item or foreign object related to any operative or invasive procedure that is left inside a patient. Common items include sponges and towels; retractors, unretrieved device components or fragments, parts of trocars, guidewires, catheters, and pieces of drains; needles and other sharps.
53	To be determined.	N	N/A	Wrong Patient	Procedure or treatment performed on the wrong patient.	Example: <ul style="list-style-type: none"> Performing an invasive procedure on the wrong patient; Performing a non-invasive procedure on the wrong patient i.e. ambulating the wrong patient.
Improper Supervision or Allowing Unlicensed Practice						
54	G2	U	Allowing or Aiding Unlicensed Practice.	Allows or assists someone practice without a license.	Example: <ul style="list-style-type: none"> Knowingly allows unlicensed practice.
54	G1	U	Improper or Inadequate Supervision or Delegation.	Fails to supervise adequately or properly those assigned to you.	Example: <ul style="list-style-type: none"> Failing to supervise adequately or properly those assigned to you.
Improper Prescribing, Dispensing, Administering Medication/Drug Violation						
55	H6	U	Inappropriate Acquisition or Diversion of Controlled Substance.	Diverts prescription medication from a patient or a healthcare facility with intent to sell, distribute or consume for personal misuse.	Example: <ul style="list-style-type: none"> Removing a prescribed medication from a patient's inventory, unused portion, waste, trash or healthcare facility inventory for self or someone other than the patient.
55	H5	U	Error in Prescribing, Dispensing or Administering Medication or Sedation.	Makes an error when prescribing, dispensing, or administering medications.	Examples: <ul style="list-style-type: none"> Giving the wrong medication; Giving medication to the wrong patient; Giving the wrong dosage of medication; Improper storage of medication.
55	H1	M	Narcotics Drug Violation or Other Violation of Drug Statutes.	Drug Violation or Other Violation of Drug Statutes.	Controlled substance violation regardless of conviction.	Examples: <ul style="list-style-type: none"> Controlled substance violation regardless of conviction. Explanation: <ul style="list-style-type: none"> If there is a conviction, also use Code 19 Criminal Conviction.
55	H4	U	Inappropriate or Unauthorized Administration of Medication or Sedation.	Administers medications improperly or without the appropriate prescription or medication order.	Example: <ul style="list-style-type: none"> Failure to administer medications properly or without the appropriate prescription/order.
55	H3	U	Inappropriate or Unauthorized Dispensing of Medication.	Dispenses medication improperly or without the appropriate authorization.	Example: <ul style="list-style-type: none"> Failure to obtain authorization or prescription to dispense medication.
55	H2	U	Inappropriate or Unauthorized Prescribing of Medication.	Improper prescribing or attempting to prescribe without authority or altering medication order.	Examples: <ul style="list-style-type: none"> Forging signature on order/prescription; Altering an order/prescription; Failure to obtain prescriber authorization or signature.
Other						
56	99	U	Other—Not Classified, Specify.	Use only if no other code is applicable.	

Table Key:

- Table # and name as it appears in published NPDB Code Lists.
- Code # as it appears in published NPDB Code Lists. NOTE: Code number is subject to change with the next published version.
- Status: Unchanged (U), Modified (M), Retired (R), New (N).
- Current Code Description.
- New or Modified Code Description.
- Guideline: a new category of information to help explain the code.
- Code use examples and explanations: a new category of information to show how to apply the code.

Diana Espinosa,
Acting Administrator.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Rural Health Clinic COVID-19 Reporting Portal, OMB No. 0906-0056—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 4, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443-9094.

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

Information Collection Request Title: Rural Health Clinic COVID-19 (RHC

COVID-19) Reporting Portal OMB No. 0906-0056—Revision.

Abstract: In October 2020, HRSA created a monthly, aggregate data report to collect information on COVID-19 testing and related expenses conducted by funded organizations participating in the RHC COVID-19 Testing (RHCCT) Program funded through the Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116-139). HRSA is expanding this data report to collect information on COVID-19 testing, COVID-19 mitigation, and related expenses conducted by funded organizations participating in the RHC COVID-19 Testing and Mitigation (RHCCTM) Program funded through the American Rescue Plan Act (Pub. L. 117-2). Funded organizations were identified by Tax Identification Number (TIN), and a TIN organization may operate one or more RHC sites which were identified by unique Centers for Medicare and Medicaid Services Certification Numbers. Respondents are TIN organizations who received funding for COVID-19 testing, COVID-19 mitigation, and related expenses. HRSA issued RHCCTM funding as one-time payments to 2,301 TIN organizations based on the number of certified RHC sites they operate, providing \$100,000 per clinic site (4,459 RHC sites total across the country). Data report information is needed to comply with federal requirements to monitor funds distributed under the Paycheck Protection Program and Health Care Enhancement Act and the American Rescue Plan Act.

Need and Proposed Use of the Information: The RHC COVID-19 Reporting Portal collects information from RHC-funded providers who use RHCCT Program funding and RHCCTM Program funding to support COVID-19 testing, expand access to testing in rural communities, and other related expenses. The RHC COVID-19 Reporting Portal also collects information from RHC-funded providers who use RHCCTM Program funding to support COVID-19 mitigation and other related expenses. These data are critical to meet HRSA requirements to monitor and report on how federal funding is

being used and to measure the effectiveness of the RHCCT Program and RHCCTM Program. Revisions include a confirmation page for TIN organization self-certification following completion of each program after the period of availability. Specifically, data will be used to assess the following:

- Whether program funds are being spent for their intended purposes;
- COVID-19 testing or testing related use(s) of RHCCTM funds;
- COVID-19 mitigation or mitigation related use(s) of RHCCTM funds;
- Where COVID-19 testing supported by these funds is occurring;
- Number of at-home (*i.e.* home collection, direct-to-consumer, over-the-counter) COVID-19 tests distributed (optional);
- Number of COVID-19 tests;
- Number of positive COVID-19 tests;
- TIN organizations self-certification of complete expenditure of RHCCT Program funds and/or full or partial return of RHCCT Program funds; and
- TIN organizations self-certification of complete expenditure of RHCCTM Program funds and/or full or partial return of RHCCTM Program funds.

Likely Respondents: Respondents are TIN organizations who own or operate one or more RHC who received funding for COVID-19 testing, COVID-19 mitigation, and related expenses.

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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
RHC COVID-19 Reporting Portal	2,301	19	43,719	0.33	14,427
Total	2,301	43,719	14,427