

108TH CONGRESS  
1ST SESSION

# H. R. 3458

To amend titles XVIII and XIX of the Social Security Act to provide for coverage under the Medicare and Medicaid Programs of certain screening procedures for diabetic retinopathy, and to amend the Public Health Service Act to establish pilot programs to foster such screening, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 6, 2003

Mr. COOPER introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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

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## A BILL

To amend titles XVIII and XIX of the Social Security Act to provide for coverage under the Medicare and Medicaid Programs of certain screening procedures for diabetic retinopathy, and to amend the Public Health Service Act to establish pilot programs to foster such screening, and for other purposes.

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

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Diabetic Retinopathy  
3 Prevention Act of 2003”.

4 **SEC. 2. FINDINGS.**

5 The Congress finds as follows:

6 (1) Type 2 diabetes affects 17,000,000 Ameri-  
7 cans, with over 1,000,000 new cases diagnosed each  
8 year, and costs the Nation an estimated  
9 \$138,000,000,000 per year.

10 (2) Diabetic retinopathy is the most common  
11 complication resulting from diabetes, and causes  
12 degradation in visual acuity and eventual blindness.  
13 Diabetic retinopathy is the leading cause of blind-  
14 ness in people aged 20 to 74, and up to 24,000 dia-  
15 betics become legally blind each year.

16 (3) Most individuals with diabetes will ulti-  
17 mately develop diabetic retinopathy, and the risk of  
18 diabetic retinopathy increases with the duration of  
19 diabetes. Onset of type 2 diabetes is today occurring  
20 at younger ages, which will increase the prevalence  
21 of diabetic retinopathy in the future.

22 (4) Clinical trials have demonstrated that early  
23 detection and treatment of diabetic retinopathy can  
24 reduce vision loss by 90 percent, and remote assess-  
25 ment of diabetic retinopathy has the potential to  
26 reach large numbers of diabetic patients who live in

1 rural, remote or underserved areas and who lack  
2 geographical or financial access to regular, in-office  
3 eye examinations by eye specialists.

4 **SEC. 3. MEDICARE COVERAGE OF REMOTE ASSESSMENT OF**  
5 **DIABETIC RETINOPATHY.**

6 (a) COVERAGE.—Section 1861 of the Social Security  
7 Act (42 U.S.C. 1395x) is amended—

8 (1) in paragraph (s)(1)—

9 (A) in subparagraph (U), by striking  
10 “and” at the end;

11 (B) in subparagraph (V)(iii), by adding  
12 “and” at the end; and

13 (C) by inserting after subparagraph (V)  
14 the following new subparagraph:

15 “(W) remote assessment of diabetic retinopathy  
16 (as defined in subsection (ww));”; and

17 (2) by adding at the end the following new sub-  
18 section:

19 “Remote Assessment of Diabetic Retinopathy

20 “(ww) The term ‘remote assessment of diabetic ret-  
21 inopathy’ means a diagnostic examination of the retina for  
22 the purpose of early detection of diabetic retinopathy  
23 that—

1           “(1) is provided not more frequently than on an  
2           annual basis to an individual who has been diag-  
3           nosed with diabetes;

4           “(2) meets technical standards set forth by the  
5           Secretary (which shall be determined in consultation  
6           with industry and practitioner groups with expertise  
7           in ophthalmic photography, telemedicine, or related  
8           fields); and

9           “(3) is furnished via a telecommunications sys-  
10          tem by a physician (as defined in subsection (r)), a  
11          practitioner (described in section 1842(b)(18)(C) of  
12          this title), or a non-physician technician deemed to  
13          be qualified by the Secretary under the regulations  
14          promulgated pursuant to this Act, to an eligible pa-  
15          tient enrolled under this part, notwithstanding that  
16          the individual physician or practitioner providing the  
17          service is not at the same location as the bene-  
18          ficiary.”.

19          (b) PAYMENT NOTWITHSTANDING LIMITATION ON  
20          STORE AND FORWARD TECHNOLOGY.—Notwithstanding  
21          any limitations to the contrary that are set forth in section  
22          1834(m)(1) of the Social Security Act (42 U.S.C.  
23          1395m(m)(1)), the amendments made by subsection (a)  
24          shall be applicable to remote assessments of diabetic ret-  
25          inopathy that are furnished through the use of store-and-

1 forward technologies that provide for the asynchronous  
2 transmission of health care information in single or multi-  
3 media formats.

4 (c) INTERIM PAYMENT PENDING PUBLICATION OF  
5 FINAL RULE.—For the period beginning 30 days after the  
6 date of the enactment of this Act and ending on the date  
7 the Secretary of Health and Human Services publishes a  
8 final regulation to carry out section 1861(s)(1)(W) of the  
9 Social Security Act, as added by subsection (a), the Sec-  
10 retary shall provide for payment of retinopathy assess-  
11 ments furnished under such section during such period,  
12 and assign such temporary HCPCS code as is necessary  
13 to provide for such payment.

14 (d) STUDY ON REIMBURSEMENT FOR REMOTE AS-  
15 SESSMENTS OF DIABETIC RETINOPATHY.—(1) Not later  
16 than 1 year after the date of the enactment of this Act,  
17 the Secretary of Health and Human Services shall conduct  
18 a study on the costs incurred by health care providers to  
19 provide remote assessment of diabetic retinopathy serv-  
20 ices, including an analysis of—

21 (A) per-patient cost, and

22 (B) start-up and administrative costs.

23 (2) Not later than 2 years after the date of the enact-  
24 ment of this Act, the Secretary shall submit a report to

1 Congress on the study conducted under paragraph (1) and  
2 shall include recommendations as respect to—

3 (A) the adequacy of reimbursements for remote  
4 assessment of diabetic retinopathy under the medi-  
5 care program; and

6 (B) whether the study under paragraph (1)  
7 should be repeated, and if so, how frequently.

8 (e) EFFECTIVE DATE.—The amendments made by  
9 subsection (a) shall apply to assessments performed on or  
10 after the date that is 30 days after the date of the enact-  
11 ment of this Act.

12 **SEC. 4 MEDICAID COVERAGE OF REMOTE ASSESSMENT OF**  
13 **DIABETIC RETINOPATHY.**

14 (a) REQUIREMENT.—Section 1905(a)(13) of the So-  
15 cial Security Act (42 U.S.C. 1396d(a)(13)) is amended by  
16 inserting “remote assessment of diabetic retinopathy (as  
17 defined in section 1861(s)(1)(ww)),” after “including”.

18 (b) EFFECTIVE DATE.—The amendments made by  
19 subsection (a) shall apply to assessments performed on or  
20 after the date of the enactment of this Act.

21 (c) STATE COMPLIANCE.—In the case of a State plan  
22 for medical assistance under title XIX of the Social Secu-  
23 rity Act which the Secretary of Health and Human Serv-  
24 ices determines requires State legislation (other than legis-  
25 lation authorizing or appropriating funds) in order for the

1 plan to meet the additional requirement imposed by the  
 2 amendments made by subsection (a), the State plan shall  
 3 not be regarded as failing to comply with the requirements  
 4 of such title solely on the basis of its failure to meet this  
 5 additional requirement before the first day of the first cal-  
 6 endar quarter beginning after the close of the first regular  
 7 session of the State legislature that begins after the date  
 8 of the enactment of this Act. For purposes of the previous  
 9 sentence, in the case of a State that has a 2-year legisla-  
 10 tive session, each year of such session shall be deemed to  
 11 be a separate regular session of the State legislature.

12 **SEC. 5. MOBILE DIABETIC RETINOPATHY SCREENING**  
 13 **PILOT PROGRAM.**

14 Title III of the Public Health Service Act (42 U.S.C.  
 15 241 et seq.) is amended—

16 (1) by moving section 317R so that it follows  
 17 section 317Q; and

18 (2) by inserting after section 317R (as so  
 19 moved) the following:

20 **“SEC. 317S. MOBILE DIABETIC RETINOPATHY SCREENING**  
 21 **PILOT PROGRAM.**

22 **“(a) IN GENERAL.—**

23 **“(1) ESTABLISHMENT.—**The Secretary shall es-  
 24 tablish a grant program, to be known as the “Mobile  
 25 Diabetic Retinopathy Screening Pilot Program”, to

1 make grants to 5 eligible entities for the purpose of  
2 establishing mobile diabetic retinopathy screening  
3 programs.

4 “(2) USE OF FUNDS.—The Secretary may not  
5 make a grant to an eligible entity under this section  
6 unless the entity agrees to use the grant to carry out  
7 a project consisting of the design, demonstration,  
8 and implementation of a mobile diabetic retinopathy  
9 screening program.

10 “(3) MAXIMUM AMOUNT.—The Secretary may  
11 not make any grant under this section in an amount  
12 that is greater than \$1,000,000 for any year.

13 “(4) SOLICITATION OF APPLICATIONS.—Not  
14 later than 90 days after the date on which amounts  
15 are first made available to carry out this section, the  
16 Secretary shall publish a notice of solicitation for ap-  
17 plications for grants under this section that specifies  
18 the information to be included in each application.

19 “(5) APPLICATIONS.—To seek a grant under  
20 this section, an eligible entity shall submit an appli-  
21 cation to the Secretary at such time, in such form,  
22 and containing such information as the Secretary  
23 may require.

1           “(6) PRIORITY.—In making grants under this  
2 section, the Secretary shall give priority to any ap-  
3 plicant that—

4           “(A) has experience in evaluating diabetic  
5 retinopathy using telecommunications equip-  
6 ment, including store and forward technologies;  
7 and

8           “(B) proposes to serve rural, impoverished,  
9 minority, and remote populations.

10          “(7) CONGRESSIONAL NOTIFICATION.—The  
11 Secretary may not make a grant under this section  
12 unless, not less than 3 days before making the  
13 grant, the Secretary provides notification of the  
14 grant to the appropriate committees of the Congress.

15          “(b) EVALUATION AND REPORT.—

16          “(1) EVALUATION.—Not later than 3 years  
17 after making the first grant under this section, the  
18 Secretary shall convene an advisory committee for  
19 the purposes of conducting an evaluation of the Mo-  
20 bile Diabetic Retinopathy Screening Pilot Program.  
21 In conducting the evaluation, the advisory committee  
22 shall determine—

23           “(A) whether the Program has been effec-  
24 tive in increasing early detection of diabetic ret-  
25 inopathy, whether preventative measures taken

1           upon such detection have been effective in de-  
2           creasing the prevalence and severity of diabetic  
3           retinopathy, and whether these findings war-  
4           rant continued or expanded support of the Pro-  
5           gram; and

6                       “(B) whether the program may serve as a  
7           useful model for similar screening programs to  
8           detect complications associated with diabetes,  
9           high blood pressure, high cholesterol, and other  
10          chronic conditions.

11                   “(2) REPORT.—Not later than 42 months after  
12          making the first grant under this section, the Sec-  
13          retary shall submit a report to the appropriate com-  
14          mittees of the Congress containing the results of the  
15          advisory committee’s evaluation.

16                   “(c) DEFINITIONS.—In this section:

17                           “(1) ADVISORY COMMITTEE.—The term ‘advi-  
18          sory committee’ means the advisory committee con-  
19          vened under subsection (b).

20                           “(2) ELIGIBLE ENTITY.—The term ‘eligible en-  
21          tity’ means—

22                                   “(A) a hospital (as defined in section  
23                                   1861(e) of the Social Security Act (42 U.S.C.  
24                                   1395x(e))); or

1           “(B) a State, an institution of higher edu-  
2           cation, a local government, a tribal government,  
3           a nonprofit health organization, or a community  
4           health center receiving assistance under section  
5           330.

6           “(3) MOBILE DIABETIC RETINOPATHY SCREEN-  
7           ING PROGRAM.—The term ‘mobile diabetic retinop-  
8           athy screening program’ means any program—

9           “(A) that offers remote assessment of dia-  
10          betic retinopathy as described in Section  
11          1861(s)(1) of the Social Security Act (42  
12          U.S.C. 1395x);

13          “(B) whose patients primarily reside in  
14          rural, underserved, and remote areas; and

15          “(C) that is mobile (as determined by the  
16          Secretary).

17          “(4) PROGRAM.—The term ‘Program’ means  
18          the Mobile Diabetic Retinopathy Screening Pilot  
19          Program established under this section.

20          “(d) AUTHORIZATION OF APPROPRIATIONS.—

21          “(1) IN GENERAL.—There is authorized to be  
22          appropriated to carry out this section (except for  
23          subsection (b)) \$5,000,000 for each of fiscal years  
24          2005 through 2009.

1           “(2) EVALUATION AND REPORT.—There are  
2 authorized to be appropriated to carry out sub-  
3 section (b) such sums as may be necessary.”.

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