

**Terry Clark,**  
*Office of the Secretary, Paperwork Reduction*  
*Act Reports Clearance Officer.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0945-0003-60D]

### Agency Information Collection Request. 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before September 17, 2019.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

#### FOR FURTHER INFORMATION CONTACT:

When submitting comments or requesting information, please include the document identifier 0945-0003-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), or call 202-795-7714.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* HIPAA Privacy, Security, and Breach Notification Rules, and Supporting

Regulations Contained in 45 CFR parts 160 and 164.

*Type of Collection:* Extension.

*OMB No. 0945-0003:* Office for Civil Rights (OCR)—Health Information Privacy Division.

*Abstract:* Office for Civil Rights (OCR) requests approval to extend this existing, approved collection without changing any collecting requirements while OCR obtains public comment through a Notice of Proposed Rulemaking (NPRM) proposing modifications to the HIPAA Rules that will affect the hourly burdens associated with the Rules. When the NPRM is published, we expect to receive robust public comment on existing burdens associated with compliance with the HIPAA Rules and on changes in burden that could result from the modifications proposed in the NPRM. OCR will update this ICR to reflect the input we receive on this notice and through the rulemaking process.

*Likely Respondents:* HIPAA covered entities, business associates, individuals, and professional and trade associations of covered entities and business associates.

### ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
45 CFR 160.204: Process for Requesting Exception Determinations (states or persons).	A state's chief elected official or designee.	1	1	16	16
45 CFR 164.308: Risk Analysis—Documentation.	Covered entities; business associates.	1,700,000	1	10	17,000,000
45 CFR 164.308: Information System Activity Review—Documentation.	Covered entities; business associates.	1,700,000	12	0.75	15,300,000
45 CFR 164.308: Security Reminders—Periodic Updates.	Covered entities; business associates.	1,700,000	12	1	20,400,000
45 CFR 164.308: Security Incidents (other than breaches)—Documentation.	Covered entities; business associates.	1,700,000	52	5	442,000,000
45 CFR 164.308: Contingency Plan—Testing and Revision.	Covered entities; business associates.	1,700,000	1	8	13,600,000
45 CFR 164.308: Contingency Plan—Criticality Analysis.	Covered entities; business associates.	1,700,000	1	4	6,800,000
45 CFR 164.310: Maintenance Records .....	Covered entities; business associates.	1,700,000	12	6	122,400,000
45 CFR 164.314: Security Incidents—Business Associate reporting of incidents (other than breach) to Covered Entities.	Business associates .....	1,000,000	12	20	240,000,000
45 CFR 164.316: Documentation—Review and Update.	Covered entities; business associates.	1,700,000	1	6	10,200,000
45 CFR 164.404: Individual Notice—Written and E-mail Notice (drafting).	Covered entities .....	58,481	1	0.5	29,241
45 CFR 164.404: Individual Notice—Written and E-mail Notice (preparing and documenting notification).	Covered entities .....	58,481	1	0.5	29,241
45 CFR 164.404: Individual Notice—Written and E-mail Notice (processing and sending).	Covered entities .....	58,481	353	0.008	165,150
45 CFR 164.404: Individual Notice—Substitute Notice (posting or publishing).	Covered entities .....	2,746	1	1	2,746
45 CFR 164.404: Individual Notice—Substitute Notice (staffing toll-free number).	Covered entities .....	2,746	1	5.75	15,790

## ESTIMATED ANNUALIZED BURDEN HOUR TABLE—Continued

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
45 CFR 164.404: Individual Notice—Substitute Notice (individuals' voluntary burden to call toll-free number for information).	Covered entities .....	11,326,440	1	0.125	1,415,805
45 CFR 164.406: Media Notice .....	Covered entities .....	267	1	1.25	334
45 CFR 164.408: Notice to Secretary (notice for breaches affecting 500 or more individuals).	Covered entities .....	267	1	1.25	334
45 CFR 164.408: Notice to Secretary (notice for breaches affecting <500 individuals).	Covered entities .....	58,215	1	1	58,215
45 CFR 164.410: Business associate notice to covered entity—500 or more Affected Individuals.	Business associates .....	20	1	50	1,000
45 CFR 164.410: Business associate notice to covered entity—Less than 500 Affected Individuals.	Business associates .....	1,165	1	8	9,320
45 CFR 164.414: 500 or More Affected Individuals (investigating and documenting breach).	Covered entities .....	267	1	50	13,350
45 CFR 164.414: Less than 500 Affected Individuals (investigating and documenting breach)—affecting 10–499.	Covered entities .....	2,479	1	8	19,832
45 CFR 164.414: Less than 500 Affected Individuals (investigating and documenting breach)—affecting <10.	Covered entities .....	55,736	1	4	222,944
45 CFR 164.504: Uses and Disclosures—Organizational Requirements.	Covered entities .....	700,000	1	0.083333333	58,333
45 CFR 164.508: Uses and Disclosures for Which Individual authorization is required.	Covered entities .....	700,000	1	1	700,000
45 CFR 164.512: Uses and Disclosures for Research Purposes.	Covered entities .....	113,524	1	0.083333333	9,460
45 CFR 164.520: Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by paper mail).	Covered entities—health plans.	100,000,000	1	0.004166667	416,667
45 CFR 164.520: Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by electronic mail).	Covered entities—health plans.	100,000,000	1	0.002783333	278,333
45 CFR 164.520: Notice of Privacy Practices for Protected Health Information (health care providers—dissemination and acknowledgement).	Covered entities—health care providers.	613,000,000	1	0.5	30,650,000
45 CFR 164.522: Rights to Request Privacy Protection for Protected Health Information.	Covered entities—health care providers, health plans.	20,000	1	0.5	1,000
45 CFR 164.524: Access of Individuals to Protected Health Information (disclosures).	Covered entities—health care providers, health plans, clearinghouses.	200,000	1	0.5	10,000
45 CFR 164.526: Amendment of Protected Health Information (requests).	Covered entities—health care providers, health plans, clearinghouses.	150,000	1	0.083333333	12,500
45 CFR 164.526: Amendment of Protected Health Information (denials).	Covered entities—health care providers, health plans, clearinghouses.	50,000	1	0.083333333	4,167
45 CFR 164.528: Accounting for Disclosures of Protected Health Information.	Covered entities—health care providers, health plans, clearinghouses.	5,000	1	0.05	250
Total .....	.....	.....	.....	.....	921,824,027

**Terry Clark,**  
*Office of the Secretary, Paperwork Reduction*  
*Act Reports Clearance Officer.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-4040-0001]

### Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the

following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before August 19, 2019.

**ADDRESSES:** Submit your comments to *OIRA\_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Ed Calimag, *ed.calimag@hhs.gov* or (202) 690-7569. When submitting comments or requesting information, please include the document identifier 4040-0001-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to

enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collections:* Application for Federal Assistance SF-424 Research and Related Forms.

*Type of Collection:* Reinstatement without change.

*OMB No.* 4040-0002.

*Abstract:* The SF-424 Research and Related Forms provide the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use the SF-424 Research and Related Forms for grant programs not required to collect all the data that is required on the SF-424 core data set and form. The IC expires on 10/31/2019. We are seeking an extension of this information collection and a three-year clearance.

### ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SF-424 R&R Multi-Project Cover .....	1,519	1	1	1,159
SF424 (R&R ) .....	109,455	1	1	109,455
SBIR/STTR Information .....	6,376	1	1	6,376
RR FedNonFed Budget .....	0	1	1	0
Research and Related Senior/Key Person Profile (Expanded) .....	108,543	1	1	108,543
Research And Related Other Project Information .....	37,603	1	1	37,603
Research & Related Budget .....	63,909	1	1	63,909
Research & Related Subaward Budget (Total Fed + Non-Fed) Attachment(s) Form .....	0	1	1	0
Research & Related Subaward Budget (Total Fed + Non-Fed) 5 YR 30 ATT .....	0	1	1	0
Research & Related Senior/Key Person Profile .....	695	1	1	695
Research & Related Personal Data .....	0	1	1	0
Research & Related Multi-Project 10 Year Budget .....	3,847	1	1	3,847
Research & Related Budget 10YR .....	0	1	1	0
R&R Subaward Budget Attachment(s) Form 5 YR 30 ATT .....	59,767	1	1	59,767
R&R Subaward Budget Attachment(s) Form 10 YR 30 ATT .....	1,023	1	1	1,023
R&R Subaward Budget Attachment(s) Form 10 YR 10 ATT .....	0	1	1	0
R&R Subaward Budget Attachment(s) Form .....	271	1	1	271
R&R R Multi-Project Subaward Budget Attachment(s) Form 10 YR 30 ATT .....	1,023	1	1	1,023
Total .....	394,031	.....	.....	394,031

**Terry Clark,**  
*Office of the Secretary, Paperwork Reduction*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-4040-0004]

### Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before August 19, 2019.

**ADDRESSES:** Submit your comments to *OIRA\_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Ed Calimag, *ed.calimag@hhs.gov* or (202) 690-7569. When submitting comments

or requesting information, please include the document identifier 4040-0004-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection