

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 2 - I-02
(December 2002)

Subject: Medicare Payment for the Medical Direction and
Supervision of Hospital-Based Clinical Laboratories

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Referred to: Reference Committee J
(Bryan Pechous, MD, Chair)

1 At the 2001 Interim Meeting, the House of Delegates adopted as amended Resolution 107, which
2 calls for the AMA to support the concept that a professional fee should be paid directly to the
3 appropriate physician for clinical laboratory work, regardless of payer source (Policy H-260.964,
4 AMA Policy Database). The resolution also calls for the AMA to study the issues and problems in
5 implementing this policy, and report back to the House at the 2002 Interim Meeting. The Board of
6 Trustees assigned the requested study to the Council on Medical Service.

7
8 The Council previously examined the issue of financial arrangements between hospitals and
9 physicians in Council on Medical Service Report C (A-91). Council Report C (A-91) investigated
10 payments made to hospitals by physicians for the privilege of serving patients at the hospital, as
11 well as for the privilege of utilizing space, supplies, equipment, utilities, hospital employees, and
12 billing information. The report recommended AMA policy and actions to address any financial
13 arrangements between hospitals and physicians that might conflict with the anti-kickback statute of
14 the Social Security Act (Policy H-225.973).

15
16 Responding to an invitation to provide the Council with additional information, the sponsor of
17 Resolution 107 (I-01), the California Medical Association (CMA), noted that some hospitals fail to
18 pay pathologists for services related to the medical direction and supervision of hospital-based
19 clinical laboratories. The CMA explained that Medicare considers these services reimbursable
20 under Part A of the diagnosis-related group (DRG) payment to hospitals. Furthermore, the
21 Department of Health and Human Services (HHS) Office of the Inspector General (OIG) has
22 issued an opinion that when hospitals do not pay physicians for these services, a potential violation
23 of the anti-kickback statute may occur.

24
25 Despite this opinion, the CMA noted that many hospitals require pathologist directors to work
26 without pay for the medical direction and supervision of clinical services in exchange for the
27 “privilege” of performing anatomical readings of laboratory specimens, which are paid by
28 Medicare to physicians under Part B. As a result, some pathologist directors of hospital
29 laboratories are not compensated for duties pertinent to the maintenance of quality standards, as
30 well as for compliance with federal certification and Joint Commission on Accreditation of
31 Healthcare Organizations (JCAHO) requirements.

32
33 While the Council recognizes that hospital-based physicians may find other financial arrangements
34 between themselves and hospitals to be problematic, the focus of Resolution 107 (I-01) and,
35 consequently, this report is on Medicare payment for the medical direction and supervision of
36 hospital-based clinical laboratories. Specifically, the report describes the professional services that

1 pathologist directors of hospital-based clinical laboratories provide; discusses non-Medicare and
2 Medicare payment, as well as hospital compensation to pathologists for these services; highlights
3 relevant AMA policies; and presents two recommendations.
4

5 PROFESSIONAL SERVICES PROVIDED BY PATHOLOGIST DIRECTORS OF HOSPITAL-
6 BASED CLINICAL LABORATORIES
7

8 Quality laboratory services are essential to the diagnosis and treatment of patients. Pathologist
9 directors of hospital-based clinical laboratories spend a significant amount of time and effort
10 fulfilling their responsibility to the patient for quality laboratory services. The pathologist is
11 professionally responsible and legally accountable for laboratory results, and federal certification
12 and JCAHO standards require that certain professional, organizational, and administrative services
13 be provided in the clinical laboratory to assure quality laboratory services to patients. Specifically,
14 pathologist directors of hospital-based clinical laboratories provide the following professional
15 services:
16

- 17 • Assuring that tests, examinations, and procedures are properly performed, recorded, and
18 reported;
- 19
- 20 • Educating the medical staff regarding issues of laboratory operations, quality, and test
21 availability;
- 22
- 23 • Designing protocols, and establishing parameters for performance of clinical testing;
- 24
- 25 • Recommending appropriate follow-up diagnostic tests;
- 26
- 27 • Supervising laboratory technicians, and advising them regarding aberrant results;
- 28
- 29 • Selecting, evaluating, and validating test methodologies;
- 30
- 31 • Directing, performing, and evaluating quality assurance and control procedures;
- 32
- 33 • Evaluating clinical laboratory data and establishing a process for review of test results prior to
34 issuance of patient reports; and
- 35
- 36 • Assuring the hospital laboratory's compliance with state licensure laws, Medicare conditions,
37 and voluntary accreditation and federal certification standards.
38

39 NON-MEDICARE PAYMENT
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41 Payment methods for the medical direction and supervision of clinical laboratory services differ
42 depending on the setting in which the service is provided, as well as on the payment source,
43 according to the College of American Pathologists (CAP), which responded to a request by the
44 Council to comment on Resolution 107 (I-01). For non-Medicare patients and payers, pathologists
45 and other physicians providing clinical laboratory testing in clinical laboratories that are
46 independent of a hospital negotiate direct payments with the payer for clinical laboratory testing.
47

48 In the hospital setting, pathologists who provide medical direction and supervision of the clinical
49 laboratory may bill these services to the patient (or the patient's insurer) or to the hospital as the
50 pathologist and the hospital may agree. The -26 modifier is required for Current Procedural

1 Terminology (CPT[®]) codes 80049-87999 in those instances when the physician is only billing for
2 the professional component (i.e., medical direction, supervision, or interpretation) of the laboratory
3 test. This method of reporting is used when the professional and technical (i.e., costs for laboratory
4 equipment, supplies, and non-physician personnel) components are reported separately. When the
5 hospital contract with the pathologist provides that the physician will bill the patient's insurer, the
6 contract usually includes a provision that the hospital will make patient and insurer information
7 available to the physician to facilitate physician billing for the service. The hospital does not
8 include these services and costs in its negotiations with health plans for payment of hospital
9 services to insured enrollees.

10 MEDICARE PAYMENT

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12
13 In the Medicare program, physicians providing clinical laboratory testing in a clinical laboratory
14 that is independent of a hospital (e.g., a physician office laboratory or an independent laboratory)
15 are paid for the performance and medical direction and supervision of clinical diagnostic laboratory
16 tests under the Medicare Part B Clinical Laboratory Fee Schedule (CLFS). Hospitals providing
17 clinical diagnostic laboratory tests to hospital outpatients also are paid under this fee schedule. For
18 hospital inpatients, payment for clinical diagnostic laboratory services is bundled into the DRG
19 payment for Part A.

20
21 Thus, physicians in other than a hospital setting are paid directly for the medical direction and
22 supervision of clinical laboratory service under Medicare's CLFS. Payment for discussion with a
23 patient and/or family concerning test results is included in payment for the evaluation and
24 management service. Physicians who provide medical direction and supervision of hospital-based
25 clinical laboratories must negotiate payment from hospitals for this service when the service is
26 provided to Medicare patients. It should also be noted that, in those instances where private payers
27 base physician payment on the DRG, the problem of non-payment for the medical direction and
28 supervision of hospital clinical laboratories may apply to these payers as well.

29
30 The Medicare regulations to implement the 1982 Tax Equity and Fiscal Responsibility Act
31 (TEFRA) require a clear distinction between physician services performed for patients, as
32 contrasted to physician services performed for the hospital provider. Physician services performed
33 for patients are defined as services ordinarily requiring performance by a physician and which
34 contribute directly to the diagnosis or treatment of an individual patient. Pathologist services that
35 satisfy this requirement are defined by the regulations, and include surgical pathology services;
36 specific cytopathology, hematology, and blood banking services; clinical pathology consultations;
37 and certain clinical pathology interpretative services. Physician services for individual patients
38 must be separately identified using CPT procedure codes, and are paid under Part B of the
39 Medicare program.

40
41 In contrast to pathologist services for individual patients, services for the hospital provider as
42 defined by the Medicare regulation are covered by Part A of the Medicare program. Examples of
43 physician services for the hospital provider under those regulations are administration of a hospital
44 laboratory, quality control, performance of autopsies, and supervision of personnel in the clinical
45 laboratory. Pathologists are precluded by Medicare regulations from billing Medicare patients for
46 Part A services. As a result, no Medicare payment is made directly to physicians for these services.
47 Instead, Medicare's payment to the hospital covers the direction and supervision services
48 performed by the pathologist. Medicare's DRG payment under the prospective payment system for
49 inpatient services, and the CLFS payments for outpatient services include the pathologist's services
50 to the hospital, and the hospital is responsible for compensating the pathologist for these services.

1 HOSPITAL COMPENSATION TO PATHOLOGISTS

2
3 The CAP has made a concerted effort to educate pathologists regarding this issue and to arm them
4 with the tools necessary to effectively negotiate with hospitals. For example, the 11th edition
5 (1999) of the *CAP Professional Relations Manual* notes that, more recently, a number of hospitals,
6 particularly those operated by for-profit chains, have sought to require pathologists to agree to
7 provide Part A services for little or no compensation. The ability of the pathologist to resist these
8 attempts depends on the bargaining strength of the pathologist. The manual advises that a useful
9 argument that can be raised by the pathologist to resist this form of contract is that such an
10 arrangement potentially violates the Medicare anti-kickback statute.

11
12 However, despite these efforts, the problem of hospital non-payment for pathologist provision of
13 medical direction and supervision for Medicare patients persists and is growing, according to the
14 CAP. Specifically, CAP survey data indicate that, in 2000, approximately one out of three
15 hospital-based pathologists, who were not hospital employees reported that they did not receive
16 payment from the hospital for their services to Medicare patients. It should be noted that the
17 salaries of pathologists who are hospital employees presumably reflect, if appropriate, the
18 provision of medical direction and supervisory services. For this reason, and because employment
19 agreements may be structured to fall within a “safe harbor” of the anti-kickback statute, the issue of
20 hospital non-payment for these services is limited to independent contractor pathologists.

21
22 A January 1991 OIG report, “Financial Arrangements between Hospitals and Hospital-Based
23 Physicians,” addressed these practices by hospitals. The findings of that report serve as an alert to
24 potential violations of the anti-kickback statute (42 U.S.C. Section 1320a-7b[b]). The anti-
25 kickback statute generally makes it illegal to knowingly and willingly solicit or receive
26 remuneration for referring patients or for arranging for or recommending the ordering of any
27 service payable in whole or in part under a federal health care program. In addition, the anti-
28 kickback statute makes it illegal to knowingly and willfully offer or pay any remuneration directly
29 or indirectly, overtly or covertly, in cash or in kind to induce such person to refer an individual for
30 the furnishing or arranging for the furnishing of any item or service for which payment may be
31 made in whole or in part under a federal health care program. The statute is very broad, covering
32 direct, indirect, overt, or covert, in cash or in kind forms of remuneration, bribes, kickbacks, and
33 rebates.

34
35 The OIG report identified potential violations in the financial arrangements between some hospitals
36 and hospital-based physicians. These arrangements: (1) require physicians to pay more than the
37 fair market value for services provided by the hospital; or (2) compensate physicians for less than
38 the fair market value of goods and services that they provide to hospitals. The report warned of the
39 potential legal liability, under the statute, when hospitals enter into agreements with hospital-based
40 physicians, who are not employees of the hospital, where the agreement calls for the exchange of
41 money or anything of value not based on the fair market value of the goods and services
42 exchanged. One such potentially illegal arrangement identified in the report is when hospitals
43 provide no or token payment to pathologists for Part A services in return for the opportunity to
44 perform and bill for Part B services at those hospitals.

45
46 The report found that such potentially illegal financial arrangements might have several
47 unfortunate results. Hospitals may award exclusive contracts based on improper financial
48 considerations instead of on traditional considerations centering on the professional qualifications
49 of the physician. The remuneration also gives hospitals a financial incentive to develop policies
50 and practices that encourage greater utilization of the services of hospital-based physicians payable
51 under Medicare Part B. In addition, hospital-based physicians, faced with lower incomes, may be

1 encouraged to conduct more procedures in order to offset the payments to hospitals. Furthermore,
2 illegal arrangements may complicate the development and updating of physician fee schedules.
3 Physician practice costs could be artificially inflated by hospitals and physicians that enter into
4 arrangements not based on fair market values.
5

6 Given the relationship between a hospital and its hospital-based physicians, contracts that require
7 hospital-based physicians to split portions of their income with hospitals are suspect, but not per se
8 violations of the statute, according to the OIG. As part of its report, the OIG reviewed agreements
9 that provide payments or remuneration from physicians to hospitals far in excess of the fair market
10 value of the services provided by them. Because these arrangements may violate the statute, the
11 OIG explained that disclosure of the terms of these agreements are rare. Therefore, the OIG noted
12 that it is very difficult to establish the prevalence of these arrangements, and that a determination of
13 whether these arrangements are illegal requires an entire review of the contract and the
14 relationships between the parties.
15

16 The report recommended that the Center for Medicare and Medicaid Services (CMS, formerly the
17 Health Care Financing Administration) instruct its intermediaries to: (1) notify hospitals about
18 potential legal liability when they enter into agreements not based on the fair market value of
19 necessary goods and services exchanged; and (2) refer suspect arrangements to the OIG for
20 possible prosecution or sanctions. It also should be noted that, in its follow-up correspondence
21 regarding its report, the OIG reiterated that some financial arrangements between hospitals and
22 hospital-based physicians may violate the criminal anti-kickback statute, putting both the hospital
23 and the physician in question at risk.
24

25 In its comments to the OIG regarding an earlier draft of the report, the American Hospital
26 Association (AHA) contended that the arrangements in question are not covered by the anti-
27 kickback statute since hospitals do not “refer” patients. The AHA asserted that such arrangements
28 have not been shown to result in overutilization, and, in fact, cannot result in over-utilization.
29 However, the OIG responded that, in these arrangements, hospitals are in a position to “refer”
30 Medicare and Medicaid business within the meaning of the statute. In addition, the statute does not
31 require proof of overutilization because, according to the OIG, Congress made the judgement that
32 the programs should not be subject to the risk of overutilization created by practices that violate the
33 anti-kickback statute. At the time that this report was written, the AHA had not responded to a
34 request for further comment on this issue.
35

36 The CAP strongly supported the OIG report, and recommended in its comments to the OIG that the
37 office prosecute hospitals that persist in maintaining abusive arrangements. However, the CAP
38 noted that some pathologists were forced to accept one-sided contracts from hospitals. Therefore,
39 the CAP “strongly believes that the OIG should not prosecute those [hospital-based physicians]
40 who are forced by the hospital to enter into these arrangements.”
41

42 In February 1998, at the CAP’s request, the OIG restated its position by including in its
43 “Compliance Program Guidance for Hospitals” a statement that “token or no payment for Part A
44 supervision and management services” may implicate the anti-kickback statute. The CAP has
45 made the Medicare program aware of this issue, and they have recognized and reiterated hospitals’
46 responsibility for paying pathologists.
47

48 RELEVANT AMA POLICIES 49

50 The AMA has established several policies related to Medicare payment for the medical direction
51 and supervision of hospital-based clinical laboratories (Policies H-260.964, H-225.973, H-390.970,

1 H-385.964, H-390.891, H-385.993, H-390.993, H-260.998, H-385.951, and H-225.997[5-8]). As
2 previously noted, Policy H-260.964 supports the concept that a professional fee should be paid
3 directly to the appropriate physician for clinical laboratory work, regardless of payer source, and
4 Policy H-225.973:

5
6 (1) opposes financial arrangements between hospitals and physicians that are unrelated to
7 professional services, or to the time, skill, education, and professional expertise of the physician;
8

9 (2) opposes any requirement which states that fee-for-services payments to physicians must be
10 shared with the hospital in exchange for clinical privileges;
11

12 (3) opposes financial arrangements between hospitals and physicians that (a) either require
13 physicians to compensate hospitals in excess of the fair market value of the services and resources
14 that hospitals provide to physicians, (b) require physicians to compensate hospitals even at fair
15 market value for hospital provided services that they neither require nor request, or (c) require
16 physicians to accept compensation at less than the fair market value for the services that physicians
17 provide to hospitals; and
18

19 (4) urges state medical associations, HHS, AHA and other hospital organizations to take actions to
20 eliminate financial arrangements between hospitals and physicians that are in conflict with the anti-
21 kickback statute of the Social Security Act, as well as with AMA policy.
22

23 In addition to Policy H-260.964, six other AMA policies—Policies H-390.970, H-385.964,
24 H-390.891, H-385.993, H-390.993, and H-385.951—oppose incorporating physician services into
25 hospital payments. Most notably, Policy H-390.970(3) encourages members of Congress to oppose
26 the inclusion of physicians in any DRG program, and Policy H-385.993(2) opposes inappropriate
27 regulations developed to implement the 1982 TEFRA.
28

29 DISCUSSION

30

31 As detailed in this report, Medicare precludes paying the appropriate physician directly for the
32 medical direction and supervision of hospital-based clinical laboratories—in contrast to the concept
33 supported by Policy H-260.964. Specifically, the Medicare regulations to implement TEFRA
34 differentiate between physician services performed for patients, as contrasted to physician services
35 performed for the hospital provider. Services for the hospital provider, as defined by the Medicare
36 regulation to include the medical direction and supervision of hospital clinical laboratories, are
37 covered by Part A of the Medicare program, and pathologists are prohibited from billing Medicare
38 patients for Part A services. As a result, no Medicare payment is made directly to the physician for
39 these services. Instead, Medicare's payment to the hospital covers the direction and supervision
40 services performed by the pathologist. Medicare's DRG payment under the prospective payment
41 system for inpatient services, and the CLFS payments for outpatient services include the
42 pathologist's services to the hospital, and the hospital is responsible for compensating the
43 pathologist for these services. As previously noted, seven AMA policies oppose incorporating
44 physician services into hospital payments.

1 Hospital non-payment for these services further exacerbates the problem. In light of this, the CAP
2 strongly recommended that current AMA policy be expanded to explicitly address the issue of
3 appropriate payment to hospital-based pathologists for the medical direction and supervision of
4 hospital clinical laboratories. The Council agrees, and, therefore, believes that the AMA should
5 oppose financial arrangements between hospitals and pathologists that force pathologists to accept
6 no or token payment for the medical direction and supervision of hospital-based clinical
7 laboratories.

8
9 The Council also concurs with the CAP's comment to the OIG that enforcement actions against
10 hospitals are necessary to ensure that hospitals appropriately compensate pathologist directors of
11 hospital-based clinical laboratories. The CAP was unaware of any enforcement actions taken, thus
12 far, against either hospitals or physicians regarding this matter. As noted above, Policy H-225.973
13 urges state medical associations, HHS, AHA, and other hospital organizations to take actions to
14 eliminate financial arrangements between hospitals and physicians that conflict with the anti-
15 kickback statute. In light of the current difficulty that many pathologists are experiencing
16 regarding this issue, the Council believes that the AMA, in conjunction with the CAP and other
17 interested parties, should continue to advocate that appropriate actions be taken to eliminate
18 financial arrangements between hospitals and pathologists that conflict with the statute. Such
19 actions could include the OIG issuing guidelines to clarify that token or non-payment for
20 pathologist Part A medical direction and supervision services in exchange for Part B referrals
21 violates the anti-kickback statute, as well as a special fraud alert to inform hospitals of the same.

22
23 It should be noted that, according to the CAP, no Medicare formula exists to determine the
24 percentage of Medicare payment to hospitals that Medicare specifies for the direction and
25 supervision of hospital clinical laboratories. The CAP also was unaware of any estimates of the
26 dollar amount in question. Finally, at the time that this report was written, the American Society of
27 Clinical Pathologists (ASCP) had not responded to a request for comment on Resolution 107
28 (I-01).

29 30 RECOMMENDATIONS

31
32 The Council on Medical Service recommends that the following be adopted and the remainder of
33 the report be filed:

- 34
35 1. That the AMA oppose financial arrangements between hospitals and pathologists that force
36 pathologists to accept no or token payment for the medical direction and supervision of
37 hospital-based clinical laboratories. (New HOD Policy)
38
39 2. That the AMA reaffirm Policy H-225.973, which urges state medical associations, the
40 Department of Health and Human Services (HHS), the American Hospital Association (AHA),
41 and other hospital organizations to take actions to eliminate financial arrangements between
42 hospitals and physicians that conflict with the anti-kickback statute of the Social Security Act,
43 as well as with AMA policy. (Reaffirm HOD Policy)
44
45 3. That the AMA urge the Department of Health and Human Service-Office of Inspector General
46 to revise its Compliance Program Guidance for the Hospital Industry to state that token
47 payment or non-payment for pathologist Part A medical direction and supervision services in
48 exchange for Part B referrals violates the anti-kickback statute. (Directive to Take Action)