

119TH CONGRESS
1ST SESSION

H. R. 4470

To amend title XI of the Social Security Act to require hospitals participating in the Medicare and Medicaid programs to establish certain notification procedures with respect to organ procurement agencies.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2025

Ms. VAN DUYNE (for herself, Ms. DELBENE, Mrs. MILLER of West Virginia, and Mr. COSTA) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XI of the Social Security Act to require hospitals participating in the Medicare and Medicaid programs to establish certain notification procedures with respect to organ procurement agencies.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Removing Burdens
5 From Organ Donation Act”.

1 **SEC. 2. NOTIFYING ORGAN PROCUREMENT AGENCIES WITH**
2 **RESPECT TO POTENTIAL ORGAN DONORS.**

3 (a) IN GENERAL.—Section 1138(a) of the Social Se-
4 curity Act (42 U.S.C. 1320b–8(a)) is amended—

5 (1) in paragraph (1)(A)(iii)—

6 (A) by adding “and” at the end;

7 (B) by striking “that such” and inserting
8 “that—

9 “(I) such”; and

10 (C) by adding at the end the following new
11 subclause:

12 “(II) subject to paragraph (4),
13 beginning on the date that is 2 years
14 after the date of the enactment of the
15 Removing Burdens From Organ Do-
16 nation Act, with respect to such a po-
17 tential organ donor, such hospital’s
18 designated organ procurement agency
19 is issued an automated electronic noti-
20 fication and is provided electronic and
21 remote access to the electronic health
22 records of such potential organ donor
23 when such electronic health records
24 are updated to indicate that such po-
25 tential organ donor is deceased or
26 that the death of such potential organ

1 donor is imminent, as determined in
2 accordance with the protocol described
3 in section 482.45(a)(1) of title 42,
4 Code of Federal Regulations (or any
5 successor regulation);” and

6 (2) by adding at the end the following new
7 paragraph:

8 “(4) EXEMPTIONS FROM AUTOMATED EHR AC-
9 CESS REQUIREMENT.—

10 “(A) EXEMPTIONS.—

11 “(i) IN GENERAL.—The Secretary
12 may exempt a hospital or critical access
13 hospital from the automated electronic no-
14 tification and remote access requirement
15 under paragraph (1)(A)(iii)(II) for a pe-
16 riod of 3 years if the Secretary determines
17 that meeting such requirement would re-
18 sult in a significant hardship, such as in
19 the case of a hospital or critical access hos-
20 pital located in a rural area without suffi-
21 cient Internet access, or other exceptional
22 circumstances demonstrated by the hos-
23 pital.

24 “(ii) AUTOMATIC EXEMPTION.—The
25 Secretary shall grant an exemption de-

1 scribed in clause (i) to a hospital or critical
2 access hospital for a period of 1 year if the
3 Secretary determines that such hospital is
4 affected by a cybersecurity attack (as de-
5 fined in subparagraph (C)), or is located in
6 an area affected by a major disaster (as
7 defined in section 5122(2) of title 42,
8 United States Code) or any other natural
9 or man-made disaster, and shall notify
10 such hospital or critical access hospital of
11 such exemption.

12 “(iii) EXTENSION.—The Secretary
13 may extend an exemption granted under
14 clause (i) or (ii) if the hospital or critical
15 access hospital demonstrates to the satis-
16 faction of the Secretary that such an ex-
17 tension is necessary.

18 “(B) REPORT.—Not later than 2 years
19 after the date of the enactment of the Remov-
20 ing Burdens From Organ Donation Act, and
21 not less frequently than annually thereafter, the
22 Secretary shall submit to the Committee on
23 Ways and Means and the Committee on Energy
24 and Commerce of the House of Representatives,
25 and to the Committee on Finance and the Com-

mittee on Health, Education, Labor, and Pen-
sions of the Senate, a report on the number of
exemptions granted under subparagraph (A)
during the previous year and the reason for
granting each such exemption.

“(C) CYBERSECURITY ATTACK DEFINED.—

For purposes of subparagraph (A), the term
‘cybersecurity attack’ means, with respect to a
hospital or a critical access hospital, any kind
of malicious activity that—

“(i) attempts to collect, modify, dis-
rupt, deny, degrade, or destroy information
system resources of the hospital, including
the information itself;

“(ii) affects the confidentiality, integ-
rity or availability of data, information, or
operational technology system resources of
the hospital; or

“(iii) poses any other threat to the in-
formation, information systems, tech-
nology, or technological capabilities of the
hospital, as determined by the Secretary.”.

(b) GUIDANCE ON BEST PRACTICES.—

(1) IN GENERAL.—Not later than 1 year after
the date of the enactment of this Act, the Secretary

1 of Health and Human Services shall issue guidance
2 to hospitals, critical access hospitals, organ procure-
3 ment agencies, and electronic health record compa-
4 nies regarding best practices for complying with the
5 automated electronic notification and remote access
6 requirement under subclause (II) of section
7 1138(a)(1)(A)(iii) of the Social Security Act (42
8 U.S.C. 1320b–8(a)(1)(A)(iii)), as added by sub-
9 section (a). Such guidance shall be based upon the
10 experiences of entities that have previous experience
11 with the implementation of similar automated elec-
12 tronic notifications and remote access, and shall pro-
13 vide insights on what worked well and what did not.

14 (2) EXPLANATION OF CHANGES TO DONORS
15 AND FAMILY MEMBERS.—Not later than 1 year after
16 the date of the enactment of this Act, the Secretary
17 of Health and Human Services shall issue guidance
18 to State health agencies (or such other State agency,
19 department, or authority as the Governor of each
20 State may determine appropriate) regarding best
21 practices for explaining the automated electronic no-
22 tification and remote access requirement under sub-
23 clause (II) of section 1138(a)(1)(A)(iii) of the Social
24 Security Act (42 U.S.C. 1320b–8(a)(1)(A)(iii)), as
25 added by subsection (a), to organ donors, potential

1 organ donors, and the family members of such do-
2 nors and potential donors.

3 (c) GAO REPORT AND STUDY.—The Comptroller
4 General of the United States (in this subsection referred
5 to as the “Comptroller General”) shall—

6 (1) carry out a study on the implementation of
7 the automated electronic notification and remote ac-
8 cess requirement under subclause (II) of section
9 1138(a)(1)(A)(iii) of the Social Security Act (42
10 U.S.C. 1320b–8(a)(1)(A)(iii)), as added by sub-
11 section (a), that takes into account—

12 (A) the cost of implementing the auto-
13 mated electronic notification and remote access
14 requirement described in such paragraph;

15 (B) the impact of hospital location on the
16 implementation of such requirement, including
17 the impact of limited broadband access in rural
18 areas, and improvements that could be made to
19 facilitate such implementation; and

20 (C) the reports submitted by the Secretary
21 pursuant to paragraph (4)(B) of section
22 1138(a) of such Act (42 U.S.C. 1320b–8(a)),
23 as added by subsection (a); and

24 (2) not later than 3 years after the date of the
25 enactment of the Removing Burdens from Organ

1 Donation Act, submit to Congress a report on the
2 results of the study carried out under paragraph (1)
3 that includes—

4 (A) an analysis of data maintained by the
5 Department of Health and Human Services re-
6 lated to the outcomes of organ transplants per-
7 formed after the enactment of the Removing
8 Burdens from Organ Donation Act;

9 (B) a review of issues related to securing
10 patient data and the roles of the Centers for
11 Medicare & Medicaid Services and the Health
12 Resources and Services Administration with re-
13 spect to those issues; and

14 (C) any recommendations for further ac-
15 tion, as appropriate.

○