Department of Health and Human Services
OMB M-21-06 (Guidance for Regulation of Artificial Intelligence Applications)

This document constitutes the Department of Health and Human Services (HHS) response to OMB Memorandum 21-06 (Guidance for Regulation of Artificial Intelligence (AI) Applications). Consistent with the guidance provided in the memorandum, HHS's plan includes the five components outlined below:

1. Statutory authorities that directly authorize agencies to regulate AI applications in the private sector
2. Collections of information (approved by OMB under the Paperwork Reduction Act) related to AI applications in the private sector
3. AI applications in the private sector that are within an agency's regulatory authorities
4. Existing regulatory barriers to developing or commercializing AI applications
5. Any planned or considered regulatory actions on AI

As outlined in the memo, the content in this plan focuses on HHS's role as a regulator of the broader health and human services industry. As such, it does not include information on the many and various ways that HHS is already working to apply AI to its mission internally, from biomedical research to fraud detection in medical claims payment. Additionally, because AI is a rapidly evolving field where new technologies and applications are being developed almost daily, this plan represents a moment in time and will continue to evolve as HHS works with the broader industry to ensure that AI is applied in a manner that promotes the health and well-being of all Americans while preserving the public's trust in how data is collected, stored, and used.

Statutory Authorities Directing or Authorizing Agency Regulation of AI Applications.
List and describe any statutes that direct or authorize your agency to issue regulations specifically on the development and use of AI applications.

This section outlines the statutory authorities that authorize HHS to issue regulations on the development and use of AI applications in the private sector.

Statute	Description
Statute: Civil Rights Act of 1964 Citation/Codification: Title VI (42 USC 2000d et seq.; 45 CFR Part 80)	The Civil Rights Act of 1964 is an Act that outlaws discrimination based on race, color, or national origin. The law prohibits unequal application of voter registration requirements, and racial segregation in schools, employment, and public accommodations. Title VI of the act prevents discrimination by programs and activities that receive federal funds, including hospitals and other health care facilities. AI applications can result in discriminatory outcomes that negatively impact individuals protected by federal civil rights law. HHS has authority to enforce this statute in the context of AI to the extent such applications result in unlawful discrimination prohibited by the statute.
Statute: Rehabilitation Act of 1973 Citation/Codification: Section 504 (29 USC 794; 45 CFR Part 84 (HHS federally assisted programs or activities); 45 CFR Part 85 (HHS federally conducted programs or activities))	The Rehabilitation Act of 1973 prohibits discrimination against people with disabilities in programs that receive federal financial assistance. Section 504 works together with the Americans with Disabilities Act (ADA) and Individuals with Disabilities Education Act (IDEA) to protect children and adults with disabilities from exclusion, and unequal treatment in schools, jobs and the community. AI applications can result in discriminatory outcomes that negatively impact individuals protected by federal civil rights law. HHS has authority to enforce this statute in the context of AI to the extent such applications result in unlawful discrimination prohibited by the statute.
Statute: Education Amendments of 1972 Citation/Codification: Title IX (20 USC 1681 et seq.; 45 CFR Part 86)	Title IX of the Education Amendments of 1972 (Title IX) prohibits sex discrimination in any education program or activity receiving federal financial assistance. AI applications can result in discriminatory outcomes that negatively impact individuals protected by federal civil rights law. HHS has authority to enforce this statute in the context of AI to the extent such applications result in unlawful discrimination prohibited by the statute.
Statute: The Age Discrimination Act of 1975 Citation/Codification: 42 USC 6101 et seq.; 45 CFR Part 90 (federally assisted programs or activities); 45 CFR Part 91 (HHS federally assisted programs or activities).	The Age Discrimination Act of 1975 (Age Act), prohibits discrimination on the basis of age in HHS-funded programs and activities. Under the Age Act, recipients may not exclude, deny, or limit services to, or otherwise discriminate against, persons on the basis of age. AI applications can result in discriminatory outcomes that negatively impact individuals protected by federal civil rights law. HHS has authority to enforce this statute in the context of AI to the extent such applications result in unlawful discrimination prohibited by the statute.
Statute: Section 1557 of the Patient Protection and Affordable Care Act Citation/Codification: Section 1557. (42	This statute prohibits discrimination on the basis of race, color, national origin, sex (including sexual orientation and gender identity), age, and disability in certain health programs or activities, including health programs or activities in the private sector that receive financial assistance from HHS.

	AI applications can result in discriminatory outcomes that negatively impact individuals protected by federal civil rights law. HHS has authority to enforce this statute in the context of AI to the extent such applications result in unlawful discrimination prohibited by the statute.
Statute: Public Health Service Act Citation/Codification: § 3001(c)(1) PHSA [Standards and Certification Criteria Review] § 3001(c)(2)(A) PHSA § 3001(c)(5)(A) and (B) PHSA [Certification Program] § 3004 PHSA [Process for adoption of endorsed recommendations; adoption of initial set of standards, implementation specifications, and	The Public Health Service Act (PHSA) provides the legal authority for HHS, among other things, to respond to public health emergencies. The act authorizes the HHS secretary to lead federal public health and medical response to public health emergencies, determine that a public health emergency exists, and assist states in their response activities. Specifically, the Office of the National Coordinator for Health Information Technology (ONC) has the authority to review and endorse standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. To the extent an AI application is involved in the exchange or use of health information, HHS has the ability to regulate it. ONC also has the authority to keep or recognize a voluntary certification program to provide for the certification of health IT.
Statute: Medical Device Amendments to Federal Food, Drug, and Cosmetic Act of 1976 Citation/Codification: 90 STAT. 539 Public Law: 94-295 Noting In Particular Post Market Surveillance Regulations Based on Information Included by HHS AI Office: 21 CFR Part 822	The United States Federal Food, Drug, and Cosmetic Act (FD&C Act) is a set of laws giving authority to the U.S. Food and Drug Administration to oversee the safety of food, drugs, medical devices, and cosmetics. The FD&C Act contains provisions (or regulatory requirements) that define The Food & Drug Administration (FDA)'s level of control over several products. To fulfill the provisions of the FD&C Act that apply to medical devices and radiation-emitting products, FDA has the authority to regulate such devices or products that use AI and Machine Learning (ML) algorithms that can result serious adverse health consequences, are expected to have significant use in pediatric populations, are intended to be implanted in the body for more than one year, or are intended to be a life-sustaining or life-supporting device used outside a device user facility.
Statute: Safe Medical Devices Act (SMDA) of 1990 Citation/Codification: H.R.3095 — 101st Congress	Safe Medical Device Amendments of 1990 (or Safe Medical Devices Act) sanctioned progressive reporting and tracking rules for medical devices classified by the Medical Device Regulation Act. The Act mandates reporting requirements by medical device manufacturers regarding adverse safety events and product effectiveness of devices classified as substantially equivalent to Class III medical devices. The United States Statute established the HHS Office of International Relations and an FDA office for regulatory activities concerning healthcare products which are considered a combinational biological, device, or drug product. To carry out the reporting provisions of SMDA, FDA has the authority to direct AI or ML algorithms that user facilities or manufacturers use to monitor products after their clearance to market and track devices for maintaining
Statute: Mammography Quality Standards Act (MQSA) of 1992 Citation/Codification: 21 CFR Part 900	MQSA required HHS to develop standards that would be enforced through strict accreditation, certification and inspection of equipment and personnel at mammography facilities. The FDA was tasked with implementing the federal regulations to establish and enforce such procedures. Mammography technologies that use AI or ML are required to meet standards enforced by the MQSA statute. Therefore, HHS has the authority to manage or direct such algorithms to ensure standards are adhered to.

Statutory Authorities Directing or Authorizing Agency Regulation of AI Applications (continued)

Given that AI is still an emerging field, there are other statutes that authorize HHS to regulate health data or health technology but may not directly reference AI. Below, the Department indicated statutes that may indirectly give HHS an authority to regulate AI, given that AI algorithms and solutions are already used as components in many health technology solutions.

Statute	Description
Statute: The Confidential Information Protection and Statistical Efficiency Act (known as the E-Government Act of 2002) Citation/Codification: 116 STAT. 2962 Public Law 107-347 107th Congress	Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)'s primary purposes are to protect information collected for statistical purposes from improper disclosure and to ensure that the information is not used for nonstatistical purposes. To achieve its purposes, CIPSEA establishes limitations on the use and disclosure of statistical data or information. As stated in CIPSEA section 512, data or information acquired under a pledge of confidentiality and for exclusively statistical purposes shall be used for exclusively statistical purposes and shall not be disclosed for a nonstatistical purpose, except with the informed consent of the respondent. CIPSEA gives National Center for Health Statistics (CDC-NCHS) broad statutory authority to protect the confidentiality of information they collect. Therefore, NCHS has the authority to restrict the application of AI/ML techniques applied to their data in order to protect confidentiality.
Statute: Health Information Technology for Economic and Clinical Health (HITECH) Act Citation/Codification: Title XIII STAT. 115 Public Law 111-5 111th Congress	The HITECH Act, enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA), established requirements for Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulated entities to provide notice of breaches of protected health information and increased penalties for non-compliance with the HIPAA Rules. The HITECH Act indirectly authorizes HHS to regulate AI applications by establishing requirements for the safeguarding and notification of a breach of protected health information which may occur through use of an AI application by a HIPAA regulated entity.

Active Collections of AI-Related Information.
List and describe any of your agency's collections of information approved by 0MB under the Paperwork Reduction Act that relate directly to the design, development, deployment, and operation of AI applications in the private sector, including if there are any statutory or regulatory restrictions on the use or sharing of this information.

This section includes collections of information related to AI applications in the private sector that were approved by OMB under the Paperwork Reduction Act.

Title / OMB Control Number	Brief Description
Reporting and Recordkeeping for Electronic Products - General Requirements 0910-0025	To protect the public from unnecessary exposure to radiation from electronic products, FDA must collect certain information from manufacturers and dealers/distributors about electronic products they sell or install. This IC helps FDA make decisions and take actions that protect the public from radiation hazards presented by electronic products. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation 0910-0073	CGMP/QS information collections assist FDA inspections of manufacturer compliance with quality system requirements encompassing design, production, installation, and servicing processes. Manufacturers must ensure that medical devices meet design specifications and that design specifications are effectively transferred from research and development to production. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Investigational Device Exemptions (IDE) Reports and Records - 21 CFR 812 0910-0078	Information collection relates to requirements in 21 CFR Part 812. The IDE regulation permits a device to be shipped in interstate commerce for clinical investigation to determine its medical safety and effectiveness. Although the IDE regulations exempts the device from certain requirements of the Act, it requires safeguards for humans who are subjects of investigations; maintenance of sound ethical standards; and procedures to assure development of reliable scientific data. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Administrative Detention and Banned Medical Devices 0910-0114	The FDA has the statutory authority under section 304(g) of the FD&C Act to detain devices during establishment inspections which are believed to be adulterated or misbranded. FDA also has the statutory authority under section 516 of the Act to ban devices that present substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct and substantial danger to the health of individuals. Under these authorities there are requirements pertaining to reporting and recordkeeping activities that are necessary in order for the Agency to carry out its mission to protect the public health. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Premarket Notification Submission 510(k), Part 807 Subpart E 0910-0120	This information collection request (ICR) collects information from persons who intend to market a medical device. Based on the information provided in the premarket notification (510(k)) submission, FDA determines whether a new device provides reasonable assurance of the safety and effectiveness of the device through substantial equivalence to a legally marketed device and whether the device can, therefore, be allowed to enter the U.S. market. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Reclassification Petition for Medical Devices 0910-0138	This ICR collects information from medical device manufactures who wish to request reclassification of a medical device. The regulation requires device manufacturers to provide, in a petition for device reclassification, specification of the type of device, a statement of the action requested, and a justification for the request to reclassify. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Premarket Approval of Medical Devices - 21 CFR Part 814 0910-0231	This ICR collects information from persons filing a premarket approval (PMA) application or a PMA supplement with FDA for approval of certain class III medical devices. The data reported to FDA and the records that are maintained allow FDA and industry to make decisions and take actions to protect the public health from defective medical devices. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Mammography Facilities, Standards, and Lay Summaries for Patients 0910-0309	Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer compliant mechanism. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Medical Devices; Humanitarian Use Devices; 21 CFR Part 814 - subpart H 0910-0332	This ICR collects information from manufactures who wish to obtain "Humanitarian Use Device" (HUD) designation for a medical device and marketing approval for the HUD notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required. To the extent consistent with the protection of the public health and

	ethical standards, this program encourages the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI- related.
Medical Devices; Reports of Corrections and Removals 0910-0359	The information collection requirements in 21 CFR Part 806 require each device manufacturer or importer to submit a written report to FDA of any action to correct or remove a device which may present a risk to health within 10-working days of initiating such correction or removal. The Information Collection also requires that each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA, shall keep a record of such correction or removal. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Medical Devices; Third Party Review Under FDAMA 0910-0375	This ICR collects information from persons who wish to be accredited by the Agency to review certain premarket notifications. The purpose of the program is: (1) to provide manufacturers of eligible devices with an alternative review process that could yield more rapid marketing clearance decisions and (2) enable FDA to target its scientific review resources at higher-risk devices while maintaining confidence in the review by third parties of low-to-moderate risk devices. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry
Medical Device Recall Authority 0910-0432	This ICR collects information from manufacturers, importers, distributors, and retailers of medical devices to provide information, requests, or reports related to mandatory recall. The primary use of the information disclosed to FDA is to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting 0910-0437	This ICR collects information from medical device manufacturers, importers, and user facilities that are required to submit electronic and paper medical device reports (MDRs) to the FDA and to maintain records, and who may also seek exemption from these requirements. The information that is obtained from these reports will be used to evaluate risks associated with medical devices and enable FDA to take appropriate regulatory measures to protect the public health. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Medical Devices; Device Tracking 0910-0442	This ICR collects information from device manufacturers and distributors who are subject to the requirements for device tracking, tracking systems, and distributor reporting. Manufacturers must track a class II or class III device if its failure would be reasonable likely to have serious adverse health consequences, or it is intended to be implanted in the human body for more than one year, or it is life-sustaining or life-supporting and used outside a device user facility, or when FDA determines that tracking would be appropriate in order to protect the general public in the event of a device recall. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Postmarket Surveillance of Medical Devices 0910-0449	This ICR collects information from manufacturers who are required to conduct postmarket surveillance of a medical device that meets the criteria set forth in the statute. The information collected and maintained enables FDA to ensure that the postmarket surveillance will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Adverse Event Program for Medical Devices (MedSun) 0910-0471	This ICR collects information for the FDA's Medical Product Safety Network (MedSun) program from a subset of medical device user facilities that constitutes a representative profile of user reports for device-related deaths and serious injuries related to medical devices. The MedSun program is unique to FDA and provides FDA with the ability to have a dialogue with the clinical community, so they may work together to learn about, understand, and solve problems with the use of medical devices. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI- related.
Medical Device Labeling Regulations 0910-0485	This ICR collects information from manufacturers, importers, and distributors of medical devices to disclose to health professionals and consumers specific information about themselves or their devices on the label or labeling of their devices. FDA may use the information to determine whether there is reasonable assurance of the safety and effectiveness of the device for its intended use. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Shortages Data Collection 0910-0491	FDA maintains a medical device database which allows FDA to identify locations and manufacturers of hard to locate medical devices in the context of a Federally-declared disaster/emergency, an official emergency preparedness exercise, or a potential public health risk posed by non-disaster-related device shortage. Because of the dynamic nature of the medical device industry, particularly with respect to specific product lines, manufacturing capabilities and raw material/subcomponent sourcing, it is necessary to update the data in the Emergency Shortages Data Collection System at regular intervals, but efforts are made to limit the frequency of outreach to a specific manufacturer to no more than every 4 months. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI- related.

Medical Devices; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) 0910-0510	This information collection supports the requirements of section 704(g) of the FD&C Act and FDA's Inspection by Accredited Persons Program (or AP Program), including requests to become an Accredited Person under the AP Program and a manufacturer's notice of their intention to use an Accredited Person to conduct inspections of their establishment. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Electronic Submission of Medical Device Registration and Listing, Form FDA 3673 0910-0625	This information collection request covers the reporting and recordkeeping provisions associated with FDA's implementation of sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which require that device establishment registrations and listings under section 21 U.S.C. 360(p) (including the submission of updated information) be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Guidance: Humanitarian Device Exemption Regulation: Q&As 0910-0661	HUDs are subject to the general restriction that no profit may be made on their use. For HUDs labeled for use in certain populations, FDA exempts a certain number of these devices each year from the prohibition on profit. This number is known as the ADN. The information gathered by this collection enables FDA to set this number. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Unique Device Identification System 0910-0720	This IC supports regulation establishing a unique device identification system for medical devices. By making it possible to rapidly and definitively identify a device and key attributes that affect its safe and effective use, the rule would reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Guidance for Center for Devices and Radiological Health Appeals Processes 0910-0738	This IC supports reporting burden associated with requests for additional review of decisions and actions by Center for Devices and Radiological Health (CDRH) employees as described in the guidance. Section 517A of the FD&C Act, added by section 603 of the FDA Safety and Innovation Act of 2012, includes new requirements pertaining to the process and timelines for 10.75 appeals of "significant decisions" regarding 510(k) premarket notifications, applications for PMAs, and applications for IDEs. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI- related.
Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer from a Disease or Condition That a Device is Intended to Treat, Diagnose, or Cure 0910-0748	This ICR collects information from medical device manufacturers who wish to obtain market clearance for a device. Respondents must submit, as part of their PMA or product development protocol (PDP), PMA amendment, PMA supplement, or humanitarian device exemption (HDE), readily available information providing a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure; and the number of affected pediatric patients. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Requests for Feedback on Medical Device Submissions (Presubmissions Guidance) 0910-0756	The guidance on Requests for Feedback on Medical Device Submissions (Pre-Submissions Program) establishes a structured process for submission and management of Pre-Submissions and supports the procedures that CDRH intends to follow when manufacturers, their representatives, or application sponsors submit a request for feedback on a medical device submission, including when the preferred method of feedback is a meeting with review staff. These voluntary information collection requirements support a structured process with clear recommendations for sponsors who submit a pre-submission feedback request and for FDA staff and managers involved in their review, as well as expected timeframes for scheduling meetings. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are
Annual Reporting for Custom Device Exemption 0910-0767	This ICR collects information from manufacturers of custom devices through submission of an annual report to FDA that identifies the number of new custom devices unit manufactured and distributed per year. Based on the information provided in the annual report, FDA will determine whether a device continues to meet the qualifications for a custom device exemption. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices 0910-0769	This ICR collects information voluntarily submitted to CDRH on allegations of regulatory misconduct associated with medical devices. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI-related.
Medical Device Accessories 0910-0823	The guidance document "Medical Device Accessories--Describing Accessories and Classification Mechanisms for Accessory Types" encourages manufacturers and other parties to utilize the "de novo request" process defined in section 513(f)(2) of the FD&C Act to request risk-based classifications of new types of medical device accessories. This process provides a pathway to class I or class II classification for accessory devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are

De Novo Classification Process (Evaluation of Automatic Class III Designation) 0910-0844	The ICR describes the information collection involved with the De Novo classification process for medical devices. FDA uses the information in the De Novo request to evaluate whether the medical device may be reclassified from Class III to Class I or II, and if applicable, to determine the general and/or special controls necessary to sufficiently regulate the medical device. Certain medical electronics and devices may incorporate AI algorithms or technologies to deliver some or all of their functionality. As a result, information gathered through this collection may include input or insights from industry that are AI- related.
UPCOMING Virtual Public Workshop – Transparency of AI/ML-enabled Medical Devices – October 14, 2021 OMB approval request will be submitted under OMB# 0910-0360 for this upcoming meeting	The purpose of the workshop will be to 1) highlight the role of information sharing to enhance trust and identify unique considerations in achieving transparency for users of AI/ML-enabled devices, and 2) gather input from various stakeholders on the types of information that a manufacturer should include in the labeling and public facing information of AI/ML- enabled medical devices as well as other potential mechanisms for information sharing. (COURSE EVALUATION)

Active Collections of AI-Related Information (continued)

There are no OMB Control Numbers associated with the collections of information related to AI below, given that "general requests" are exempt from requiring PRA clearance.

Title / OMB Control Number	Brief Description
Critical resource gaps and opportunities to support Next Generation Sequencing (NGS) test development, validation, and data interpretation, including through the use of technologies such as AI/ML	The National Institutes of Health (NIH) and the FDA are requesting information from stakeholders on what critical resource gaps exist to support Next Generation Sequencing (NGS) test validation and development (e.g., highly characterized reference materials, infrastructure) and tool development and data interpretation (e.g., AI/ML technologies). https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-162.html
Request for Information: Critical resource gaps and opportunities to support radiological tool development and clinical data interpretation using	The purpose of this RFI is to request information on what critical resource gaps exist for validation and use of AI/ML to support radiological tool development and clinical data interpretation. https://grants.nih.gov/grants/guide/notice-files/NOT- OD-21-163.html

AI Use Case Priorities.
Informed by stakeholder engagement, list and describe AI applications that are within your agency's regulatory authorities.

This section includes AI applications in the private sector that fall within HHS' regulatory authorities. In addition to the below AI applications in the private sector, HHS is engaged in developing and using AI applications internally across the Department. Given the scope of this request, internal use cases are not included in this response. HHS may be able to provide information on internal deployment of AI upon request. As AI is a constantly evolving field, this plan represents a current understanding of AI applications in the private sector that fall under the purview of HHS, but the number and type of use cases that fall under HHS' authority is likely to constantly evolve.

AI Use Case	Brief Description
AI Algorithm for Wrist Fracture Detection	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). FDA permitted marketing of a type of computer-aided detection and diagnosis software designed to detect wrist fractures in adult patients.
Clinical decision support alerting potential patient strokes	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). FDA permitted marketing of a type of clinical decision support software designed to analyze computed tomography (CT) results that may notify providers of a potential stroke in their patients.
Breast Imaging System	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). FDA approved device for use by trained and qualified healthcare providers for evaluation of palpable and non-palpable breast abnormalities in adult patients who are referred for a diagnostic imaging breast work-up, following clinical presentation or either screening or diagnostic mammography or other imaging examinations.
AI device to detect certain diabetes- related eye problems	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). FDA permitted marketing of the first medical device to use AI to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.

Cardiac Ultrasound Software Using AI to Guide User	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). FDA authorized marketing of software to assist medical professionals in the acquisition of cardiac ultrasound, or echocardiography, images. The software is an accessory to compatible diagnostic ultrasound systems and uses AI to help the user capture images of a patient's heart that are of acceptable diagnostic quality.
Digital therapy device to reduce sleep disturbance for psychiatric conditions	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). A digital therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from posttraumatic stress disorder (PTSD).
Gastrointestinal lesion software detection system	Software functions across the medical device product spectrum are being enhanced and rebuilt using AI/ML. FDA's regulatory authority is based on intended use, and, generally, software functions intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease or intended to affect the structure or function of the body are regulated by FDA (see section 201(h) of the FD&C Act). An AI/ML device system designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations.

AI Use Case Priorities (continued)

In addition to AI use cases explicitly under HHS regulatory authorities, HHS has a unique ability to shape the development and production of AI in the private sector, given the grant making authorities of various HHS Divisions. AI use cases below fall within that purview.

AI Use Case	Brief Description
Creating biomedically relevant datasets and best practices for ML analysis	The biomedical research community generates a wealth of data, but most of these data are not suitable for ML because they are incomplete. Furthermore, use of ML and AI to address biomedical challenges will require a set of best practices, training, and relevant tools. Accordingly, the NIH Common Fund's Bridge2AI program will help generate new biomedically relevant data sets that have the characteristics needed for ML analysis at scale by: • Generating new flagship biomedical and behavioral data sets that are ethically sourced, trustworthy, well-defined, and accessible • Developing software and standards to unify data attributes across multiple data sources and across data types • Creating automated tools to accelerate the creation of FAIR (Findable, Accessible, Interoperable, and Reusable) and ethically sourced data sets • Providing resources to disseminate data, ethical principles, tools, and best practices • Creating training materials and activities for workforce development that bridges the AI, biomedical, and behavioral research communities https://commonfund.nih.gov/bridge2ai
Improve datasets with broad representation from diverse communities and increase participation of underrepresented researchers and communities in AI/ML modeling and applications	The AI/ML field currently lacks diversity in its researchers and in data, including electronic health record (EHR) data. These gaps pose a risk of creating and continuing harmful biases in how AI/ML is used, how algorithms are developed and trained, and how findings are interpreted. Critically, these gaps can lead to continued health disparities and inequities for underrepresented communities. Underrepresented communities have untapped potential to contribute new expertise, data, recruitment strategies, and cutting- edge science to the AI/ML field. To close the gaps in the field and to better engage underrepresented communities, the NIH has launched the AI/ML Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program. This program seeks to increase the participation and representation of the researchers and communities that are currently underrepresented in AI/ML modeling and applications through mutually beneficial partnerships. https://datascience.nih.gov/artificial-intelligence/aim-ahead
Improve the AI/ML-readiness of NIH- Supported Data through attention to data quality, representation from diverse communities and importantly the ethical dimension. Foster the FAIR principle as foundational to biomedical research	There is a tremendous opportunity for data-driven discovery across the NIH mission, including from AI and ML technologies. This discovery requires findable, accessible, interoperable, and reusable (FAIR) and AI/ML-ready data. Making data FAIR and AI/ML-ready requires interdisciplinary skills not typically held by biomedical and behavioral researchers. Particularly for biomedical data, AI/ML-readiness should be guided by a concern for human and clinical impact and therefore requires attention to ethical, legal, and social implications of AI/ML, such as biases in datasets, algorithms, and applications; concerns related to privacy and confidentiality; impacts on disadvantaged or marginalized groups and health disparities; and unintended, adverse social consequences of research and development. https://datascience.nih.gov/artificial-intelligence/initiatives

AI for Biomedical Excellence (AIBLE) - Concept for a new NIH Common Fund program	The AIBLE concept aims to generate new biomedically relevant data sets amenable to ML analysis at scale. These ML–ready attributes will be converted into rubrics and standards that will allow planning and evaluation; allow the creation of software and hardware to speed the annotation and structuring of data sets; immediately initiate collaboration with existing projects; generate new multimodal, metadata-complete, available data that will exemplify ML–friendliness; and use those rubrics to assess and improve select public health data sets of biomedical importance.

AI Use Case Priorities (continued)

Though the AI use case below is an example of an AI application internal to HHS, AI tools developed through the use case below may be adopted by private sector technology developers for inclusion in their products supporting human service providers, providing an additional opportunity for HHS to shape how AI is applied in the broader health and human services industry.

AI Use Case	Brief Description
Predicting Risk of Adult Maltreatment (PRAM)	The Administration for Community Living (ACL), in collaboration with other HHS agencies, including the Centers for Medicare & Medicaid Services (CMS), is conducting a Predicting Risk of Adult Maltreatment (PRAM) project to leverage AI, ML, and other "big data" tools. The goal of the PRAM project is to investigate patterns of risk and protective factors within multiple data sources to determine if there is an association with reported incidence of adult maltreatment. The goal of the project will advance the field's understanding on how to design and implement primary and secondary prevention efforts. PRAM is intended to develop techniques and tools that will allow the application of AI and ML to support the prevention of abuse, neglect, and exploitation for older adults and people with disabilities. It is likely that AI tools developed through PRAM may be adopted by private sector technology developers for inclusion in their products supporting human service providers. Other agencies that fund and regulate providers offering protective services throughout the lifespan may also need to consider the impact of PRAM's AI tools on technology solutions provided by the private sector.

AI Regulatory Barriers.
Informed by stakeholder engagement, list and describe existing processes, policies, or regulations that inhibit development or commercialization of AI applications within your agency'sauthority.

This section includes existing identified limitations to the development, deployment, use, or commercialization of AI. Early engagement has revealed data sharing problems as the major limitation to development or commercialization of AI applications. Ongoing stakeholder engagement may uncover additional processes, policies, or regulations that inhibit the development or commercialization of AI, so this list may evolve over time.

Process, Policy, or Regulation	Brief Description
Poor data interoperability - joining and combining health datasets	Across the healthcare system, large amounts of data are structured in different ways, preventing stakeholders from easily exchanging and integrating this information. These challenges are in part due to a lack of common data standards and issues with enforcement where standards do exist. As a step in the right direction for common data standard, ONC issued the United States Core Data for Interoperability (USCDI), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.
Data silos and administrative hurdles	While HHS is developing more efficient ways for its agencies to share data - for example, by developing common data use agreements (DUAs) - it is still difficult for HHS agencies to share data with each other, and can be difficult for organizations outside of government to obtain data from HHS. It can take 12 to 18 months to get access to data from various agencies and offices within HHS. Culture changes are needed to reduce the administrative hurdles that prevent
Inconsistent limitations on data use	Health data types have different legal and regulatory constraints on their use. For example, administrative and claims data, clinical data, and certain types of surveillance data, such as survey data, can include sensitive, individual-level information. The use of these data types is often restricted under existing privacy frameworks such as HIPAA. Patient-generated data, such as data collected from mobile applications and wearable devices, can contain sensitive information about individuals ranging from fertility treatments to mental health conditions. However, there are relatively few legal guidelines that protect this emerging data type from misuse.
Intellectual property	Data collected in drug development trials, through private-sector health surveys, or in other ways could benefit researchers and organizations in the health sector developing AI applications, and proprietary AI models could be developed for greater accuracy if the algorithms they use were shared. But while all parties stand to benefit from sharing data and algorithms, it is difficult to balance that benefit against companies' need to protect their intellectual property for
Concerns about HIPAA and data sharing	Fears about violating HIPAA have created a risk-averse environment for data sharing within covered entities. While HIPAA is intended to protect patient privacy, it does allow data sharing and use under specific conditions. Overly sensitive interpretations of the law or unfamiliarity of the allowable data sharing within the law limits data sharing. Targeted training to increase familiarity of what data sharing is allowable would help reduce this limitation.
Federal-state legal agreements - lack of timing accountability	Data timeliness and granularity of the data shared between states and federal agencies can vary greatly. Some legal agreements between federal and state partners do not create accountability around data timeliness. Delayed state data submission has significant implications for data sharing. For internal data sharing, some data representatives do not want to share any provisional data until all states have submitted their data, which can result in delaying final cleaning, statistical weighing, and quality checks.
Federal-state legal agreements - large investment of resources to change agreements	There is significant energy involved in modifying federal-state agreements. When legal agreements are in place, negotiating changes to the data collection (including accessing data with more granularity than the public file) may require renegotiating existing agreements and receiving cooperation among state and territory partners. Depending on the data collection system, renegotiation would need to include patients, health systems, and other participants involved
Federal-state legal agreements - lack of federal mandate to share data	Many data collection systems at the Department depend on states voluntarily sharing data. For some data systems, there is no federal requirement for the states to share their data. This can limit the sharing of granular data and the capacity of federal agencies to modify, manage, and improve standard reporting.

The Interagency Agreement Process	When two different agencies share data that is not public, legal agreements are typically employed between the agencies. Many agency's general counsels work together to draft and finalize an Interagency Agreement (IAA). Sometimes, the language in the agreement is standardized; however, many agencies describe it as a time-consuming, laborious, and confusing process to coordinate and execute these agreements between general counsels. Agency personnel are often hesitant to request data when time is of the essence or when there are inadequate resources to manage the IAA process. Creating these documents and remaining within the law have proven to be a significant challenge across the Department. While no agency disputes the laws and process, the arduous nature of statute, regulation, and policy compliance serves as challenges against widespread data sharing.
Statutory Approval Process for AI/ML- Based Software as a Medical Device	The traditional pathways for medical device regulation were not designed to account for the rapid cycles of iterative modification for software-based devices. Existing statutory and regulatory authorities require a premarket submission to the FDA when AI/ML software modification significantly affects device performance, or safety and effectiveness; the modification is to the device's intended use; or the modification introduces a major change to the SaMD (Software as a Medical Device) algorithm. Typically, FDA marketing authorizations have included only AI/ML software modifications where algorithms that are "locked" prior to marketing, where algorithm changes likely require FDA premarket review for changes beyond the original market authorization. This presents a limitation to AI/ML software that employs ongoing learning, reducing power and ability to learn and improve. There is a need for an "Agile regulatory framework" that allows FDA to take a risk-based approach to regulating AI technology. An agile statutory authority will not only allow FDA to address patient safety and effectiveness of these products, but will also allow the Agency to tailor its oversight and not create a "one size fits all" approach for emerging technology that will continue to evolve and change over time.

Planned Regulatory Actions Concerning AI Applications.
List and describe any planned or considered regulatory actions and provide, to the extent possible, information about the agency's consideration of the principles and approaches described in 0MB Memorandum M-21-06.

This section includes the Department's current plans to regulate AI applications in the private sector. The list includes any considered but not yet determined or initiated regulatory actions on AI. Considering that AI is a constantly evolving field, the actions listed below represent only current considerations, and HHS expects that the regulatory landscape around AI and the Department's plans for regulating will be constantly evolving. Finally, the principles and recommendations laid out in the M-21- 06 will be considered for HHS' future planned regulatory actions

Regulatory Action	**Brief Description**
Revised Regulatory Approach for AI/ML- Based SaMD	In the proposed regulatory approach, FDA would apply a more flexible regulatory approach for AI/ML-based SaMD due to its ability to adapt and improve from real-world use. FDA would assess the culture of quality and organizational excellence of a particular company and have reasonable assurance of the high quality of their software development, testing, and performance monitoring of their products. This TPLC approach, referred to as a pre-certification approach, would enable the evaluation and monitoring of a software product from its premarket development to postmarket performance to assure safety and effectiveness. In addition to the development of guidance in this area, parts of this approach require new statutory authorities. The proposed regulatory approach considers the principles outlined in OMB M-21-06, including public trust in AI (for example, through a public workshop on the transparency of AI-enabled medical devices), public participation (for example, through solicitation of comments through a dedicated public docket), scientific integrity and information quality, risk assessment and management, fairness and discrimination, flexibility, disclosure and transparency, and safety and security, among others.
Clinical Holds in Medical Device Investigations	The proposed rule would create a regulatory framework and procedures for suspending, i.e., imposing a hold (a "clinical hold") on, a clinical investigation of a medical device. The proposed rule would implement section 520(g)(8) of the Federal FD&C Act authorizing clinical holds for device investigations. This rule would apply generally to devices, including those that contain or utilize AI. FDA's CDRH will consider the principles outlined in OMB M-21-06 during the course of the proposed rule's development.
Medical Device De Novo Classification Process	De Novo classification decreases regulatory burdens because device manufacturers can use a less burdensome application pathway under the FD&C Act to market their devices. The rule would establish procedures and criteria for the De Novo process and would make it more transparent and predictable for manufacturers. By clarifying and making more efficient the De Novo request requirements, we expect the rule would reduce the time and costs associated with reviewing De Novo requests and generate net benefits in the form of cost savings. This rule would apply generally to devices, including those that contain or utilize AI. The final rulemaking considers the principles outlined in OMB M-21-06, including but not limited to public participation (through prior proposed rulemaking and consideration of comments to the docket), scientific integrity and information quality, risk assessment and management, and benefit/costs, among others.
AI in Pharmaceutical (Drug) Manufacturing	The FDA Center for Drug Evaluation and Research, Office of Pharmaceutical Quality, expects to engage with stakeholders beginning in FY22 and beyond about the regulatory framework governing use of AI in drug manufacturing to learn of any gaps in policies and knowledge that may discourage AI adoption and successful implementation. FDA will consider the principles outlined in OMB M-21-06 during the course of the proposed rule's development.