

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS-0945-0003]

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 Information Collection Request (ICR) must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0945-0003-New-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 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 collection 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. This notice does, however, make the following revisions to estimates provided in the 60-day public comment request, which do not change the collection requirements: (1) lower the estimated number of individuals who call an entity's toll-free number for information after being affected by a breach requiring substitute notice to reflect a more realistic estimate of the proportion of individuals who choose to call; and (2) correct an error from the 2016 ICR notice that underestimated the average number of individuals affected per breach because it relied on older breach data. This notice also incorporates data from the 60-day public comment request which recognizes for the first time the burdens resulting from the pre-existing, ongoing requirements for business associates to report breaches of PHI to their covered entities.

We did not receive public comment on the 60-day public comment request published on July 19, 2019. 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. Likely Respondents: HIPAA covered entities, business associates, individuals, and professional and trade associations of covered entities and business associates.

Estimated Annualized Burden 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	58,482	1	0.5	29,241
45 CFR 164.404 Individual Notice—Written and E-mail Notice (preparing and documenting notification)	Covered entities	58,482	1	0.5	29,241
45 CFR 164.404 Individual Notice—Written and E-mail Notice (processing and sending)	Covered entities	58,482	1,941	0.008	908,108
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	3.42	9,391
45 CFR 164.404 Individual Notice—Substitute Notice (individuals’ voluntary burden to call toll-free number for information)	Covered entities	113,264	1	0.125	14,158
45 CFR 164.406 Media Notice	Covered entities	267	1	1.25	334
45 CFR 164.408	Covered entities	267	1	1.25	334

Notice to Secretary (notice for breaches affecting 500 or more individuals)					
45 CFR 164.408  Notice to Secretary (notice for breaches affecting less than 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 165.512	Covered	113,524	1	0.083333333	9,460

Uses and Disclosures for Research Purposes	entities				
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	0.05	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	0.05	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	0.05	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, clearinghouse	50,000	1	0.083333333	4,167

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45 CFR 164.528 Accounting for Disclosures of Protected Health Information	Covered entities - health care providers, health plans, clearinghouse s	5,000	1	0.05	250
<b>Total</b>					921,158,941

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Insert Name

*Office of the Secretary*

*Paperwork Reduction Act Reports Clearance Officer*