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HIPAA Administrative Simplification Compliance Review (CMS-10662)

Comment On: CMS-2023-0190-0001

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Document: CMS-2023-0190-DRAFT-0001

Comment on CMS-2023-0190-0001

Submitter Information

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General Comment

This comment is on behalf of New York Urology Specialists, a small medical practice in New York City. As a healthcare provider, we are a "covered entity" and are obligated to comply with HIPAA Administrative Simplification requirements. We could be subject to Compliance Reviews.

The Compliance Review fails to satisfy the basic requirements under HIPAA, and thus neither the program can be legally administered in the current form nor the data collection can be legally justified for approval.

The HIPAA Administrative Simplification Compliance Review fails to detect >90% of non-compliance with adopted rules, as demonstrated by the fact that most provider complaints filed with the CMS ASETT program fail to be detected with the Compliance Review. The most recent Compliance Review report for 2022 shows rampant non-compliance 10 years after the deadline for compliance. Clearly the Compliance Review failed miserably in doing what it is supposed to do.

The HIPAA Administrative Simplification Compliance Review, in the absence of financial penalties for non-compliance cannot be foreseen to "lower the costs of healthcare" and cannot be foreseen to "lower administrative burdens." Ad-hoc reviews of 10-50 plans a year by the National Standards Group among the pool of >60,000 plans cannot meaningfully improve compliance, lower costs, or lower administrative burdens. It has not been successful, has not demonstrated improved compliance in the industry as a whole, and cannot be legally implemented under the governing law, HIPAA.

Because The HIPAA Administrative Simplification Compliance Review fails to demonstrate any benefits that are greater than the cost of compliance, we request that the request to approve the collection of information be denied by the Office of Management and Budget (OMB).

This request violates the requirements 44 U.S.C. 3501–3520, specifically:

1. It fails to minimize "paperwork burden" as the data collected serves no "overarching" policy goal, does not lead to improved compliance in the industry, and has demonstrably failed in its goals.
2. It fails to "ensure the greatest possible public benefit" and to "maximize the utility of information created, collected maintained, or used" by the Federal Government.
3. It does nothing to "improve the quality and use of Federal information to strengthen decisionmaking, accountability, and openness in Government and society;" CMS does not have the ability to do truly random audits, as it lacks a complete database of all health plans in the US that are required to comply with HIPAA Administrative Simplification requirements, as it failed to adopt and implement the HPID (Health Plan ID), a HIPAA mandated identifier. There is no valid methodology for CMS National Standards Group to sample plans or vendors for

compliance. Whatever data is generated as a result has minimal value as it is not likely to be scientifically and statistically representative and cannot be relied on to “strengthen decisionmaking, accountability and openness”. The Operating Rule Response/Attestation Document fails to address the common non-compliance problems identified in CMS ASSETT Complaints, which account for >90% of non-compliance thus >90% of non-compliance would go undetected with this questionnaire, making it worthless.

In addition, there is no validation of the “self-certified” compliance claims.

The text is vague, does not require specific documentation to validate compliance. For example, each question has the same “requirement”:

- share with us the documentation you have and/or provide us a short description in the comments section below of how your organization supports and meets this requirement.

In summary, the CMS Office of Burden Reduction Division of National Standards failed to satisfy the legal requirements for the updated forms under 44 U.S.C. 3501–3520. In addition, the Compliance Program itself fails to satisfy the legal requirements under the governing HIPAA law.

Office of Management and Budget (OMB) cannot approve data collections for a program that does not satisfy legal requirements under the governing law.

Sincerely,
Alex Shteynshlyuger MD