Federal Register - April 2023

<u>Patent Center Electronic Office Action Program, 88</u> <u>Federal Register 20138, April 5, 2023</u>

NOTICE: The United States Patent and Trademark Office (USPTO or Office) will begin transitioning to the Patent Center Electronic Office (e-Office) Action program upon publication of this notice. The Patent Center e-Office Action program is designed to modernize the e-Office action process and further streamline the USPTO's service delivery processes. Implementation of the Patent Center e-Office Action program is another step in the USPTO's transition to Patent Center, a more modern, user-friendly system that provides improved system performance and a more intuitive user experience. Once fully implemented, the Patent Center e-Office Action program will replace the existing e-Office Action program available to users of the Private Patent Application Information Retrieval (PAIR) system. In addition, the Patent Center e-Office Action program offers a new option for users to receive courtesy postcards by email (e-postcards) as a reminder that there are available USPTO communications that have not been viewed or downloaded. The USPTO is implementing the e-postcard option based on feedback from customers, particularly to reduce paper consumption and mitigate the impact of potential postal delays. Through this notice, the USPTO seeks public comments on eliminating the postal postcard for all Patent Center e-Office Action program users in the future. As with the existing program, participation in the Patent Center e-Office Action program is optional. **COMMENTS DUE**: June 5, 2023

<u>DOS Exchange Visitor Program, 88 Federal Register</u> 20202, April 5, 2023

NOTICE: In accordance with the General Provisions of the Exchange Visitor Program regulations, the Department's Assistant Secretary for Educational and Cultural Affairs waives and modifies certain regulatory requirements with respect to a temporary educational and cultural exchange program established pursuant to an arrangement between the Government of the United States of America and the Government of Ukraine. This arrangement allows the Department to extend Special Student Relief to eligible Ukrainian students in the United States on J–1 visas to help mitigate the adverse impact on them resulting from the full-scale Russian invasion of Ukraine that began on February 24, 2022.

EFFECTIVE DATE: August 18, 2022 – October 23, 2023

Federal Acquisition Regulation: Small Business Innovation Research and Technology Transfer Programs, 88 Federal Register 20822, April 7, 2023 PROPOSED RULE: DoD, GSA and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement changes related to data rights in the Small Business Administration's Policy Directive for the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs, published in the Federal Register on April 2, 2019. In addition, this proposed rule would implement competition requirements unique to Phase II and III awards under the SBIR/STTR Programs. COMMENTS DUE: June 6, 2023

Nondiscrimination on the Basis of Sex in Education
Programs or Activities Receiving Federal Financial
Assistance: Sex-Related Eligibility Criteria for Male and
Female Athletic Teams, 88 Federal Register 22860, April
13, 2023

NOTICE OF PROPOSED RULEMAKING: The U.S. Department of Education (Department) proposes to amend its regulations implementing Title IX of the Education Amendments of 1972 (Title IX) to set out a standard that would govern a recipient's adoption or application of sex-related criteria that would limit or deny a student's eligibility to participate on a male or female athletic team consistent with their gender identity. The proposed regulation would clarify Title IX's application to such sex-related criteria and the obligation of schools and other recipients of Federal financial assistance from the Department (referred to below as "recipients" or "schools") that adopt or apply such criteria to do so consistent with Title IX's nondiscrimination mandate.

Notice of Expiration of Certain Notifications of Enforcement Discretion Issued in Response to the COVID-19 Nationwide Public Health Emergency, 88 Federal Register 22380, April 13, 2023

COMMENTS DUE: May 15, 2023

NOTICE: This document is to inform the public that four Notifications of Enforcement Discretion ("Notifications") issued by the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR) regarding how the Privacy, Security, and Breach Notification Rules ("HIPAA Rules") promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act will be applied to certain violations during the COVID-19 nationwide public health emergency ("COVID-19 PHE"), will expire upon expiration of the COVID-19 PHE, which is currently scheduled for 11:59 p.m. on May 11, 2023. Accordingly, upon expiration of the COVID-19 PHE, the Notifications will not provide a basis for OCR to exercise enforcement discretion with respect to imposing penalties for violations of the HIPAA Rules. OCR will continue to exercise enforcement discretion consistent with the Notifications for violations of the HIPAA Rules that occurred during the period that each Notification was in effect. In addition, OCR is affording covered health care providers a 90-calendar day transition period to come into compliance with the HIPAA Rules with respect to their provision of telehealth using non-public facing remote communication technologies.

EXPIRATION DATE: May 11, 2023; the 90-calendar day transition period with respect to telehealth will expire at 11:59 p.m. on August 9, 2023.

NTIA AI Accountability Policy Request for Comment, 88 Federal Register 22433, April 13, 2023

NOTICE: The National Telecommunications and Information Administration (NTIA) hereby requests comments on Artificial Intelligence ("AI") system accountability measures and policies. This request focuses on self-regulatory, regulatory, and other measures and policies that are designed to provide reliable evidence to external stakeholders—that is, to provide assurance—that AI systems are legal, effective, ethical, safe, and otherwise trustworthy. NTIA will rely on these comments, along with other public engagements on this topic, to draft and issue a report on AI accountability policy development, focusing especially on the AI assurance ecosystem.

COMMENTS DUE: June 12, 2023

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Nurse Corps Supplemental Funding Evaluation, 88 Federal Register 23091, April 17, 2023

NOTICE: The objective of Nurse Corps Loan Repayment Program (LRP) and Scholarship Program (SP) is to lessen the financial burden of those pursuing nursing careers in the hope of increasing nursing workforce participation in underserved areas. The programs support HRSA's overall mission to improve health outcomes and achieve health equity through access to quality services by optimizing the distribution of the nursing workforce. The Nurse Corps LRP reimburses educational loans for nurses who serve a minimum 2-year commitment in a critical shortage facility or work as nurse faculty in accredited schools of nursing. The Nurse Corps SP similarly pays for educational expenses of nursing students who agree to a minimum 2-year service commitment in critical shortage facilities upon graduation. COMMENTS DUE: June 13, 2023

PTO Comment Request; Secrecy and License To Export, 88 Federal Register 23008, April 17, 2023

NOTICE: In the interest of national security, patent laws and regulations place certain limitations on the disclosure of information contained in patents and patent applications and on the filing of applications for patents in foreign countries.

HIPAA Privacy Rule To Support Reproductive Health Care
Privac Notice Inviting Postsecondary Educational
Institutions To Participate in Experiments Under the
Experimental Sites Initiative; Federal Student Financial
Assistance Programs Under Title IV of the Higher
Education Act of 1965, 88 Federal Register 23506, April
17, 2023

NOTICE OF PROPOSED RULEMAKING: The Department of Health and Human Services (HHS or "Department") is issuing this notice of proposed rulemaking (NPRM) to solicit comment on its proposal to modify the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act). The proposal would modify existing standards permitting uses and disclosures of protected health information (PHI) by limiting uses and disclosures of PHI for certain purposes where the use or disclosure of information is about reproductive health care that is lawful under the circumstances in which such health care is provided. The proposal would modify existing standards by prohibiting uses and disclosures of PHI for criminal, civil, or administrative investigations or proceedings against individuals, covered entities or their business associates (collectively, "regulated entities"), or other persons for seeking, obtaining, providing, or facilitating reproductive health care that is lawful under the circumstances in which it is provided.

ED Notice Inviting Postsecondary Educational
Institutions To Participate in Experiments Under the
Experimental Sites Initiative; Federal Student Financial
Assistance Programs Under Title IV of the Higher
Education Act of 1965, as Amended, 88 Federal Register
23652, April 18, 2023

NOTICE: The Secretary invites postsecondary educational institutions (institutions) that currently participate in the Second Chance Pell experiment to apply to participate in a revised Second Chance Pell institution-based experiment under the Experimental Sites Initiative (ESI). The revised Second Chance Pell experiment will provide new waivers to allow current Second Chance Pell institutions to continue serving their students after July 1, 2023 while also continuing to allow the Department to learn more about the challenges schools face when implementing the new regulations. This will give participating institutions time to seek Department approval of their PEPs (as defined under the new regulations in 34 CFR part 668 subpart P) and avoid interrupting the educational

COMMENTS DUE: June 16, 2023

opportunities of students currently enrolled in approved programs under the experiment. **DEADLINE FOR SUBMITTING LETTER OF INTEREST**: May 18, 2023 Health Data, Technology, and Interoperability: PROPOSED RULE: This proposed rule would implement the Certification Program Updates, Algorithm Transparency, Electronic Health Record (EHR) Reporting Program provision of and Information Sharing, 88 Federal Register 23746, the 21st Century Cures Act by establishing new Conditions and April 18, 2023 Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program). This proposed rule would also make several updates to certification criteria and implementation specifications recognized by the Program, including a revised certification criterion for decision support and revised certification criteria for patient demographics and observations and electronic case reporting. This proposed rule would establish a new baseline version of the United States Core Data for Interoperability (USCDI). Additionally, this proposed rule would provide enhancements to support information sharing under the information blocking regulations. The implementation of these provisions would advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. The proposed rule would also update the Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs. COMMENTS DUE: June 20, 2023 HHS Modernization of Compliance Program Guidance **NOTICE**: HHS–OIG is modernizing the accessibility and usability Documents, 88 Federal Register 25000, April 25, 2023 of our publicly available resources, including OIG's Compliance Program Guidances (CPGs). OIG developed CPGs as voluntary, nonbinding guidance documents to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. OIG will no longer publish updated or new CPGs in the Federal Register. All current, updated, and new CPGs will be available on our website. (https://oig.hhs.gov/compliance/complianceguidance/). We will publish a General CPG (GCPG) that applies to all individuals and entities involved in the health care industry. The GCPG will address topics such as: federal fraud and abuse laws, compliance program basics, operating effective compliance programs, and OIG processes and resources. We anticipate updating the GCPG as changes in compliance practices or legal requirements warrant. OIG plans to publish the GCPG by

the end of calendar year 2023. Second, we will publish industry-specific CPGs (ICPGs) for different types of providers, suppliers, and other participants in health care industry

reduce these risks. ICPGs are intended to be updated periodically to address newly identified risk areas and compliance measures and to ensure timely and meaningful

subsectors or ancillary industry sectors relating to Federal health care programs. ICPGs will be tailored to fraud and abuse risk areas for each industry subsector and will address compliance measures that the industry subsector participants can take to

	guidance from OIG. OIG expects to begin publishing ICPGs in		
	calendar year 2024.		
ED Annual Updates to the Income-Contingent	NOTICE: The Secretary announces the annual updates to the		
Repayment (ICR) Plan Formula for 2023-William D. Ford	ICR plan formula for 2023 to give notice to borrowers and the		
Federal Direct Loan Program, 88 Federal Register 25388,	public regarding how monthly ICR payment amounts will be		
April 26, 2023	calculated for the 2023–2024 year under the William D. Ford		
	Federal Direct Loan (Direct Loan) Program, Assistance Listing		
	Number 84.063.		
	EFFECTIVE DATE : July 1, 2023 – June 30, 2024		
Patient Protection and Affordable Care Act, HHS Notice	FINAL RULE: This final rule includes payment parameters and		
of Benefit and Payment Parameters for 2024, 88 Federal	provisions related to the HHS-operated risk adjustment and risk		
Register 25740, April 27, 2023	adjustment data validation programs, as well as 2024 user fee		
10g/3001 237 40, Npm 27, 2023	rates for issuers offering qualified health plans (QHPs) through		
	Federally-facilitated Exchanges (FFEs) and State-based		
	Exchanges on the Federal platform (SBE–FPs). This final rule also		
	has requirements related to updating standardized plan options		
	and reducing plan choice overload; the automatic re-enrollment		
	hierarchy; plan and plan variation marketing name requirements		
	for QHPs; essential community providers (ECPs) and network		
	adequacy; failure to file and reconcile; special enrollment		
	periods (SEPs); the annual household income verification; the		
	deadline for QHP issuers to report enrollment and payment		
	inaccuracies; requirements related to the State Exchange		
	improper payment measurement program; and requirements		
	for agents, brokers, and web-brokers assisting FFE and SBE–FP		
	consumers.		
	EFFECTIVE DATE: June 18, 2023		
Agency New Information Collection Request. 30-Day	NOTICE : The Office of the Assistant Secretary for Health, Office		
Public Comment Request, Research Complaint Form, 88	for Human Research Protections (OHRP), is requesting a new		
Federal Register 25666, April 27, 2023	approval from the Office of Management and Budget of OHRP's		
	Research Complaint Form. This form will provide a simplified		
	standardized format for submitting to OHRP allegations of		
	noncompliance involving human subject research conducted or		
	supported by HHS, which should significantly improve OHRP's		
	capacity to review and process these allegations. The		
	information collected will help OHRP ensure the rights of human		
	subjects involved in such research and that OHRP-assured		
	institutions are complying with the HHS Protection of Human		
	Subjects regulations.		
	COMMENTS DUE: May 30, 2023		
Ownership and Control and Contractual Assistance	FINAL RULE: This final rule makes several changes to the		
Requirements for the 8(a) Business Development	ownership and control requirements for the 8(a) Business		
Program, 88 Federal Register 26164, April 27, 2023	Development (BD) program, including recognizing a process for		
	allowing a change of ownership for a former Participant that is		
	still performing one or more 8(a) contracts and permitting an		
	individual to own an applicant or Participant where the		
	individual can demonstrate that financial obligations have been		
	settled and discharged by the Federal Government. The rule also		
	makes several changes relating to 8(a) contracts, including		
	clarifying that a contracting officer cannot limit an 8(a)		
	competition to Participants having more than one certification		
	and clarifying the rules pertaining to issuing sole source 8(a)		
	orders under an 8(a) multiple award contract. The rule also		
	orders under an o(a) multiple award contract. The full diso		

Request for Information (RFI) on Developing a Roadmap for the Directorate for Technology, Innovation, and

makes several other revisions to incorporate changes to SBA's other government contracting programs, including changes to implement a statutory amendment from the National Defense Authorization Act for Fiscal Year 2022, to include blanket purchase agreements in the list of contracting vehicles that are covered by the definitions of consolidation and bundling, and to more clearly specify the requirements relating to waivers of the nonmanufacturer rule.

EFFECTIVE DATE: May 30, 2023

REQUEST FOR INFORMATION: The National Science Foundation (NSF) requests input from the full range of institutions and organizations across all sectors—industry, academia, non-profits, government, venture capital, and others—to inform the development of a roadmap for its newlyestablished Technology, Innovation, and Partnerships (TIP) Directorate, in accordance with the CHIPS and Science Act of 2022. This legislation tasks the TIP Directorate to develop a roadmap to guide investment decisions in use-inspired and translational research over a 3-year time frame, working towards the goal of advancing U.S. competitiveness in the identified key technology focus areas and addressing the identified societal, national, and geostrategic challenges. Investments would be in use-inspired research, translation of research results to impact, and education, training, and development of talent in the key technology areas and societal, national, and geostrategic challenges.

COMMENTS DUE: July 27, 2023

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; SelectUSA Client Intake Survey, 88 Federal Register 26273, April 28, 2023

Partnerships at the National Science Foundation, 88

Federal Register 26245, April 28, 2023

NOTICE: SelectUSA, within the International Trade Administration, provides programs and services that focus on facilitating job-creating business investment into the United States and raising awareness of the critical role that economic development plays in the U.S. economy. These programs include information products, services, and trade events to potential foreign investors into the United States and to U.S.-based economic development organizations. To accomplish its mission effectively, SelectUSA requires detailed information from clients in order to provide resources and services that meet each specific client's need....Upon approval by OMB, ITA will use the approved information collection to collect client input by the use of multiple data collection methods, including Comment Cards (i.e., transactional-based surveys), web-enabled surveys sent via email, telephone interviews, automated telephone surveys, and in-person surveys via mobile devices/laptops/tablets at trade events/shows. The use of these multiple data collection methods is suggested solely to reduce the public burden in responding to requests for input. Without this information, ITA is unable to systematically determine the actual and relative levels of user needs for its programs and products/services and to provide clear, actionable insights for client use. This information will be used for strategic planning, allocation of resources, and stakeholder reporting.

COMMENTS DUE: June 27, 2023

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Board of Accountancy Guidance Documents, Virginia Register of Regulations, Volume 39, Issue 17, April 10, 2023

Change of Decision Following Periodic Review of
Regulations to Assure the Protection of Participants in
Human Research 12VAC35-180, Virginia Register of
Regulations, Volume 39, Issue 18, April 24, 2023

NOTICE: Among other agency Guidance Documents, the Board of Accountancy provides its annual list of guidance documents for public review.

CHANGE IN DECISION: The agency decision following the periodic review published in the Virginia Register at 39:15 VA.R. 2046 March 13, 2023 for the Regulations to Assure the Protection of Participants in Human Research (12VAC35-180) is changed from "amend" to "retain as is." The last action initiated, which was on October 10, 2018, occurred after the federal final rule was published. The Federal Policy for the Protection of Human Subjects (also known as the "Common Rule" and codified for the U.S. Department of Health and Human Services (HHS) at 45 CFR Part 46, Subpart A) was originally promulgated in 1991 and amended in 2005. This version of the Common Rule is referred to as the "pre-2018 Common Rule" is available at this link: 45 CFR Part 46, Subpart A as published in the 2016 edition of the Code of Federal Regulations (CFR). A comprehensive revision to the Common Rule was published in the Federal Register (FR) January 19, 2017 (82 FR 7149). The revised Common Rule has been amended twice, in an interim final rule published on January 22, 2018 (83 FR 2885), and in a final rule published on June 19, 2018 (83 FR 28497). The revised Common Rule is referred to as the "2018 Requirements." The Agency decision following periodic review is to retain the retgulation as it is, making no change, instead of to amend the regulation as no federal change requires the regulation to be amended.