Prostate Cancer Misdiagnosis Elimination Act of 2016 (HR 5763, 114th Congress)

Clarifies the treatment of certain DNA Specimen Provenance Assay tests as reasonable and necessary for the diagnosis or treatment of illness for coverage under the Medicare program.

Updated last November 7, 2016 for the 07/13/16 version of HR 5763.

WHAT IT DOES

For coverage and payment under Medicare Part B, HR 5763 establishes the DNA Specimen Provenance Assay test (DSPA test) as a "reasonable and necessary" measure for diagnosis or treatment of an illness or injury (42 U.S.C. 1395y(a)(1)(A)).

The bill permits Medicare to pay for the DSPA test if the patient is enrolled in the program and has first had a presumed positive prostate cancer biopsy. Medicare will not cover a DSPA test if the treating physician does not believe prostate cancer treatment is medically necessary. The bill also requires the Secretary of Health and Human Services to assign a Current Procedural Terminology code, used to uniquely identify medical services provided in a clinical setting, to the DSPA test within 60 days of the bill's enactment.

RELEVANT SCIENCE

When a physician suspects a patient might have cancer, the physician may order a biopsy, or a tissue sample from the suspected cancer, to determine whether the tissue is indeed cancerous. A biopsy might deliver an inaccurate result to a patient; one reason being if their tissue samples get mixed up or contaminated with those of another patient. Research has found that roughly 6% of cancer biopsies have some sort of contamination; for prostate biopsy identification, 0.26% of biopsy samples are completely mislabeled (i.e., incorrectly attributed to a patient) and 0.67% contaminated with other patients’ tissues. DSPA testing has been suggested as a way to reduce this biopsy identification problem.

DSPA testing methodology is based on the Combined DNA Index System (CODIS) developed by the Federal Bureau of Investigation to uniquely identify a DNA sample. Both CODIS and DSPA testing work by comparing specific, repeating segments (known as short tandem repeats) of a DNA sample with similar segments of DNA collected by a cheek swab. Matching DNA segments between the two samples suggests the samples derived from the same person. In the context of prostate cancer, DSPA testing compares the known DNA from the patient to the DNA present in the prostate biopsy to either confirm or reject the patient’s ownership, creating a lower chance of the patient receiving somebody else’s results. Additionally, this test can be used to identify tissue contamination issues. Some research suggests that regular use of this tool could “eliminate patient identity errors among needle biopsies.”

BACKGROUND

Medicare, established in 1965 as an amendment to the Social Security Act (42 U.S.C. 301 et seq.), currently provides health insurance for over 55 million Americans. Medicare provides healthcare for four groups of individuals, including people who: are aged 65 and older, are permanently disabled, have end stage renal disease (i.e., kidney disease), or have amyotrophic lateral sclerosis (i.e., Lou Gehrig’s disease).

Medicare is comprised of four parts. Part A covers hospital costs; Part B covers non-hospital, medically necessary treatment (including diagnostic tests, physician visits, etc.) and preventive treatment (including cancer screenings and certain vaccinations); Part C is Medicare Advantage, a private insurance option that provides additional benefits; and Part D covers prescription drugs.
ENDORSEMENTS & OPPOSITION

At present, there have not been publicly reported endorsements or opposition to this bill.

STATUS

This bill was introduced on July 13, 2016, and on the same date was referred to the House Committee on Ways and Means. Most recently on August 1, 2016, the bill was referred to the Subcommittee on Health.

RELATED POLICIES

No other bills in the current Congress discuss genetic testing under Medicare, but DNA testing does play a role in some proposed legislation:

- **HR 320: Rapid DNA Act of 2015** — Establishes a method for law enforcement officers to implement Rapid DNA testing in order to reduce waiting times for DNA test results so as to reduce violent crime.
- **S 2348: Rapid DNA Act of 2016** — Expands upon the above in order to implement Rapid DNA testing for the purposes of pretrial release/detention, solve and prevent violent crimes, exonerate the innocent, and other uses of DNA analysis.

SPONSORS

Sponsor: [Representative Larry Bucshon](https://www.house.gov/bucshon) (R-IN-8)

Cosponsors:
- [Representative Donald Payne Jr.](https://www.house.gov/payne) (D-NJ-10)
- [Representative Andre Carson](https://www.house.gov/carson) (D-IN-7)
- [Representative Markwayne Mullin](https://www.house.gov/mullin) (R-OK-2)

PRIMARY AUTHOR

Charles Hedges, MA Candidate

EDITOR(S)

Andrew Pericak, MEM & Aubrey Incorvaia, MPP

RECOMMENDED CITATION