

116TH CONGRESS  
2D SESSION

# H. R. 8658

To establish a Federal strategy for preventing, diagnosing, and treating nonalcoholic steatohepatitis, commonly referred to as “NASH”.

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IN THE HOUSE OF REPRESENTATIVES

OCTOBER 23, 2020

Mr. CRENSHAW (for himself and Mr. RUIZ) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To establish a Federal strategy for preventing, diagnosing, and treating nonalcoholic steatohepatitis, commonly referred to as “NASH”.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Nonalcoholic Steatohepatitis Care Act of 2020” or the  
6 “NASH Care Act of 2020”.

7 (b) TABLE OF CONTENTS.—The table of contents for  
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. National prevention program for diabetes, nonalcoholic fatty liver disease, and metabolic syndrome.

- Sec. 3. Grants for community-based patient education and provider training and outreach.
- Sec. 4. National Academies of Sciences study on education and policy needs for nonalcoholic steatohepatitis and nonalcoholic fatty liver disease.
- Sec. 5. National surveillance program for nonalcoholic fatty liver disease and nonalcoholic steatohepatitis.
- Sec. 6. Recommendations for the prevention, screening, diagnosis, and treatment of interrelated conditions developed by multidisciplinary task force.
- Sec. 7. Renaming of NIH institute to reflect liver diseases and creation of division of liver diseases.

1 **SEC. 2. NATIONAL PREVENTION PROGRAM FOR DIABETES,**  
 2 **NONALCOHOLIC FATTY LIVER DISEASE, AND**  
 3 **METABOLIC SYNDROME.**

4 Section 399V–3 of the Public Health Service Act  
 5 (280g–14) is amended—

6 (1) in subsection (a)—

7 (A) by inserting “or continue” after “es-  
 8 tablish”;

9 (B) by striking “national diabetes”;

10 (C) by inserting “, nonalcoholic fatty liver  
 11 disease, and metabolic syndrome” after “high  
 12 risk for diabetes”; and

13 (D) by striking “burden of diabetes” and  
 14 inserting “such conditions”;

15 (2) in subsection (b)—

16 (A) by striking paragraph (1)

17 (B) by redesignating paragraphs (2)  
 18 through (4) as paragraphs (3) through (5); and

19 (C) by inserting before paragraph (3) (as  
 20 so redesignated) the following;

1           “(1) competitive grants to eligible entities for  
2           the purposes of identifying, developing, or dissemi-  
3           nating best practices on the prevention, detection,  
4           and treatment of diabetes, nonalcoholic fatty liver  
5           disease, and metabolic syndrome;

6           “(2) competitive grants for eligible entities for  
7           the development of community-based prevention pro-  
8           gram model sites;”;

9           (3) by redesignating subsection (d) as sub-  
10          section (e);

11          (4) by inserting after subsection (c) the fol-  
12          lowing:

13          “(d) PREFERENCE.—In awarding grants under sub-  
14          section (b), the Secretary may give preference to eligible  
15          entities that—

16                 “(1) provide lifestyle interventions, including  
17                 nutrition and exercise consultation; and

18                 “(2) serve racial and ethnic minority commu-  
19                 nities with high rates of diabetes, nonalcoholic fatty  
20                 liver disease, and metabolic syndrome.” ; and

21                 (5) in subsection (e) (as redesignated by para-  
22                 graph (3)), by striking “such sums as may be nec-  
23                 essary for each of fiscal years 2010 through 2014”  
24                 and inserting “\$27,300,000 for each of fiscal years  
25                 2021 through 2025”.

1 **SEC. 3. GRANTS FOR COMMUNITY-BASED PATIENT EDU-**  
2 **CATION AND PROVIDER TRAINING AND OUT-**  
3 **REACH.**

4 (a) IN GENERAL.—The Secretary of Health and  
5 Human Services, acting through the Director of the Cen-  
6 ters for Disease Control and Prevention, shall establish  
7 a grant program under which the Secretary may award  
8 grants to eligible entities to provide education in the pre-  
9 vention of nonalcoholic steatohepatitis (referred to in this  
10 Act as “NASH”), which shall be know as the National  
11 NASH Prevention and Education Program (referred to in  
12 this section as “the Program”). To the extent practicable,  
13 the Secretary shall align such program with the eligibility  
14 criteria to receive grants under the National Diabetes Pre-  
15 vention Program of the Centers for Disease Control and  
16 Prevention.

17 (b) ELIGIBLE ENTITIES.—An entity is eligible to re-  
18 ceived a grant under the Program if such entity—

19 (1)(A) provides lifestyle interventions such as  
20 promotion of liver health interventions or nutrition  
21 and exercise consultation; or

22 (B) serves racial and ethnic minority commu-  
23 nities with high rates of nonalcoholic fatty liver dis-  
24 ease (as determined by Secretary); and

25 (2) is a community-based, nonprofit organiza-  
26 tion located in any state or is an experienced organi-

1 zation in developing liver health education and  
2 awareness programs.

3 (c) APPLICATION.—An eligible entity seeking a grant  
4 under this section shall submit an application to the Sec-  
5 retary at such time, in such manner, and containing such  
6 information as the Secretary may require.

7 (d) TERM.—The term of a grant awarded under this  
8 section shall not exceed 5 years.

9 (e) CURRICULUM DEVELOPMENT.—

10 (1) IN GENERAL.—The Secretary shall develop,  
11 taking into consideration the best practices devel-  
12 oped by grantees under section 399V–3(b)(1) of the  
13 Public Health Service Act, as amended by section 2  
14 of this Act, directly or through grants to eligible en-  
15 tities, a curriculum to provide education in NASH  
16 prevention for use by recipients of grants under this  
17 section.

18 (2) FOCUS AREAS.—The curriculum shall pro-  
19 vide for consistency in—

20 (A) application of screening and diagnostic  
21 recommendations;

22 (B) collection of population data and qual-  
23 ity measures; and

1 (C) delivery of recommended evidence-  
2 based lifestyle interventions specific to nutrition  
3 and exercise.

4 (f) POPULATIONS CONSIDERED.—In carrying out  
5 this section, the Secretary shall consider the needs of pedi-  
6 atric and minority populations at risk for NASH.

7 (g) COORDINATION WITH CONTINUING MEDICAL  
8 EDUCATION.—The task force established under section 6  
9 shall, to the extent practicable, coordinate the availability  
10 of training and outreach under this subsection with the  
11 opportunity for providers receiving training pursuant to  
12 this section to earn continuing medical education credits.

13 (h) AUTHORIZATION OF APPROPRIATIONS.—There  
14 are authorized to be appropriated to carry out this section  
15 such sums as may be necessary for each of fiscal years  
16 2021 through 2025.

17 **SEC. 4. NATIONAL ACADEMIES OF SCIENCES STUDY ON**  
18 **EDUCATION AND POLICY NEEDS FOR NON-**  
19 **ALCOHOLIC STEATOHEPATITIS AND NON-**  
20 **ALCOHOLIC FATTY LIVER DISEASE.**

21 (a) IN GENERAL.—Not later than 180 days after the  
22 date of the enactment of this Act, the Secretary of Health  
23 and Human Services shall offer to enter into a contract  
24 with the National Academies of Sciences to conduct a

1 study on nonalcoholic fatty liver disease and nonalcoholic  
2 steatohepatitis in the United States.

3 (b) FOCUS AREAS.—The study conducted pursuant  
4 to subsection (a) shall focus on education and policy needs  
5 involving nonalcoholic fatty liver disease and nonalcoholic  
6 steatohepatitis, including—

7 (1) opportunities to strengthen prevention of  
8 nonalcoholic fatty liver disease and nonalcoholic  
9 steatohepatitis, including through enhanced delivery  
10 of nutrition services;

11 (2) barriers to diagnosis and treatment of non-  
12 alcoholic fatty liver disease and nonalcoholic  
13 steatohepatitis, including opportunities to strengthen  
14 coverage under the Medicare program under title  
15 XVIII of the Social Security Act (42 U.S.C. 1395 et  
16 seq.), the Medicaid program under title XIX of such  
17 Act (42 U.S.C. 1396 et seq.), group health plans (as  
18 defined in section 2791 of the Public Health Service  
19 Act (42 U.S.C. 300gg–91)), and group or individual  
20 health insurance coverage (as such terms are defined  
21 in such section 2791);

22 (3) recommendations for enhancing provider  
23 education on nonalcoholic fatty liver disease and  
24 nonalcoholic steatohepatitis; and

1           (4) recommendations for enhancing patient  
2 awareness of nonalcoholic fatty liver disease and  
3 nonalcoholic steatohepatitis, including early identi-  
4 fication of risk factors and linkage to appropriate  
5 care.

6           (c) REPORT.—The agreement entered into under sub-  
7 section (a) shall require the National Academies of  
8 Sciences to, not later than January 1, 2022, submit a re-  
9 port on the findings of the study to the Secretary and the  
10 Chairman and Ranking Member of each of the following  
11 committees:

12           (1) The Committee on Energy and Commerce  
13 of the House of Representatives.

14           (2) The Committee on Ways and Means of the  
15 House of Representatives.

16           (3) The Committee on Finance of the Senate.

17           (4) The Committee on Health, Education,  
18 Labor, and Pensions of the Senate.

19           (d) AUTHORIZATION OF APPROPRIATIONS.—There  
20 are authorized to be appropriated to carry out this section  
21 \$1,000,000 for each of fiscal years 2021 and 2022.



1 **SEC. 5. NATIONAL SURVEILLANCE PROGRAM FOR NON-**  
2 **ALCOHOLIC FATTY LIVER DISEASE AND NON-**  
3 **ALCOHOLIC STEATOHEPATITIS.**

4 (a) IN GENERAL.—The Secretary of Health and  
5 Human Services, acting through the Director of the Cen-  
6 ters for Disease Control and Prevention, shall establish  
7 a program to provide for surveillance on the prevalence  
8 of nonalcoholic fatty liver disease and nonalcoholic  
9 steatohepatitis in the United States.

10 (b) PROGRAM ACTIVITIES.—

11 (1) SURVEILLANCE ACTIVITIES.—The program  
12 established under subsection (a) shall include, at a  
13 minimum, each of the following surveillance activi-  
14 ties:

15 (A) Conducting local surveillance activities  
16 to collect data on the prevalence and severity of  
17 nonalcoholic fatty liver disease and nonalcoholic  
18 steatohepatitis.

19 (B) Compiling and annually publishing  
20 data on the number of individuals with non-  
21 alcoholic fatty liver disease and nonalcoholic  
22 steatohepatitis nationally as well as in each  
23 state.

24 (C) To the extent practicable, providing  
25 data on the general population at risk of devel-  
26 oping the conditions.

1           (2) TECHNICAL ASSISTANCE ON VITAL STATIS-  
2           TICS.—In carrying out the program under sub-  
3           section (a), the Secretary of Health and Human  
4           Services, acting through the Director of the Centers  
5           for Disease Control and Prevention, shall issue guid-  
6           ance that provides technical assistance to health care  
7           providers and State and local health departments on  
8           best practices to ensure appropriate collection of  
9           vital statistics for purposes of birth and death cer-  
10          tificates, including vital statistics on populations  
11          with nonalcoholic fatty liver disease and nonalcoholic  
12          steatohepatitis.

13          (c) AUTHORIZATION OF APPROPRIATIONS.—There  
14          are authorized to be appropriated—

15               (1) to carry out surveillance activities described  
16               in subsection (b)(1), \$10,000,000 for each of fiscal  
17               years 2021 and 2022;

18               (2) to carry out technical assistance activities  
19               described in subsection (b)(3), \$10,000,000 for each  
20               of fiscal years 2021 and 2022; and

21               (3) to carry out the activities described in sub-  
22               section (b)(2), \$5,000,000 for each of fiscal years  
23               2021 through 2025.

1 **SEC. 6. RECOMMENDATIONS FOR THE PREVENTION,**  
2 **SCREENING, DIAGNOSIS, AND TREATMENT OF**  
3 **INTERRELATED CONDITIONS DEVELOPED BY**  
4 **MULTIDISCIPLINARY TASK FORCE.**

5 (a) **IN GENERAL.**—Not later than 180 days after the  
6 date of the enactment of this Act, the Secretary of Health  
7 and Human Services shall establish a multidisciplinary  
8 task force, and appoint members to such task force, to  
9 develop recommendations for the prevention, screening, di-  
10 agnosis, and treatment for several interrelated conditions,  
11 including, at a minimum—

- 12 (1) nonalcoholic fatty liver disease;
- 13 (2) nonalcoholic steatohepatitis;
- 14 (3) obesity;
- 15 (4) diabetes and other metabolic disorders; and
- 16 (5) any other conditions determined appropriate  
17 by the Secretary.

18 (b) **MEMBERSHIP.**—The task force established under  
19 subsection (a) shall be composed of not more than 12  
20 members to be appointed by the Secretary and shall in-  
21 clude representatives of each of the following groups:

- 22 (1) Physician specialists, including in  
23 hepatology, gastroenterology, endocrinology, cardi-  
24 ology, and endocrinology.
- 25 (2) Experts in public health and epidemiology.
- 26 (3) Patient advocates.

1           (4) Non-voting representatives of Federal agen-  
2           cies, including the Food and Drug Administration,  
3           the National Institutes of Health, the Centers for  
4           Disease Control and Prevention, and the Office of  
5           the Assistant Secretary for Health of the Depart-  
6           ment of Health and Human Services.

7           (5) Non-voting representatives of manufactur-  
8           ers of drugs, devices, or diagnostic tools approved by  
9           the Food and Drug Administration for the treat-  
10          ment of any of the conditions specified in subsection  
11          (a).

12          (c) DEVELOPMENT OF RECOMMENDATIONS.—In de-  
13          veloping the recommendations under subsection (a), the  
14          task force established under such subsection shall con-  
15          sider—

16               (1) guidelines issued by the American Associa-  
17               tion for the Study of Liver Diseases, published evi-  
18               dence, recommendations of the United States Pre-  
19               ventive Services Task Force, and other information  
20               it determines appropriate in developing such rec-  
21               ommendations; and

22               (2) whether a combined protocol addressing a  
23               range of conditions specified in such subsection is  
24               advised for populations affected by more than one

1 condition for which such recommendations are being  
2 developed.

3 (d) DEADLINE FOR COMPILING RECOMMENDA-  
4 TIONS.—The task force shall compile screening and diag-  
5 nosis recommendations developed under subsection (a) not  
6 later than 18 months after the date on which the first  
7 meeting of the task force concludes.

8 (e) PUBLIC HEALTH ACTION PLAN.—

9 (1) IN GENERAL.—Not later than 1 year after  
10 the date of the enactment of this Act, the task force  
11 shall develop an action plan to combat nonalcoholic  
12 steatohepatitis (referred to in this section as “the  
13 Action Plan”).

14 (2) ISSUES ADDRESSED.—The Action Plan  
15 shall identify key goals and implementation strate-  
16 gies for—

17 (A) assuring appropriate surveillance of  
18 the public health impact in the United States of  
19 nonalcoholic steatohepatitis;

20 (B) increasing awareness among the gen-  
21 eral public of the United States of risk factors;

22 (C) enhancing clinical education on the  
23 prevention, diagnosis, and treatment of non-  
24 alcoholic steatohepatitis among physicians and

1 health care professionals within the United  
2 States;

3 (D) supporting research on therapies and  
4 cures for nonalcoholic steatohepatitis; and

5 (E) other areas determined appropriate by  
6 the Secretary.

7 (3) EVALUATION AND REPORT.—

8 (A) EVALUATION.—The Secretary shall, at  
9 least every 2 years, evaluate the implementation  
10 of the Action Plan under this section to provide  
11 any updates or modifications to such plan.

12 (B) REPORT.—Not later than 18 months  
13 after the date on which the Action Plan devel-  
14 oped under paragraph (1) is released, the Sec-  
15 retary shall submit to Congress a report that  
16 discusses any updated recommendations for up-  
17 dates or modifications considering initial  
18 progress made in advancing the action plan’s  
19 goals or barriers to attaining such goals.

20 (f) REPORT REGARDING LIVER CANCER.—Not later  
21 than 1 year after the date on which the first meeting of  
22 the working group is held, the working group shall trans-  
23 mit to the Director of the NIH a report providing rec-  
24 ommendations with respect to preventive and diagnostic  
25 measures that could, in consideration of the relationship

1 between the prevalence of liver cancer and the prevalence  
2 of certain liver diseases, help reduce liver cancer rates and  
3 make liver cancer more treatable when detected.

4 **SEC. 7. RENAMING OF NIH INSTITUTE TO REFLECT LIVER**  
5 **DISEASES AND CREATION OF DIVISION OF**  
6 **LIVER DISEASES.**

7 (a) INSTITUTE RENAMED.—Effective on January 1,  
8 2021, title IV of the Public Health Service Act is amended  
9 by striking “National Institute for Diabetes and Digestive  
10 and Kidney Diseases” each place it appears in section  
11 401(b) (42 U.S.C. 281(b)), in section 409A(a) (42 U.S.C.  
12 284a(a)), in the heading of subpart 3 of part C, in section  
13 426 (42 U.S.C. 285c), and section 430 (42 U.S.C. 285c–  
14 4) and inserting “The National Institute of Diabetes and  
15 Digestive, Kidney, and Liver Diseases”.

16 (b) CONFORMING CHANGES.—Effective on January  
17 1, 2021, any reference to the National Institute for Diabe-  
18 tes and Digestive and Kidney Diseases in any law, regula-  
19 tion, document, record, or other paper of the United  
20 States shall be deemed to be a reference to the National  
21 Institute of Diabetes and Digestive, Kidney, and Liver  
22 Diseases.

23 (c) ESTABLISHMENT OF DIVISION FOR LIVER DIS-  
24 EASES.—

1           (1) IN GENERAL.—Section 428 of the Public  
2 Health Service Act (42 U.S.C. 285c–2) is amend-  
3 ed—

4           (A) in subsection (a)(1)—

5           (i) in the matter preceding subpara-  
6 graph (A), by inserting “a Division Direc-  
7 tor for Liver Diseases,” after “and Nutri-  
8 tion,”; and

9           (ii) in subparagraph (A), by inserting  
10 “liver diseases,” after “and nutrition,”;  
11 and

12          (B) in subsection (b)—

13          (i) in the matter preceding paragraph  
14 (1), by inserting “the Division Director for  
15 Liver Diseases,” after “and Nutrition,”;  
16 and

17          (ii) in paragraph (1), by inserting  
18 “liver diseases,” after “and nutritional dis-  
19 orders,”.

20           (2) TRANSFER OF AUTHORITY.—Effective on  
21 January 1, 2021, the Secretary of Health and  
22 Human Services, acting through the Director of the  
23 National Institutes of Health, shall transfer to the  
24 Division Director of Liver Diseases of the National  
25 Institute of Diabetes and Digestive, Kidney, and



1       Liver Diseases, the authorities (including all budget  
2       authorities, available appropriations, and personnel),  
3       duties, obligations, and related legal and administra-  
4       tive functions prescribed by law or otherwise pre-  
5       viously granted to the Liver Disease Research  
6       Branch within the Division of Digestive Diseases  
7       and Nutrition of the National Institute for Diabetes  
8       and Digestive and Kidney Diseases.

○