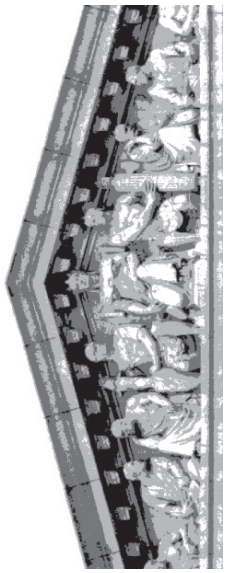

G-2 Compliance Report

WASHINGTON G-2 REPORTS

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For Hospitals, Laboratories and Physician Practices

Compliance Officer Survey

Compliance Programs Moving To Maturity
HIPAA Privacy Demands Are Top Concern

Healthcare compliance programs are growing up, for the most part moving from the development and implementation stage to the maintenance stage, according to the fourth annual *Profile of Health Care Compliance Officers.*

Compliance programs were uncommon in healthcare prior to 1996, notes the profile, compiled from a survey of compliance officers. Today, these programs are part of the operational fabric of healthcare organizations. Between 1996 and 1999, most were in the setting-up phase; now, most are up and running, according to survey data.

The survey, conducted annually by the Health Care Compliance Association and Walker Information, reflects the responses of 665 corporate compliance officers.

Healthcare corporate compliance programs across the U.S. are also continuing to grow, becoming more common, better known and larger, both in terms of employees and budgets, according to the survey. Since 1999, the percentage of the

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Free Gloves, Safety Needles To Doctors
Does Self-Referral Law Ban Them?

The answers might surprise you. Asked for comment at the 19th annual Lab Institute, sponsored by Washington G-2 Reports on Oct. 24-27, a top official of the HHS Office of Inspector General said there is a clear prohibition against free gloves under the physician self-referral (Stark II) final rule, but he declined to address the issue of free safety needles.

According to the OIG's Lewis Morris, the preamble to the final rule issued by the Centers for Medicare & Medicaid Services states that because the provision of gloves would be difficult to oversee and because the gloves potentially could be used for more than just taking samples for lab testing, furnishing them gratis would be considered compensation and would violate the law.

The Stark law prohibits physicians from referring to entities with which they have a financial relationship, either by ownership/investment interest or a compensation arrangement, unless a specific exception applies.

"In our view, it seems that CMS has [drawn] a bright line," said Morris. "This is not one of those areas where you have to wonder whether Stark applies."

What About Safety Needles?

Morris declined to comment on whether providing free safety needles to physician offices would

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Free Gloves, *from page 1*

constitute a violation, saying he "did not have an informed opinion." But attorney Robert Mazer with Ober/Kaler (Baltimore, MD) believes the Stark II final rule does not prohibit labs from supplying free safety needles.

The Stark statute, Mazer notes, excludes from "remuneration" a laboratory's provision of items, devices or supplies used solely to collect, transport, process or store specimens for the lab. According to the rule, the exception does not permit a lab to furnish physicians, without charge, sterile gloves or biopsy needles and like devices which can be used for purposes other than specimen collection. A lab may, however, provide physicians with single-use needles, vials and specimen cups.

"The fact that an OIG official could not answer the question indicates there is no clear or easy answer on safety needles," Mazer tells *G-2 Compliance Report*. "However, the Stark statute does indicate that devices used exclusively to draw specimens are not considered remuneration, resulting in a financial relationship, and that is precisely what these [safety needles] are."

Until the OIG or CMS or other government agency says otherwise, Mazer believes that a lab can provide a reasonable number of safe drawing devices to physicians without violating the Stark statute. "Obviously, if the lab provides an excessive number of these devices such that the physician would be using them for purposes unrelated to drawing specimens to be sent to the lab for testing, that would be a different story altogether."

OSHA Mandate Also A Factor

While the Stark II rule might not prohibit the practice of supplying a reasonable number of free safety

Robert Mazer

Sheila Dunn

needles, the practice is not advisable under the bloodborne pathogen standard issued by the Occupational Safety & Health Administration, says Sheila Dunn, DA, head of Quality America Inc. (Asheville, NC).

The standard, which took effect Apr. 18 (with a 90-day grace period), requires not only that safety needles be used, but also that they be identified, evaluated and selected by the "end user"—the phlebotomist or other front-line healthcare worker. States with their own OSHA plans had until Oct. 18 to comply.

The OSHA standard puts reference labs in a difficult position, says Dunn, because many physician offices have come to expect that the lab will provide, for free, devices used to take specimens, such as needles and collection tubes.

One solution she sees is that labs could provide physician offices only with a brand of safety needles that the end-users have already evaluated and been trained to use.

Resources

- Robert Mazer: 410-347-7359
- Sheila Dunn: 828-645-3661

New, Deleted Codes On 2002 Lab Fee Schedule

As of Jan. 1, Medicare will add and delete codes on its lab fee schedule, in accord with a Nov. 5 memo to carriers and fiscal intermediaries.

Below are new codes that are mapped to comparable current codes. Fee amounts will be the same as this year's.

New	*Mapped To*	*Natl. Cap*
82570QW	82570	$7.15
83001QW	83001	$25.69
83605QW	83605	$14.76
83950	84233	$89.01
84460QW	84460	$7.32
86141	83520	$17.89
86618QW	86618	$23.54
87198	87260	$16.58
87199	87260	$16.58
87802	87880	$16.58
87803	87810	$16.58
87804	87810	$16.58
87902	87901	$355.78

*Billing this code must reflect the diagnostic reason.
Note: QW=waived.

Three new codes will be carrier-priced via the gap-fill method: 82274 and 82274QW (occult blood, fecal hemoglobin determination by immunoassay), and 86336 (Inhibin A).

Deleted lab codes are: 80072, 85535, 86683, 86683QW, 87076QW, 87339QW.

Medicare Modifies, Clarifies ABN Instructions
Agency Still Accepting Public Comments

The Centers for Medicare & Medicaid Services has made more changes to draft carrier instructions on use of the new, standardized Advance Beneficiary Notices for Part B items/services and is accepting comments before finalizing the instructions, said a CMS official at Lab Institute 2001, sponsored by Washington G-2 Reports on Oct. 24-27.

CMS published the latest version in the Oct. 12 *Federal Register* and is accepting comments until Dec. 11.

The agency hopes to publish final instructions by year's end, but probably won't mandate use of the general ABN (CMS-R-131-G) and the lab ABN (CMS-R-131-L) until June or July of 2002, said Denis Garrison, director of CMS's consumer protection division. Labs may use either form and may even start now.

Among the most recent changes and clarifications regarding ABN use:

- **Frequency limits:** When any item or service is to be furnished for which Medicare has established a frequency limit (in a national coverage decision or a local medical review policy), the provider may routinely use an ABN, but must state the limit in the ABN-G's "Because" box.
- **Authorized representative:** CMS defines this as someone who, in most cases, has legal authority to act on the beneficiary's behalf or someone who has the beneficiary's best interest at heart and has no conflict of interest with the beneficiary. A provider normally would not be considered such.
- **Modifiers:** CMS will require use of one of the following modifiers on claims: GA (item of service expected to be denied as not reasonable and necessary; ABN was collected); GY (item or service statutorily excluded or does not meet the definition of any Medicare benefit); or GZ (item or service expected to be denied as not reasonable and necessary; ABN not collected). GZ would typically be used when a lab gets a specimen from a physician but cannot get an ABN signed because of time or other constraints.
- **Interaction with HIPAA:** The HIPAA statute authorizes civil money penalties when claims are submitted for a pattern of services that the provider knows or should know are not medically necessary. Use of ABNs won't risk HIPAA sanctions, the instructions say, because the latter are aimed at fraudulent claims for patently unnecessary medical care.
- **Size of font:** CMS will let providers use font size as small as 10 point (vs. 12 point in previous instructions) as long as the font is Arial, Arial Narrow or a similar readable font in blue or black ink (no italics allowed).

Asked whether a lab could simply absorb the cost of providing a test rather than providing an ABN, Garrison cautioned against this as a potentially illegal inducement. "If a lab did that routinely and advertised that in the paper, my guess is you would hear from the OIG."

He confirmed that providers can use an electronic ABN as long as the beneficiary signs electronically with a stylus or similar device (the signature may not be typed).

Resources

- *Federal Register*, Oct. 12, '01, p. 52139.
- Denis Garrison: 410-786-5643
- Our previous coverage: "One More Crack at ABN Instructions" Oct. '01, p. 2

More Oversight Slated For CLIA Waived Testing

Following up on quality concerns identified by government studies, the Centers for Medicare & Medicaid Services early next year plans to survey 2% of labs performing CLIA-waived tests, a CMS official told Lab Institute 2001 participants.

The aim is to ensure compliance with CLIA rules and verify that the test manufacturer's instructions are being followed, said Judy Yost, director of CMS's division of laboratories and acute care services.

As part of the educational effort, CMS also will establish a product labeling workgroup to help improve test instructions, she added.

"If education doesn't work, we'll have to go to Plan B," which could include regular surveys of a greater number of waived labs.

Other CLIA news from Yost:

- Revised quality control standards should be published by April 2002. "We have streamlined the language, simplified it and added QC flexibility—that's the piece we're most excited about."
- Meetings will be held with the Centers for Disease Control & Prevention on oversight of unregulated or "unestablished" tests, such as live blood cell analysis and food allergy testing.
- Yost's office will work with CDC on genetic testing regulations. CDC expects to have a proposed rule out next year.

Resource

- Judy Yost: 410-786-3407
- Our previous coverage: "Waived, PPM Tests Come Under The Microscope" Oct. '01, p. 4

HHS Inspector General's Office Sets Priorities, Projects For 2002
Lab, Hospital Scrutiny Continues; More Sectors To Get Guidance

Want to know what compliance issues the HHS Office of Inspector General plans to target next year? Take a look at the agency's recently released 2002 work plan.

The work plan lists investigative and enforcement projects that the OIG and its different divisions plan to undertake in the coming year. While some of the priorities are carried over from previous years, several new ones are identified for 2002.

Laboratory Services

❖ ***Outpatient clinical diagnostic lab services:*** In this new project, the OIG plans to review Medicaid payments to hospitals for these services in states that use an ambulatory procedures group payment methodology. Investigators will look at whether rates for certain lab and pathology tests exceed the rates allowed by Medicare.

❖ ***CLIA certification:*** This is an oldie, but goodie. The OIG intends to continue investigating whether labs are performing tests and billing Medicare within the scope of their certification under the Clinical Laboratory Improvement Amendments (CLIA).

❖ ***Cholesterol screening:*** Still concerned that cholesterol tests billed to Medicare may not be medically necessary and accurately coded, the OIG will continue to scrutinize claims for frequency of testing and the medical necessity of lipid panels.

❖ ***Proficiency testing:*** The OIG will continue to assess the policies and procedures used for proficiency testing under CLIA, with a focus on the testing and grading process.

❖ ***Lab audit follow-up:*** The OIG plans to follow up on prior audits of clinical lab services in 22 states, examining whether Medicare payments for chemistry, hematology and urinalysis tests were duplicated or exceeded the allowed amounts.

Hospitals

❖ **DRG Payment Window, Part B Providers:** This review will determine the extent of duplicate claims submitted by Part B providers for services such as ambulance, laboratory or x-ray services to hospital inpatients. Under the prospective payment system, hospitals are reimbursed a predetermined amount, depending on the illness and its classification under a diagnosis-related group for inpatient services furnished to Medicare beneficiaries. Separate payments for non-physician services rendered within the current 72-hour DRG payment window are not allowed whether the claims are submitted by hospital providers or Part B providers.

Physicians

❖ ***Beneficiary access to preventive services:*** The OIG plans to evaluate access to the expanded preventive services offered by Medicare since the passage of the Balanced Budget Act of 1997. The Act created four classes of covered preventive services: annual screening mammography for all women aged 40 and over; screening Pap smear and pelvic exams every three years; colorectal screening; and bone mass measurements.

❖ ***Advance Beneficiary Notices:*** Continuing prior years' work, the OIG will examine use of ABNs and their financial impact on beneficiaries and providers. The OIG is concerned "that practices vary widely regarding when ABNs are provided, especially with respect to non-covered laboratory services."

❖ ***Physician E&M codes:*** Medicare payments for these codes total approximately $18 billion per year and account for almost half of Medicare spending for physician services, notes the OIG. It plans to examine whether physicians correctly code E&M services in physician offices and effectively use documentation guidelines.

❖ ***Bone density screening:*** The OIG plans to evaluate the impact of the recent standardization and expansion of Medicare coverage of this benefit, noting that "as the number of claims for bone density screening increases, there are questions about the appropriateness and quality of some services."

❖ ***Inpatient dialysis:*** The OIG plans to examine whether Medicare payments for these services have met Part B billing requirements. Medicare requires that the physician be physically present with the patient at some time during the dialysis and that the medical records document this in order for the physician to be paid on the basis of dialysis procedure codes.

Legal

❖ ***Compliance program guidance:*** The OIG plans to issue guidance for ambulance companies, pharmaceutical companies and mental health service providers during 2002.

❖ ***Corporate integrity agreements:*** The OIG plans to increase coordination with the Centers for Medicare & Medicaid Services on appropriate measures regarding entities with ongoing problems. The Office will also modify some CIA requirements, such as audit and training provisions, to reduce the costs associated with implementing the agreements (*related story, p. 11*).

❖ ***Safe harbors:*** In fiscal 2002, the OIG anticipates publishing regulations for several new safe harbor exemptions from the anti-kickback statute.

Resource

❖ OIG Fiscal Year 2002 Work Plan: *www.hhs.gov/oig/wrkpln/2002/Work_Plan_2002.htm.*

COMPLIANCE PERSPECTIVES

Indirect Compensation Arrangements Under Stark: *A Beneficial New Approach*

Elizabeth McLaughlin is counsel in the Government Regulation Group/Trade & Regulatory Law Practice of the Washington, DC, office of Jones, Day, Reavis & Pogue

Since it took effect in 1992, the federal law prohibiting various physician "self-referrals" (the so-called Stark Law) has presented healthcare providers and their advisors with tremendous challenges in interpreting statutory and regulatory language that is often nearly impenetrable.

Stark regulations issued by the Centers for Medicare & Medicaid Services (CMS, formerly the Health Care Financing Administration) have generally been years in the making, and when issued, have raised as many questions as they have answered. No less was expected, or received, when CMS issued "Phase I" of its final rule under the Stark Law last Jan. 4, with an effective date of Jan. 4, 2002. While the Phase I final rule affords much needed guidance on several fronts, it leaves unresolved—or creates—other issues.

This article focuses on one key aspect of that final rule: the definition of an indirect compensation arrangement, and the creation of a new exception for certain indirect compensation arrangements.

These provisions of the rule appear to hold significant promise as a broad and rational regulatory scheme that could simplify Stark Law analysis of virtually every compensation arrangement between a hospital, laboratory or other provider and a physician group. Unfortunately, ambiguous and sometimes contradictory CMS commentary on the rule creates a lack of clarity regarding these provisions. Nonetheless, because of their great potential as a tool for Stark Law analysis, they merit careful consideration when analyzing compensation arrangements with physician groups.

Stark Law Overview

Under the Stark Law, if a physician (or an immediate family member) has a financial relationship with an entity, the *physician* may not make a referral *to the entity* for the furnishing *by the entity* of certain designated health services (DHS), and the entity may not present a claim for services furnished pursuant to a prohibited referral, unless a Stark Law exception applies.

Financial relationships include ownership/investment interests and compensation arrangements. The latter are broadly defined as any arrangement involving any remuneration, direct or indirect, between a physician and an entity. DHS include a wide range of healthcare-related items or services, including inpatient and outpatient hospital services, clinical laboratory services and a host of diagnostic and other ancillary services, but only when these are reimbursed by Medicare/Medicaid.

Indirect Compensation Ties

Significantly, the Stark prohibitions apply to referrals by an *individual physician* to an entity that furnishes DHS. Thus, each time a compensation arrangement is structured not with an individual physician but rather with a physician group—or not with an entity that itself "furnishes" DHS (which generally means bills Medicare for DHS) but rather with an affiliate of such an entity—a critical threshold issue is presented under the Stark Law.

That issue is whether such an arrangement creates an *indirect* compensation arrangement between an individual physician in the physician group and an entity that furnishes DHS. If it does, this would trigger precisely the same Stark Law restrictions as a direct compensation arrangement.

To resolve this critical threshold issue, the definition of an indirect compensation arrangement in the Phase I final rule potentially affords great assistance. CMS changed course from its previously expansive view of such arrangements; instead, it offered a far narrower new definition. Applying this new definition, an indirect compensation arrangement will often *not* be found, with the significant consequence that if no Stark Law financial relationship is found, no Stark Law prohibitions will apply.

CMS provides a three-pronged definition of an indirect compensation arrangement:

1 Between the referring physician and the entity furnishing the DHS there is an unbroken chain of persons or entities, with each link having a financial relationship (ownership/investment interest or compensation arrangement) with the preceding link;

2 The referring physician receives aggregate compensation, from the person or entity with which the physician has a *direct* financial relationship, that varies with or otherwise reflects the volume or value of referrals or other business generated by the physician *for the entity furnishing the DHS;* and

3 The entity furnishing the DHS has actual knowledge or acts in reckless disregard or deliberate ignorance of the fact that the referring physician receives such aggregate compensation.

Hypothetical Case

This definition can be applied to a hypothetical arrangement between a physician group (the Physician Group) and a hospital, laboratory or other entity (the Contracting Entity) that has entered into an agreement (the Service Contract) under which the Physician Group either provides items or services to, or receives items or services from, the Contracting Entity. The threshold issue then becomes whether the Service Contract creates an indirect compensation arrangement between individual physicians in the Physician Group and the Contracting Entity (or an affiliate of the Contracting Entity).

Note that analysis of an indirect compensation arrangement applies to both sides of the contracting equation. That is, it applies both to determine whether such an arrangement is created for the individual physician member of the Physician-Group *and* to determine whether such an arrangement is created with any affiliate of the Contracting Entity. This latter analysis is important in arrangements in which the Contracting Entity does not itself furnish the DHS but is an affiliate of an entity, such as a hospital, that does furnish such services.

The new definition of an indirect compensation arrangement can be applied to our hypothetical arrangement as follows. Each physician who is employed by (or has an ownership interest in) the Physician Group will almost certainly meet the first prong of the definition because he/she will have a financial relationship with the Physician Group, which in turn will have a compensation arrangement with the Contracting Entity by virtue of the Service Contract.

Certain provisions of the Stark II rule appear to hold significant promise as a broad and rational regulatory scheme that could simplify Stark law analysis of virtually every compensation arrangement between a hospital, laboratory or other provider and a physician group

Some commentators have said the first prong of the definition could be interpreted such that no "financial relationship" exists if the relevant compensation arrangement or ownership interest meets a Stark Law exception. That is, if an exception applies to a compensation arrangement or an ownership interest, then under the Stark Law it technically does not constitute a "financial relationship"; thus, the literal language of the first prong (requiring a financial relationship) would not be met. It is clear that CMS did not intend this result, and this article assumes that the first prong of the definition applies in the situation described above.

It is at the second prong of the new definition that the Stark Law analysis will end for many arrangements and an indirect compensation arrangement will *not* be found. The second prong will *only* be met and, thus, an indirect compensation arrangement will *only* be found between an individual physician and a Contracting Entity (or its affiliate) *if* the individual physician receives compensation from the entity with which he/she has a *direct* financial relationship (the Physician Group) that varies with or otherwise reflects the volume or value of referrals or other business generated by the physician *for the entity furnishing the DHS* (the Contracting Entity if it furnishes the DHS or an affiliate of it that furnishes the DHS).

That is, if a physician member of the Physician Group does *not* receive compensation under his/her employment agreement with the Group or distributions from any ownership interest in the Group that varies with or otherwise reflects the volume or value of referrals or other business generated *by that physician for the Contracting Entity (or an affiliate)*, then this prong will *not* be met. If so, no Stark Law indirect compensation arrangement will be found.

Many arrangements that previously would have been viewed as creating indirect compensation arrangements will *not* meet this prong, with the result that an indirect compensation arrangement will *not* be found. To meet this prong, a Physician Group would need to distribute revenue such that an individual physician received compensation (or distributions from his/her ownership interest) based on the *physician's referrals for DHS to the Contracting Entity* (or an affiliate).

Thus, one option to ensure Stark Law compliance in contractual arrangements is for the parties to agree that a physician group will not pay its individual physicians compensation that varies with the volume or value of DHS referrals to, or other

business generated for, the entity with which it has contracted (or an affiliate of that entity). Any such agreement should be reflected in the parties' written agreement.

Whether a Contracting Entity will meet the third prong of the definition of an indirect compensation arrangement depends on the specific facts and circumstances of the relationship between the Entity and the Physician Group.

The knowledge element requires, in CMS's view, that the Contracting Entity need only know or have reason to suspect the existence of aggregate compensation that varies with referral volume or value or other business generated by the referring physician for it. There is no affirmative obligation to inquire as to the existence of indirect financial relationships *so long as* no information exists that would put a reasonable person on alert that such a relationship exists. If such information exists, however, the duty imposed is one of reasonable inquiry into the circumstances. If the Physician Group and the Contracting Entity (or its affiliate) have a longstanding relationship, this prong could be met.

As discussed above, applying this new definition is likely to result, in many instances, in a finding that an indirect compensation arrangement has *not* been created. In those instances where an indirect compensation arrangement is found, a new exception may nonetheless apply.

New Exception Under Stark

The Phase I final rule sets forth a new exception that will be met by an indirect compensation arrangement which conforms to the following three criteria:

1 The compensation received by the referring physician is *fair market value for services and items actually provided, not taking into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS*;

2 The compensation arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement (except for a *bona fide* employment relationship, which need not be in writing but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer); and

3 The compensation arrangement does not violate the anti-kickback statute or any laws or regulations governing billing or claims submission.

Upon initial analysis, it is not entirely clear how this exception—requiring as it does that compensation be at fair market value, *but not taking into account* the value or volume of referrals or other business generated by the referring physician for the entity furnishing the DHS—is intended to be reconciled with the definition of an indirect compensation arrangement, which is found only if compensation *varies with or otherwise reflects* the volume or value of referrals or other business generated by the physician for the entity furnishing the DHS.

The following analysis offers an interpretation that affords a surprisingly broad—and rational—exception.

Interpretation of the "volume or value" and "other business generated" standards used in the indirect compensation arrangement definition and exception is critical in assessing the meaning of these provisions. The Phase I final rule created a great deal of confusion regarding these standards. A cogent argument can be made, however, that the first prong of the exception—likely the most difficult to meet—will be met if the compensation paid to a physician is at fair market value for the services rendered, with such compensation not inflated to compensate for the physician's ability to generate referrals or other business for the entity furnishing the DHS.

Under this view, what is paramount is the fair market value nature of the compensation, with that standard incorporating the concept that compensation is not inflated to reflect referrals or other business.

What's the rationale for this interpretation? The key phrase in the portion of the *definition* relating to the "volume or value" standard is that the referring physician receives "*aggregate compensation that varies with, or otherwise reflects,* the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS."

A careful review of the Phase I final rule indicates that this phrase is intended to be broadly construed and, simply put, means that if the physician's total compensation varies in whole or in part based on his/her referrals to, or other business generated for, the DHS entity, this element of the definition is met. (A careful review of the rule also indicates that the "otherwise reflects" language applies only in very limited instances; for example, if a compensation arrangement is impermissibly conditioned on the physician's making referrals or generating other business, or if compensation is inflated to reflect referral volume or value or other business generated.)

The key phrase in the portion of the indirect compensation arrangement *exception* relating to the "volume or value" standard is that the referring physician receives compensation that is at "fair market value for services and items actually provided, not *taking into account* the value or volume of referrals or other business generated by the referring physician."

Under new special provisions in the Phase I final rule, CMS states that compensation (including time-based or unit-of-service-based compensation) will be deemed not to *take into account* referral volume or

value if the compensation is at fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS. Similarly, compensation will be deemed not to *take into account* other business generated between the parties so long as the compensation is at fair market value and does not vary during the term of the agreement in any manner that takes into account referrals or other business generated by the referring physician.

These provisions clearly suggest that it is the fair market value nature of the compensation that is paramount in determining whether the critical first prong of the exception is met. This interpretation is further supported by commentary on the Phase I final rule, in which CMS clearly states it would permit volume-based compensation methodologies (*e.g.*, unit-of-service-based payments) even when the physician receiving the payment has generated the payment through a DHS referral *so long as* the payment per unit is at fair market value at inception and does not subsequently change during the term in any manner that takes into account DHS referrals or other business generated by the physician.

CMS further states its desire to establish a straightforward test that compensation arrangements should be at fair market value for the work or service performed—not inflated to compensate for the physician's ability to generate other revenue.

"Muddy Water"

While CMS's reasoning discussed above is fairly straightforward, the agency muddies the water considerably in its commentary on when compliance with the "volume or value" standard requires that such compensation be "fixed in advance" or "set in advance." The lengthy CMS commentary on the Phase I final rule precedes the actual text of the regulations and is intended to explain the content and to respond to comments received in the process of developing the rule. Significantly, the commentary does *not* constitute binding law. The actual text of the rule, when effective, does.

"Fixed In Advance"

In various lengthy—and often confusing—portions of its commentary, CMS appears to engraft a "fixed in advance" requirement onto the special provisions regarding "volume or value of referrals" and "other business generated." Engrafting such a requirement onto these standards will significantly limit the broad, rational interpretation discussed previously, which ties the standards primarily to a showing of fair market value without inflation to reflect referrals or other business.

Significantly, however, the actual *text* of the Phase I final rule does *not* impose any "set" or "fixed in advance" requirement on the special provisions regarding the "volume or value of referrals" and "other business generated" or on compensation arrangements that seek to qualify for the indirect compensation exception. Thus, while CMS arguably views a "set in advance" requirement as a part of its special rules regarding the "volume or value of referrals" and "other business generated," the actual text of the final regulations themselves, and *not* CMS's commentary on them, will constitute the governing law in this regard.

Under the rationale discussed above, compensation paid under our hypothetical Service Contract would meet the first prong of the exception for indirect compensation arrangements *if* it will result in fair market value compensation and that compensation does not vary over the term of the arrangement in any manner that "takes into account"—as interpreted above—referrals or other business generated by the physician. The determination should be properly supported by clear evidence, ideally an opinion from a qualified compensation consultant or similar objective data substantiating the fair market value of the compensation. Given that this standard is required as well under other laws, such as the anti-kickback statute, the potential breadth of the exception for indirect compensation arrangements is significant.

The second and third prongs of the exception are relatively straightforward to apply and must, of course, also be met. Parties may, unfortunately, experience added uncertainty regarding satisfying the third prong—requiring compliance with the anti-kickback statute—given the inability, absent an advisory opinion, to be certain that such compliance has been achieved.

Clarification Expected

It is reasonable to anticipate that CMS has received numerous comments on these provisions during the comment period on the Phase I final rule. Thus, the agency may further clarify provisions discussed in this article in Phase II of the rulemaking or some earlier public pronouncement.

While there is substantial authority for the conclusions reached above, CMS's intent is unclear and the author cannot, of course, definitively state that the interpretation discussed herein is how the indirect compensation arrangement exception will be applied. Nonetheless, the potential breadth of the interpretations discussed above offer significant hope of a rational approach to analyzing indirect compensation arrangements under the Stark Law.

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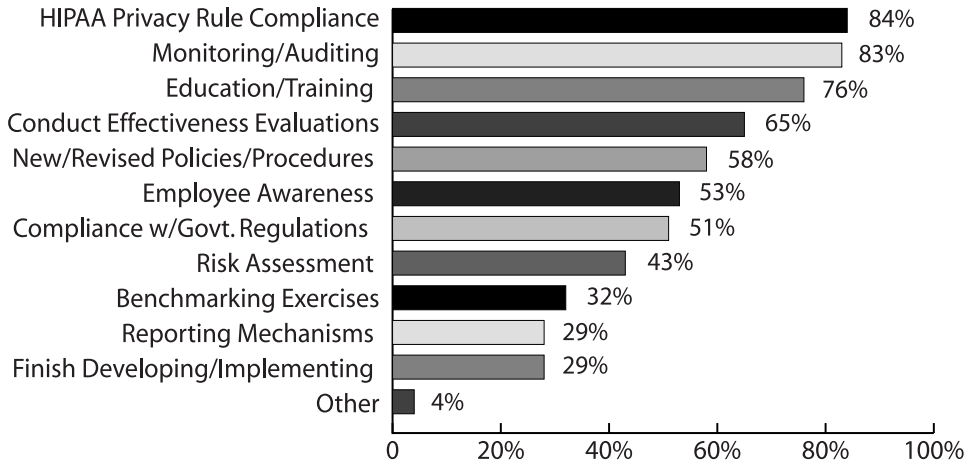
What Specific Goal Do You Hope To Achieve With Your Compliance Program In The Next 3 Years?



Source: 2001 Profile, Health Care Compliance Association. Note: Results total more than 100% because respondents said they had more than one goal for the program.

Compliance, *from page 1*
healthcare organizations with active compliance programs has risen from 55% to 80%, and budgets have increased by more than 10%.

Compliance Officer Status

Along with program growth has come growth in the Corporate Compliance Officer (CCO) position. Compared to just a few years ago, today's CCO is better educated, receives higher compensation and is a more integral part of a healthcare organization, the survey finds.

The average salary is $98,220, up from last year's average of $90,000. Salaries vary by organizational size, location and revenue. CCOs in the West and Northeast tend to have higher salaries, as do those at larger organizations. Salary growth has been particularly strong in the Northeast, where the average has risen to $104,910, 17% above that for 2000 ($89,410).

The CCO typically reports to the CEO/President (58%) or the Board of Directors (11%) and is considered part of the senior management team; 60% of those surveyed say the CCO has his or her own department with budgetary responsibilities and staff. The average departmental budget is $326,610, a 12% increase over last year's average of $292,990.

As in previous years, CO staff members tend to be administrative (66%) or internal auditors (36%) in terms of training and skills. Staff salaries range between $44,074 for Coders/CPCs and $69,513 for regulatory affairs personnel.

Issues & Trends

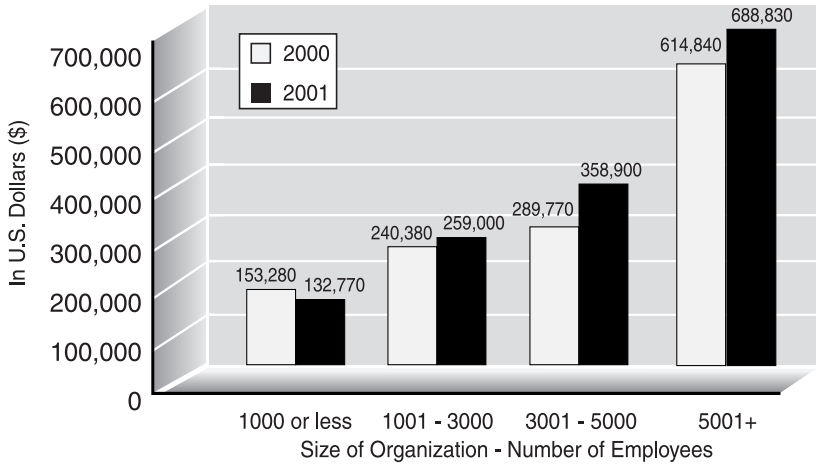
The privacy standards required by the Health Insurance Portability & Accountability Act (HIPAA) have challenged compliance programs across the country, the survey shows. HIPAA compliance is listed by 62% of survey respondents as the biggest issue facing their program today, followed by monitoring/auditing (50%), education/training (37%) and compliance with government regulations (36%). Last year's top issue––program development and implementation––has become less important: 29% say it is their top issue vs. 66% last year.

HIPAA compliance also edged out monitoring/auditing as the top goal over the next three years. Eighty-four percent ranked it as the top goal, followed by monitoring/auditing (83%), education/training (76%) and conducting program effectiveness evaluations (65%). Results add up to more than 100% because respondents stated they had more than one goal.

Resource

❖ *Fourth Annual Survey: 2001 Profile of Health Care Compliance Officers,* online at *www.hcca-info.org.*

Annual Budget Of Compliance Department *(by size of organization)*



Source: 2001 Profile, Health Care Compliance Association.

Providers Turning To Computer-Based Compliance Training

Just a year ago, Intermountain Health Care, an integrated delivery system based in Salt Lake City, UT, kept laboratory personnel up-to-date on key compliance issues through presentations at its 23 lab facilities. Employees were tested on their comprehension, with results tabulated manually. While effective, the approach was sometimes inconvenient and time-consuming, according to Hyde Frederickson, IHC's laboratory compliance officer.

"We had a trainer who would give a presentation during a class, but that meant we had to get everyone together at the same time, which wasn't easy to do," he explains.

Today, however, IHC, which employs about 1,000 people at its lab sites in Utah and Idaho, has streamlined its compliance training through use of the company's Intranet, or internal computer network. Now, rather than attending a class, lab personnel can log onto the IHC Intranet at their convenience, review training materials online, and take a quiz, all in less than 30 minutes. Quizzes are graded automatically and results are sent by computer directly to the Human Resources Department, which maintains training records on all staff.

IHC is just one of many healthcare systems across the country that have turned to computer-based training programs to meet standards urged by the HHS Office of Inspector General. The OIG, which has published guidance for most sectors of the healthcare industry, recommends that providers, suppliers and others develop an effective education and training system as part of their compliance program.

In the guidance for clinical laboratories, for example, the OIG suggests using a variety of teaching methods, including interactive training. "Targeted training should be provided to corporate officers, managers and other employees whose actions affect the accuracy of claims submitted to the government and private payers, such as employees involved in the coding, billing and marketing processes."

User- & Company-Friendly

IHC's lab division turned to computer-based training to simplify training and make training materials more accessible to lab personnel, explains Frederickson.

"We have two different modules each year that deal with different topics. We usually cover about five different topics in each module, which is posted on the Intranet for six weeks." IHC's current lab training module, for example, addresses standing orders, quality of care and false claims, confidentiality and HIPAA, bloodborne pathogens and CBCs.

Lab employees must answer 80% of the questions correctly in order to complete the training successfully, which is a condition of employment. Staff members who don't pass the first time can review the materials and retake the test.

"This is a much simpler process to administer, and it's easier for staff members to take because they can do it at their convenience, generally during their regular shift," says Frederickson. "We don't have to get a bunch of people together for a meeting and arrange coverage for them."

IHC hopes to enhance future training modules by adding narration to the written materials available online. "As we get better at this and as the technology improves, we hope to be able to do even more," adds Frederickson. "We may even do it more often than twice a year if the amount of information that needs to be conveyed increases."

Labs, hospitals and physician practices that want to use e-training but don't have an Intranet or aren't able to develop their own online training programs can contract with an outside vendor to provide training via the Internet. MCF Compliance (Barrington, IL) is one such company that offers specialized training for labs and small hospitals.

Through MCF, healthcare organizations can choose from eight different online courses, each consisting of two modules that take about 20 minutes to complete, explains Charles Root, company president and CEO. Among the offerings: Basic Compliance for Hospitals, Basic Compliance for Clinical Laboratories, Medicare Rules and Regulations for Laboratories, and Basic CPT Coding for Laboratories.

At the end of each course, employees or "students" take a short test, and results are forwarded to their sponsoring organization. Students who successfully complete the training receive certification from the National Commission on Compliance Education.

Customized Training

MCF will customize training programs for organizations and also will track which employees have completed their training requirements and which have not. The cost of MCF's online training runs about $20-30 per employee per year. On average, a small lab or hospital with about 150 employees might expect to pay $3,000-4,000 a year for the service, according to Root, which he says is a significant cost savings over most seminar-based training programs.

"At small organizations, compliance officers might spend half their time on education and training. We can free up a lot of that time and provide the training for about a third of what it would normally cost an organization to do it."

Resources

- Hyde Frederickson: 801-442-2860
- Charles Root: 847-381-5465

OIG Plans Changes To Corporate Integrity Agreements

The HHS Office of Inspector General is in the process of streamlining corporate integrity agreements (CIAs) to reduce the financial impact on providers while at the same time improving and increasing internal controls, Inspector General Janet Rehnquist told healthcare attorneys and compliance officers in her first public appearance since being sworn in as IG in August.

"We've amended compliance provisions contained in certain settlement agreements," Rehnquist said during the keynote address of the Fraud and Compliance Forum, held in October in Washington, D.C.

The forum is co-sponsored by the American Health Lawyers Association and the Health Care Compliance Association.

"We also will be changing several of the corporate integrity independent review organization requirements to reduce further costs, and we will redesign the sampling methodology to improve its effectiveness while reducing costs," Rehnquist added.

Modifications to CIAs could mean that providers demonstrating sufficient internal controls may not be required to enter into a CIA in cases where there is a False Claims Act settlement, she explained. In other cases, providers may be allowed to complete a False Claims Act settlement before entering into CIA negotiations, she noted.

Cases where insufficient internal controls exist, however, would be subject to the same kinds of actions currently required, said Rehnquist. Any benefits created by the modification of CIAs will be passed on to providers currently operating under such agreements.

For the Record

A reader submitted this scenario and question: A pathology practice receives a specimen for examination at the lab (non-hospital based) on a reference patient. The specimen is accessioned at the lab, and the technical component (TC) in preparing the slide is provided by the practice at the lab location, while the professional component (PC or interpretation) is furnished by a physician within the same group, but at a hospital-based location.

In billing Medicare, must the TC be split from the PC in order to report the CLIA number where each service is performed or should the procedure be reported as a global service? In the latter case, which CLIA number do we use—where the TC was done or where the PC was provided? No purchased services are involved since the TC and PC were done by the same group/entity, just at different locations.

Coding consultant Dennis Padget, head of Padget & Associates (Simpsonville, KY) responds:

"I assume from the above that the performing lab (1) is licensed as an independent lab, (2) has its own Medicare provider number and (3) is classified by the Part B carrier as a specialty 69 (independent lab) provider. I also assume that (1) the pathologist who reads the slide has assigned to the independent lab his/her right to receive payment from Medicare (Section 3060.1 or 3060.5, *Medicare Carrier Manual*) and (2) you desire to submit a single claim for the global service.

"The independent lab may submit a single HCFA-1500 claim to the carrier, showing its name and provider number in the payee field (box 33) and its federal EIN in box 25. The lab will post the global CPT code (for example, 88305, with no modifier) to box 24d, and box 20 (*outside lab?*) will be checked 'No.' The place-of-service box (24b) will be marked 81 (*independent lab*). If required by the local carrier, the performing pathologist's ID number linked to the independent lab's provider number will appear in box 24k.

"CLIA number reporting is driven by where the pathologist is when he/she reads the slide. In the situation you describe, the CLIA number of the hospital will be posted to box 23, and its name and address will appear in box 32 as well, because that is where the slide was examined. The hospital must agree to the independent lab's use of its CLIA number in this way. (As an aside, an independent lab that operates solely as a processing center for histology and/or non-gynecological cytology specimens—with no diagnostic services being rendered on-site—does not need to be CLIA-certified, according to Section 493.2 of the CLIA rules in the Code of Federal Regulations.)"

Have a compliance question you'd like answered? E-mail it to Kimberly Scott, managing editor, at *kimscott@yahoo.com*. We'll select one to address in this column.

The Back Page

News-At-A-Glance

HIPAA Privacy Rule: Proposed modifications to this rule that were expected by the end of the year are unlikely to be published until January or February, according to an official with the U.S. Department of Health & Human Services.

"September 11 has altered our original timeline," said Susan McAndrew, senior policy specialist on HIPAA for the Office of Civil Rights, at a meeting of the National Committee on Vital and Health Statistics. "We had been hopeful of having the modifications done by April 2002 so that there would be a full year before the original compliance deadline. I am not that optimistic that we can have a final rule out by that date."

Billing Settlement: Impath Inc. has agreed to preliminary terms with the U.S. Department of Justice to settle an investigation into one of the company's billing practices. The company will pay $9 million to resolve an investigation of claims submitted to Medicare and Medicaid between 1990 and 1998 for one of the tests necessary to perform Impath's diagnostic and prognostic services. The company, which does not admit any wrongdoing, will record a one-time charge in the third quarter for the payment and an estimated $700,000 in associated costs.

SUD Enforcement Change: The Food & Drug Administration has extended the deadline for active enforcement of the following postmarket requirements on reprocessing of single-use devices: medical device reporting, tracking, corrections and removals, quality system and labeling (the enforcement schedule for other requirements remains unchanged). While the agency has begun inspecting hospital SUD reprocessors, it does not plan to take enforcement action on the above requirements until Aug. 14, 2002. The revised policy does not apply to third-party processors.

Regulatory Schedule: As part of its stated aim to become more responsive to the provider community, the Centers for Medicare & Medicaid Services is proposing to issue agency notices on a regular schedule. In the Nov. 1 *Federal Register*, the agency says it will publish CMS business in the *Register* on the fourth Friday of each month unless prevented from doing so. In addition, the agency says it will issue quarterly updates that list all of the regulations it plans to publish in the forthcoming quarter as well as an index of each regulation released in the preceding quarter.

Fraud Investigators: The National Health Care Anti-Fraud Association (NHCAA) will begin certifying fraud investigators in 2002, giving them professional designation that signals, among other things, their experience exceeds most state requirements for special investigation units. Eligibility requirements include a minimum of five years of relevant professional experience and a minimum 75 hours of health care anti-fraud training as a participant or instructor. Applicants must also pass an Accredited Health Care Fraud Investigator (AHFI) exam, submit three letters of reference, and pay an application fee of $600 for NHCCA members or $1,000 for nonmembers.

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