H.R. 2557
Prostate Cancer Misdiagnosis Elimination Act of 2017

As ordered reported by the House Committee on Energy and Commerce on October 4, 2017

SUMMARY

H.R. 2557 would require the Medicare program to cover a certain type of laboratory test for beneficiaries who test positive for prostate cancer. CBO estimates that H.R. 2557 would, on net, decrease direct spending by $7 million over the 2018-2027 period.

Enacting H.R. 2557 would affect direct spending; therefore, pay-as-you-go procedures apply. The legislation would not affect revenues.

CBO estimates that enacting H.R. 2557 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

H.R. 2557 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary effect of H.R. 2557 is shown in the following table. The costs of this legislation fall within budget function 570 (Medicare).

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BASIS OF ESTIMATE

For this estimate, CBO assumes that H.R. 2557 will be enacted early in fiscal year 2018.

H.R. 2557 would establish Medicare coverage of and payment for the DNA specimen provenance assay (DSPA) laboratory test. The DSPA tests genetic material in a prostate cancer biopsy specimen to ensure that the sample came from the beneficiary to whom it is attributed.

CBO analyzed Medicare utilization data and estimates that Medicare paid for about 148,000 prostate biopsies in 2016. Based on discussions with stakeholders and a review of clinical literature, CBO estimates that about 40 percent of biopsies are positive. CBO expects that it would take some time for clinicians to adopt the DSPA technology. By the end of the 2018-2027 period, CBO estimates that about half of all positive biopsies would lead to a DSPA test. H.R. 2557 would set the Medicare payment for DSPA at $200 until January 1, 2028, after which it would be paid under the Medicare’s fee schedule for clinical laboratory tests. CBO estimates that Medicare would spend $46 million over the 2018-2028 period on DSPA tests.

When men are diagnosed with prostate cancer, they can choose either active treatment (including surgery, radiation, and chemotherapy) or they can choose active surveillance, also called watchful waiting. CBO estimates that the average annual cost of prostate cancer treatment, accounting for both active treatment and active surveillance, is about $13,000. Clinical data indicate that some prostate biopsies yield false positives, resulting in treatment for men who do not actually have the disease. CBO expects that Medicare coverage would lead to more DSPA testing, which would reduce the number of false positives and thus fewer men would be treated for prostate cancer they do not have. Based on clinical information and discussions with stakeholders, CBO estimates that about 1.5 percent of these tests would reveal a false positive and prevent some men from receiving unnecessary treatment. CBO estimates the number of men who are not treated because of DSPA results would rise from about 60 in 2019 to 450 in 2027. Over the 2018-2027 period, CBO expects that Medicare coverage of DSPA would reduce treatment costs associated with false positive tests by about $51 million.

On net, taking into account both increased spending for the DSPA test and averted treatment costs, CBO estimates that H.R. 2557 would decrease Medicare spending for patients in the fee-for-service sector by $5 million. After taking into account interactions with the Part B premium and payments to Medicare Advantage plans, CBO estimates that the legislation would reduce net direct spending by $7 million over the 2018-2027 period.
PAY-AS-YOU-GO CONSIDERATIONS

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays that are subject to those pay-as-you-go procedures are shown in the following table.

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<td>NET INCREASE OR DECREASE (-) IN THE DEFICIT</td>
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INCREASE IN LONG-TERM DIRECT SPENDING AND DEFICITS

CBO estimates that enacting the legislation would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2028.

INTERGOVERNMENTAL AND PRIVATE-SECTOR IMPACT

H.R. 2557 contains no intergovernmental or private-sector mandates as defined in UMRA.

ESTIMATE PREPARED BY:

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Impact on State, Local, and Tribal Governments and the Private Sector: Amy Petz

ESTIMATE APPROVED BY:

Theresa Gullo
Assistant Director for Budget Analysis