

114TH CONGRESS
2D SESSION

H. R. 5088

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

IN THE HOUSE OF REPRESENTATIVES

APRIL 28, 2016

Ms. SPEIER (for herself, Mr. McDERMOTT, 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

A BILL

To prevent abusive billing of ancillary services to the
Medicare program, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Promoting Integrity
5 in Medicare Act of 2016” or “PIMA of 2016”.

6 **SEC. 2. FINDINGS; PURPOSES.**

7 (a) FINDINGS.—Congress finds the following:

1 (1) Recent studies by the Government Account-
2 ability Office (GAO) examining self-referral practices
3 in advanced diagnostic imaging and anatomic pa-
4 thology determined that financial incentives were the
5 most likely cause of increases in self-referrals.

6 (2) For advanced diagnostic imaging, GAO
7 stated that “providers who self-referred made
8 400,000 more referrals for advanced imaging serv-
9 ices than they would have if they were not self-refer-
10 ring”, at a cost of “more than \$100 million” in
11 2010.

12 (3) For anatomic pathology, GAO found that
13 “self-referring providers likely referred over 918,000
14 more anatomic pathology services” than they would
15 have if they were not self-referring, costing Medicare
16 approximately \$69,000,000 more in 2010 than if
17 self-referral was not permitted.

18 (4) For radiation oncology, GAO found that in-
19 tensity modulated radiation therapy (IMRT) utiliza-
20 tion among self-referring groups increased by 356
21 percent, with overall increases in IMRT utilization
22 rates and spending due entirely to services per-
23 formed by limited-specialty groups. The GAO con-
24 cluded that “the higher use of IMRT by self-refer-
25 ring providers results in higher costs for Medicare

1 and beneficiaries. To the extent that treatment deci-
2 sions are driven by providers' financial interest and
3 not by patient preference, these increased costs are
4 difficult to justify''.

5 (5) For physical therapy, GAO found that "in
6 the year a provider began to self-refer, physical ther-
7 apy service referrals increased at a higher rate rel-
8 ative to non-self-referring providers of the same spe-
9 cialty''.

10 (6) Noting the rapid growth of services covered
11 by the in-office ancillary services (IOAS) exception
12 and evidence that these services are sometimes fur-
13 nished inappropriately by referring physicians, the
14 Medicare Payment Advisory Commission (MedPAC)
15 stated that physician self-referral of ancillary serv-
16 ices creates incentives to increase volume under
17 Medicare's current fee-for-service payment systems
18 and the rapid volume growth contributes to Medi-
19 care's rising financial burden on taxpayers and bene-
20 ficiaries.

21 (7) The President's Fiscal Year 2017 Budget
22 includes the change to remove the four services: ad-
23 vanced diagnostic imaging, anatomic pathology, radi-
24 ation oncology, and physical therapy from the IOAS
25 exception to the Stark Law and cited the change as

1 generating a savings score of \$4,980,000,000 over
2 10 years. The nonpartisan Congressional Budget Of-
3 fice's analysis of the President's Fiscal Year 2017
4 Budget listed the change as generating a savings of
5 \$3,300,000,000 over 10 years.

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

12 (9) It is necessary, therefore, to distinguish be-
13 tween services and procedures that were intended to
14 be covered by the IOAS exception, such as routine
15 clinical laboratory services or simple x-rays that are
16 provided during the patient's initial office visit, and
17 other health care services which were clearly not en-
18 visioned to be covered by that exception because they
19 cannot be performed during the patient's initial of-
20 fice visit.

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

1 (11) According to a 2012 Health Affairs study,
2 urologists' self-referrals for anatomic pathology serv-
3 ices of biopsy specimens is linked to increased use
4 and volume billed along with a lower detection of
5 prostate cancer.

6 (12) According to an October 2011 Laboratory
7 Economics report, there has been an increase in the
8 number of anatomic pathology specimen units billed
9 to the Medicare part B program from 2006 through
10 2010, specifically for CPT Code 88305, and the rate
11 of increase billed by physician offices for this service
12 is accelerating at a far greater pace than the rest of
13 the provider segments.

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

20 (14) In November 2012, Bloomberg News re-
21 leased an investigative report that scrutinized or-
22 deals faced by California prostate cancer patients
23 treated by a urology clinic that owns radiation ther-
24 apy equipment. The report found that physician self-
25 referral resulted in a detrimental impact on patient

1 care and drove up health care costs in the Medicare
2 program. The Wall Street Journal, the Washington
3 Post, and the Baltimore Sun have also published in-
4 vestigations showing that urology groups owning ra-
5 diation therapy machines have utilization rates that
6 rise quickly and are well above national norms for
7 radiation therapy treatment of prostate cancer.

8 (15) According to a 2010 MedPAC report, only
9 3 percent of outpatient physical therapy services
10 were provided on the same day as an office visit,
11 only 9 percent within 7 days of an office visit, and
12 only 14 percent within 14 days of an office visit.
13 These services are not integral to the physician's ini-
14 tial diagnosis and do not improve patient conven-
15 ience because patients must return for physical ther-
16 apy treatments.

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

20 (17) The exception to the ownership or invest-
21 ment prohibition for rural providers in the "Stark"
22 rule is not affected by this legislation.

23 (b) PURPOSES.—The purposes of this Act are the fol-
24 lowing:

1 (1) Maintain the in-office ancillary services ex-
 2 ception and preserve its original intent by removing
 3 certain complex services from the exception—specifi-
 4 cally, advanced imaging, anatomic pathology, radi-
 5 ation therapy, and physical therapy.

6 (2) Protect patients from misaligned provider
 7 financial incentives.

8 (3) Protect Medicare resources by saving bil-
 9 lions of dollars.

10 (4) Accomplish the purposes described in para-
 11 graphs (1), (2), and (3) in a manner that does not
 12 alter the existing exception to the ownership or in-
 13 vestment prohibition for rural providers.

14 **SEC. 3. LIMITATION ON APPLICATION OF PHYSICIANS’**
 15 **SERVICES AND IN-OFFICE ANCILLARY SERV-**
 16 **ICES EXCEPTIONS.**

17 (a) IN GENERAL.—Section 1877(b) of the Social Se-
 18 curity Act (42 U.S.C. 1395nn(b)) is amended—

19 (1) in paragraph (1), by inserting “, other than
 20 specified non-ancillary services,” after “section
 21 1861(q))”; and

22 (2) in paragraph (2), by inserting “, specified
 23 non-ancillary services,” after “(excluding infusion
 24 pumps)”.

1 (b) INCREASE OF CIVIL MONEY PENALTIES.—Sec-
 2 tion 1877(g) of the Social Security Act (42 U.S.C.
 3 1395nn(g)) is amended—

4 (1) in paragraph (3), by inserting “, unless
 5 such bill or claim included a bill or claim for a speci-
 6 fied non-ancillary service, in which case the civil
 7 money penalty shall be not more than \$25,000 for
 8 each such service” before the period at the end of
 9 the first sentence; and

10 (2) in paragraph (4), by inserting “(or
 11 \$150,000 if such referrals are for specified non-an-
 12 cillary services)” after “\$100,000”.

13 (c) ENHANCED SCREENING OF CLAIMS.—Section
 14 1877(g) of the Social Security Act (42 U.S.C. 1395nn(g))
 15 is further amended by adding at the end the following new
 16 paragraph:

17 “(7) COMPLIANCE REVIEW FOR SPECIFIED
 18 NON-ANCILLARY SERVICES.—

19 “(A) IN GENERAL.—Not later than 180
 20 days after the date of the enactment of this
 21 paragraph, the Secretary, in consultation with
 22 the Inspector General of the Department of
 23 Health and Human Services, shall review com-
 24 pliance with subsection (a)(1) with respect to
 25 referrals for specified non-ancillary services in

1 accordance with procedures established by the
2 Secretary.

3 “(B) FACTORS IN COMPLIANCE REVIEW.—
4 Such procedures—

5 “(i) shall, for purposes of targeting
6 types of entities that the Secretary deter-
7 mines represent a high risk of noncompli-
8 ance with subsection (a)(1) with respect to
9 such billing for such specified non-ancillary
10 services, apply different levels of review
11 based on such type; and

12 “(ii) may include prepayment reviews,
13 claims audits, focused medical review, and
14 computer algorithms designed to identify
15 payment or billing anomalies.”.

16 (d) DEFINITION OF SPECIFIED NON-ANCILLARY
17 SERVICES.—Section 1877(h) of the Social Security Act
18 (42 U.S.C. 1395nn(h)) is amended by adding at the end
19 the following new paragraphs:

20 “(8) SPECIFIED NON-ANCILLARY SERVICES.—

21 “(A) Subject to subparagraph (B), the
22 term ‘specified non-ancillary service’ means the
23 following:

24 “(i) Anatomic pathology services, as
25 defined by the Secretary and including the

1 technical or professional component of the
2 following:

3 “(I) Surgical pathology.

4 “(II) Cytopathology.

5 “(III) Hematology.

6 “(IV) Blood banking.

7 “(V) Pathology consultation and
8 clinical laboratory interpretation serv-
9 ices.

10 “(ii) Radiation therapy services and
11 supplies, as defined by the Secretary.

12 “(iii) Advanced diagnostic imaging
13 studies (as defined in section
14 1834(e)(1)(B)).

15 “(iv) Physical therapy services (as de-
16 scribed in paragraph (6)(B)).

17 “(v) Any other service that the Sec-
18 retary has determined is not usually pro-
19 vided and completed as part of the office
20 visit to a physician’s office in which the
21 service is determined to be necessary.

22 “(B) The term ‘specified non-ancillary
23 service’ does not include the following:

24 “(i) Any service that is furnished—

1 “(I) in an urban area (as defined
2 in section 1886(d)(2)(D)) to an indi-
3 vidual who resides in a rural area (as
4 defined in such section); and

5 “(II) to such individual in its en-
6 tirety on the same day as the day on
7 which, with respect to the condition
8 for which the service is furnished, the
9 initial office visit of the individual for
10 such condition occurs.

11 “(ii) Any service that is furnished—

12 “(I) by a provider of services or
13 supplier participating in an account-
14 able care organization that partici-
15 pates in the shared savings program
16 established under section 1899; and

17 “(II) to a Medicare fee-for-serv-
18 ice beneficiary (as defined in section
19 1899(h)(3)) assigned to such account-
20 able care organization.

21 “(iii) Any service that is furnished by
22 a provider or supplier pursuant to the par-
23 ticipation of the provider or supplier in a
24 payment and service delivery model se-
25 lected under section 1115A(a).

1 “(iv) Any service that is provided by
2 an integrated health care delivery system.

3 “(9) INTEGRATED HEALTH CARE.—The term
4 ‘integrated health care delivery system’ means a
5 group practice, as defined by the Secretary, that—

6 “(A) consists of at least—

7 “(i) primary care physicians who pro-
8 vide primary care services (as defined in
9 section 1842(i)(4)); and

10 “(ii) seven or more different and dis-
11 tinct physician specialties (not including
12 subspecialties) which are practiced by phy-
13 sicians who are board certified in the phy-
14 sician specialty associated with the services
15 that they provide;

16 “(B) is governed by a governing body that
17 has made a determination (and has documented
18 such determination) that the system is focused
19 on—

20 “(i) promoting accountability for the
21 quality, cost, and overall care for individ-
22 uals entitled to benefits under part A or
23 enrolled in part B, including by managing
24 and coordinating care for such individuals;
25 and

1 “(ii) encouraging investment in infra-
2 structure and redesigned care processes for
3 high quality and efficient service delivery
4 for patients, including individuals described
5 in clause (i); and

6 “(C) meets, with respect to the program
7 under this title, such cost reduction and quality
8 goals as the Secretary determines appro-
9 priate.”.

10 (e) CONSTRUCTION.—Nothing in this section (or the
11 amendments made by this section) shall be construed to
12 affect the authority of the Secretary of Health and Human
13 Services to waive under section 1899 of the Social Security
14 Act (42 U.S.C. 1395jjj) the requirements imposed under
15 the provisions of this section (or such amendments) or to
16 affect the authority of the Secretary to implement the pro-
17 visions under section 1848(q) of such Act (42 U.S.C.
18 1395w–4(q)) (relating to the eligible professionals Merit-
19 Based Incentive Payment System under the Medicare pro-
20 gram) or section 1833(z) of such Act (42 U.S.C. 1395l(z))
21 (relating to incentive payments for participation in eligible
22 alternative payment models under such program).

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

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

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

5 Section 1877(h) of the Social Security Act (42 U.S.C.
6 1395nn(h)) is further amended by adding at the end the
7 following new paragraph:

8 “(9) CLARIFICATION OF CERTAIN ENTITIES
9 SUBJECT TO ANTI-MARKUP RULE.—In applying this
10 section, the term ‘entity’ shall include a physician’s
11 practice when it bills under this title for the tech-
12 nical component or the professional component of a
13 specified non-ancillary service, including when such
14 service is billed in compliance with section
15 1842(n)(1).”.

16 **SEC. 5. CLARIFICATION OF SUPERVISION OF TECHNICAL**
17 **COMPONENT OF ANATOMIC PATHOLOGY**
18 **SERVICES.**

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

21 (1) by striking “and” at the end of subpara-
22 graph (A);

23 (2) by redesignating subparagraph (B) as sub-
24 paragraph (C); and

1 (3) by inserting after subparagraph (A) the fol-
2 lowing new subparagraph:

3 “(B) with regard to the provision of the
4 technical component of anatomic pathology
5 services, meets the applicable supervision re-
6 quirements for laboratories certified in the sub-
7 specialty of histopathology, pursuant to section
8 353 of the Public Health Service Act; and”.

9 **SEC. 6. EXEMPTION FROM BUDGET NEUTRALITY UNDER**
10 **PHYSICIAN FEE SCHEDULE.**

11 Section 1848(c)(2)(B)(v) of the Social Security Act
12 (42 U.S.C. 1395w-4(c)(2)(B)(v)) is amended by adding
13 at the end the following new subclause:

14 “(VIII) CHANGES TO LIMITA-
15 TIONS ON CERTAIN PHYSICIAN REFER-
16 RALS.—Effective for fee schedules es-
17 tablished beginning with 2017, re-
18 duced expenditures attributable to the
19 Promoting Integrity in Medicare Act
20 of 2016.”.

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