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116TH CONGRESS
1ST SESSION

H. R. 2143

To prevent wasteful and abusive billing of ancillary services to the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 2019

Ms. SPEIER (for herself and Ms. TITUS) 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 prevent wasteful and abusive billing of ancillary services to the Medicare program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Promoting Integrity in Medicare Act of 2019'' or ''PIMA of 2019''.

SEC. 2. FINDINGS; PURPOSES.

(a) FINDINGS.—Congress finds the following:

(1) Recent studies by the Government Accountability Office (GAO) examining self-referral practices

in advanced diagnostic imaging and anatomic pathology determined that financial incentives were the most likely cause of increases in self-referrals.

(2) For advanced diagnostic imaging, GAO stated that ''providers who self-referred made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring'', at a cost of ''more than $100 million'' in 2010.

(3) For anatomic pathology, GAO found that ''self-referring providers likely referred over 918,000 more anatomic pathology services'' than they would have if they were not self-referring, costing Medicare approximately $69,000,000 more in 2010 than if self-referral was not permitted.

(4) For radiation oncology, GAO found that intensity modulated radiation therapy (IMRT) utilization among self-referring groups increased by 356 percent, with overall increases in IMRT utilization rates and spending due entirely to services performed by limited-specialty groups. The GAO concluded that ''the higher use of IMRT by self-referring providers results in higher costs for Medicare and beneficiaries. To the extent that treatment decisions are driven by providers' financial interest and

not by patient preference, these increased costs are difficult to justify''.

(5) For physical therapy, GAO found that ''in the year a provider began to self-refer, physical therapy service referrals increased at a higher rate relative to non-self-referring providers of the same specialty''.

(6) Noting the rapid growth of services covered by the in-office ancillary services (IOAS) exception and evidence that these services are sometimes furnished inappropriately by referring physicians, the Medicare Payment Advisory Commission (MedPAC) stated that physician self-referral of ancillary services creates incentives to increase volume under Medicare's current fee-for-service payment systems and the rapid volume growth contributes to Medicare's rising financial burden on taxpayers and beneficiaries.

(7) The President's Fiscal Year 2017 Budget includes the change to remove the four services: advanced diagnostic imaging, anatomic pathology, radiation oncology, and physical therapy from the IOAS exception to the Stark Law and cited the change as generating a savings score of $4,980,000,000 over 10 years. The nonpartisan Congressional Budget Of-

fice's analysis of the President's Fiscal Year 2017 Budget listed the change as generating a savings of $3,300,000,000 over 10 years.

(8) According to the Centers for Medicare & Medicaid Services, a key rationale for the IOAS exception was to permit physicians to provide ancillary services in their offices to better inform diagnosis and treatment decisions at the time of the patient's initial office visit.

(9) It is necessary, therefore, to distinguish between services and procedures that were intended to be covered by the IOAS exception, such as routine clinical laboratory services or simple x-rays that are provided during the patient's initial office visit, and other health care services which were clearly not envisioned to be covered by that exception because they cannot be performed or completed during the patient's initial office visit.

(10) According to a 2010 Health Affairs study, less than 10 percent of CT, MRI, and Nuclear Medicine scans take place on the same day as the initial patient office visit.

(11) According to a 2012 Health Affairs study, urologists' self-referrals for anatomic pathology services of biopsy specimens is linked to increased use

and volume billed along with a lower detection of prostate cancer.

(12) According to an October 2011 Laboratory Economics report, there has been an increase in the number of anatomic pathology specimen units billed to the Medicare part B program from 2006 through 2010, specifically for CPT Code 88305, and the rate of increase billed by physician offices for this service is accelerating at a far greater pace than the rest of the provider segments.

(13) According to a 2013 American Academy of Dermatology Pathology Billing paper, arrangements involving the split of the technical and professional components of anatomic pathology services among different providers may endanger patient safety and undermine quality of care.

(14) In November 2012, Bloomberg News released an investigative report that scrutinized ordeals faced by California prostate cancer patients treated by a urology clinic that owns radiation therapy equipment. The report found that physician self-referral resulted in a detrimental impact on patient care and drove up health care costs in the Medicare program. The Wall Street Journal, the Washington Post, and the Baltimore Sun have also published in-

vestigations showing that urology groups owning radiation therapy machines have utilization rates that rise quickly and are well above national norms for radiation therapy treatment of prostate cancer.

(15) According to a 2010 MedPAC report, only 3 percent of outpatient physical therapy services were provided on the same day as an office visit, only 9 percent within 7 days of an office visit, and only 14 percent within 14 days of an office visit. These services are not integral to the physician's initial diagnosis and do not improve patient convenience because patients must return for physical therapy treatments.

(16) In an April 2018, European Urology article authored by leading urologists about Medicare beneficiaries with prostate cancer diagnoses, researchers found, ''Urologists practicing in single-specialty groups with an ownership interest in radiation therapy are more likely to treat men with prostate cancer, including those with a high risk of noncancer mortality.''. This suggests that urologists practicing in single-specialty groups with an ownership interest in radiation therapy are more likely to treat, and even potentially overtreat, patients with IMRT than

those affiliated with a multispecialty practice or a group without an ownership stake.

(17) In a January 2019, JAMA Oncology article, authors systematically reviewed 18 studies to assess physicians' response to reimbursement incentives on cancer care delivery across various clinical settings. Across the studies, the authors consistently found that ''the ability to self-refer for radiation oncology services was associated with increased use of radiation therapy''.

(18) Those services intended to be covered under the IOAS exception are not affected by this legislation.

(19) The exception to the ownership or investment prohibition for rural providers in the ''Stark'' rule is not affected by this legislation.

(b) PURPOSES.—The purposes of this Act are the following:

(1) Maintain the in-office ancillary services exception and preserve its original intent by removing certain complex services from the exception—specifically, advanced imaging, anatomic pathology, radiation therapy, and physical therapy.

(2) Protect patients from misaligned provider financial incentives.

(3) Protect Medicare resources by saving billions of dollars.

(4) Accomplish the purposes described in paragraphs (1), (2), and (3) in a manner that does not alter the existing exception to the ownership or investment prohibition for rural providers.

SEC. 3. LIMITATION ON APPLICATION OF PHYSICIANS' SERVICES AND IN-OFFICE ANCILLARY SERVICES EXCEPTIONS.

(a) IN GENERAL.—Section 1877(b) of the Social Security Act (42 U.S.C. 1395nn(b)) is amended—

(1) in paragraph (1), by inserting ", other than specified non-ancillary services," after "section 1861(q))"; and

(2) in paragraph (2), by inserting ", specified non-ancillary services," after "(excluding infusion pumps)".

(b) INCREASE OF CIVIL MONEY PENALTIES.—Section 1877(g) of the Social Security Act (42 U.S.C. 1395nn(g)) is amended—

(1) in paragraph (3), by inserting ", unless such bill or claim included a bill or claim for a specified non-ancillary service, in which case the civil money penalty shall be not more than $25,000 for

each such service'' before the period at the end of the first sentence; and

(2) in paragraph (4), by inserting ''(or $150,000 if such referrals are for specified non-ancillary services)'' after ''$100,000''.

(c) ENHANCED SCREENING OF CLAIMS.—Section 1877(g) of the Social Security Act (42 U.S.C. 1395nn(g)) is further amended by adding at the end the following new paragraph:

''(7) COMPLIANCE REVIEW FOR SPECIFIED NON-ANCILLARY SERVICES.—

''(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall review compliance with subsection (a)(1) with respect to referrals for specified non-ancillary services in accordance with procedures established by the Secretary.

''(B) FACTORS IN COMPLIANCE REVIEW.—Such procedures—

''(i) shall, for purposes of targeting types of entities that the Secretary determines represent a high risk of noncompli-

ance with subsection (a)(1) with respect to such billing for such specified non-ancillary services, apply different levels of review based on such type; and

''(ii) may include prepayment reviews, claims audits, focused medical review, and computer algorithms designed to identify payment or billing anomalies.''.

(d) DEFINITION OF SPECIFIED NON-ANCILLARY SERVICES.—Section 1877(h) of the Social Security Act (42 U.S.C. 1395nn(h)) is amended by adding at the end the following new paragraphs:

''(8) SPECIFIED NON-ANCILLARY SERVICES.—

''(A) Subject to subparagraph (B), the term 'specified non-ancillary service' means the following:

''(i) Anatomic pathology services, as defined by the Secretary and including the technical or professional component of the following:

''(I) Surgical pathology.

''(II) Cytopathology.

''(III) Hematology.

''(IV) Blood banking.

"(V) Pathology consultation and clinical laboratory interpretation services.

"(ii) Radiation therapy services and supplies, as defined by the Secretary.

"(iii) Advanced diagnostic imaging studies (as defined in section 1834(e)(1)(B)).

"(iv) Physical therapy services (as described in paragraph (6)(B)).

"(v) Any other service that the Secretary has determined is not usually provided and completed as part of the office visit to a physician's office in which the service is determined to be necessary.

"(B) The term 'specified non-ancillary service' does not include the following:

"(i) Any service that is furnished—

"(I) in an urban area (as defined in section 1886(d)(2)(D)) to an individual who resides in a rural area (as defined in such section); and

"(II) to such individual in its entirety on the same day as the day on which, with respect to the condition

for which the service is furnished, the initial office visit of the individual for such condition occurs.

''(ii) Any service that is furnished—

''(I) by a provider of services or supplier participating in an accountable care organization that participates in the shared savings program established under section 1899; and

''(II) to a Medicare fee-for-service beneficiary (as defined in section 1899(h)(3)) assigned to such accountable care organization.

''(iii) Any service that is furnished by a provider or supplier pursuant to the participation of the provider or supplier in a payment and service delivery model selected under section 1115A(a).

''(iv) Any service that is provided by an integrated multi-specialty group practice.

''(9) INTEGRATED MULTI-SPECIALTY GROUP PRACTICE.—The term 'integrated multi-specialty group practice' means a group practice, as defined by the Secretary, that—

''(A) consists of at least—

''(i) primary care physicians who provide primary care services (as defined in section 1842(i)(4)); and

''(ii) seven or more different and distinct physician specialties (not including subspecialties) which are practiced by physicians who are board certified in the physician specialty associated with the services that they provide;

''(B) is governed by a governing body that has made a determination (and has documented such determination) that the system is focused on—

''(i) promoting accountability for the quality, cost, and overall care for individuals entitled to benefits under part A or enrolled in part B, including by managing and coordinating care for such individuals; and

''(ii) encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including individuals described in clause (i);

''(C) engages in risk-based payment arrangements with government and commercial payers, including shared savings, bundled payment arrangements, withholds, and capitated payment arrangements; and

''(D) meets, with respect to the program under this title, such cost reduction and quality goals as the Secretary determines appropriate.''.

(e) CONSTRUCTION.—Nothing in this section (or the amendments made by this section) shall be construed to affect the authority of the Secretary of Health and Human Services to waive under section 1899 of the Social Security Act (42 U.S.C. 1395jjj) the requirements imposed under the provisions of this section (or such amendments) or to affect the authority of the Secretary to implement the provisions under section 1848(q) of such Act (42 U.S.C. 1395w–4(q)) (relating to the eligible professionals Merit-Based Incentive Payment System under the Medicare program) or section 1833(z) of such Act (42 U.S.C. 1395l(z)) (relating to incentive payments for participation in eligible alternative payment models under such program).

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after the first day of the first month beginning more

than 12 months after the date of the enactment of this Act.

SEC. 4. CLARIFICATION OF CERTAIN ENTITIES SUBJECT TO STARK RULE AND ANTI-MARKUP RULE.

Section 1877(h) of the Social Security Act (42 U.S.C. 1395nn(h)) is further amended by adding at the end the following new paragraph:

''(10) CLARIFICATION OF CERTAIN ENTITIES SUBJECT TO ANTI-MARKUP RULE.—In applying this section, the term 'entity' shall include a physician's practice when it bills under this title for the technical component or the professional component of a specified non-ancillary service, including when such service is billed in compliance with section 1842(n)(1).''.

SEC. 5. CLARIFICATION OF SUPERVISION OF TECHNICAL COMPONENT OF ANATOMIC PATHOLOGY SERVICES.

Section 1861(s)(17) of the Social Security Act (42 U.S.C. 1395x(s)(17)) is amended—

(1) by striking ''and'' at the end of subparagraph (A);

(2) by redesignating subparagraph (B) as subparagraph (C); and

(3) by inserting after subparagraph (A) the following new subparagraph:

''(B) with regard to the provision of the technical component of anatomic pathology services, meets the applicable supervision requirements for laboratories certified in the subspecialty of histopathology, pursuant to section 353 of the Public Health Service Act; and''.

SEC. 6. EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN FEE SCHEDULE.

Section 1848(c)(2)(B)(v) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(B)(v)) is amended by adding at the end the following new subclause:

''(XII) CHANGES TO LIMITATIONS ON CERTAIN PHYSICIAN REFERRALS.—Effective for fee schedules established beginning with 2019, reduced expenditures attributable to the Promoting Integrity in Medicare Act of 2019.''.

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