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G2 Compliance Advisor

For Clinical and AP Laboratories and Pathology Practices

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G2 Upcoming G2 Events

Lab Revolution
April 6-8, 2016, Sheraton Wild Horse Pass Resort & Spa, Chandler, AZ
www.labrevolution.com

Lab Institute 2016
Oct. 26-28, 2016, Hyatt Regency Washington on Capitol Hill, Washington, DC

Webinar
Genetic Test Utilization Management: Practical strategies for achieving efficiency, cost savings and appropriate test selection
Feb. 24, 2016 , 2-3:30pm EST
Cheryl Hess, MS, CGC, NextGxDx
Jessie Conta, MS, LCGC, Dept. of Laboratories, Seattle Children's Hospital

7 Service Terms to Include in Your Patient Debt Collection Agency Services Contract

Outsourcing patient collections enables labs to generate needed cash flow and concentrate on clinical operations. That, at least, is the theory. But the strategy does not always work. One of the key factors of success is the actual services contract the lab signs with the agency. Many a lab has seen the anticipated benefits of outsourcing go up in smoke because of a bad contract. In the first installment of this series, we explained the three legal protections to include in your services contract. Now let's concentrate on the seven business provisions you need to ensure that your agency delivers you the highest quality services and support.

1. Services Agency Will Provide

Problem: Do not assume that the agency's form contract is limited to collecting patient debts. Many agencies offer a full range of services from patient collection to full management of the patient revenue cycle and just about anything in-between, including medical coding and billing, interfacing with insurers and third-party payers, patient accounting, etc.

Solution: You need to read, understand, and, if necessary, modify the part of the services contract that describes what services the agent will provide you to ensure you do not sign up for services that you do not need.

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CMS Issues Deficiency Letter to Theranos

Theranos is once again in the media spotlight due to negative attention it has received from a government regulatory agency. Last year, the U.S. Food and Drug Administration (FDA) released documents indicating its position that Theranos' nanotainer used for collecting blood samples is a class II medical device and listing concerns about certain aspects of operations (see box). This year, in January, a Centers for Medicare & Medicaid Services (CMS) letter said Theranos' Newark, Calif. laboratory had condition level deficiencies and posed an immediate danger to patients in the area of hematology.

The CMS letter arises from an onsite survey completed in November 2015, to determine compliance with the Clinical Laboratory Improvement Amendments (CLIA). The letter indicates the laboratory facility was not in compliance with CLIA certification conditions re-

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CMS Issues Deficiency Letter to Theranos, *from page 1*

lating to analytic systems (42 C.F.R. 493.1250), laboratory director requirements for high complexity testing labs (42 C.F.R. 493.1441), requirements concerning technical supervisor for high complexity testing labs (42 C.F.R. 493.1447), and testing personnel conditions for high complexity testing labs (42 C.F.R. 493.1487).

As to the hematology deficiencies giving rise to immediate jeopardy, the letter explains that CLIA defines immediate jeopardy as "a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public."

CMS gave Theranos 10 days to issue a plan of correction, a typical requirement of an immediate jeopardy letter. Health care attorney Robert E. Mazer, of Ober Kaler in Baltimore, who assists laboratories with CMS inspection and CLIA issues, indicated he has not seen the actual survey report and therefore can't comment on the specific nature of the alleged deficiencies but explains that this letter means that CMS has advised Theranos that "sanctions will not be imposed" if CMS is able to confirm that Theranos has demonstrated that it has "removed jeopardy" and "come into Condition-level compliance." A follow-up survey must also verify compliance with "all CLIA requirements" after corrective action evidence is supplied by the lab. "If [compliance] has not been demonstrated to CMS' satisfaction, the agency can impose various penalties, including revocation of the laboratory's CLIA certificate required to perform testing, or cancellation of its right to receive Medicare payment for its tests," Mazer adds. CMS' letter warns that civil money penalties of up to $10,000 per day of noncompliance could be imposed.

Theranos issued a statement that the problems were all but corrected and reiterated that it was among the few labs that invited a higher level of scrutiny than required. "Theranos remains the sole company to call for—and voluntarily submit itself to—stronger regulatory oversight," it said, in reference to the fact that it had decided to submit all of its test to the U.S. Food and Drug Administration for approval.

"It's important to note this particular survey was conducted months ago and is not a reflection of the current state of our lab in Newark, CA," the statement continued. "As the survey took place we were simultaneously conducting a comprehensive review of our laboratory's systems, processes and procedures to ensure that we

Theranos Addresses FDA Scrutiny

Late last year, Theranos received two Form 483s from the U.S. Food and Drug Administration (FDA) indicating that its nanotainer is a class II medical device and expressing concerns with regard to complaint handling, audits, design validation and documentation regarding risk analysis. Theranos responded to the FDA reports publicly, stating "none of these observations were specific to Theranos' analytical devices, software, or chemistries, or the manufacturing infrastructure for Theranos' analytical devices or chemistries. All observations from this inspection pertained to quality systems associated with the use of one of our Nanotainer tubes under the CLIA lab quality framework instead of the FDA quality framework." Theranos also emphasized that these 483s were not final agency determinations of compliance but rather observations made by FDA during inspection visits. FAQs on the FDA website confirm that 483s are not final agency determinations as to compliance and are issued "when an investigator(s) has observed any conditions that in their judgement may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."

Theranos has voluntarily pledged to put the company's assays through the FDA's approval process. In a March 6, 2015 statement regarding the FDA's framework for overseeing laboratory developed tests (LDTs), the company stated: "Theranos is submitting and will continue to submit all our tests to the FDA. We are not required to do so, but we have made this commitment because we believe that FDA oversight plays a critical role in ensuring that individuals and their physicians get the most accurate test results." So far, in July 2015, the FDA approved one of the tests on Theranos' menu—it herpes simplex 1 virus IgG assay.

have best-in-class quality systems. CMS' findings included standard and condition-level deficiencies, and one finding at the "immediate jeopardy" level.... To be clear, that finding does not apply to the whole lab, and none of these findings relate to our Arizona lab, where we currently process over 90 percent of our tests."

With regard to the personnel-related deficiencies cited in the letter, Theranos said it has added two new key personnel: Kingshuk Das, M.D. a board-certified pathologist and associate medical director of UCLA Health's Clinical Laboratories; and Waldo Concepcion, M.D., chief of clinical transplantation and professor of surgery at Stanford University Medical Center.

"In some cases, a laboratory may attempt to satisfy CMS that all of its concerns have been addressed through changes in laboratory operations, without admitting that condition-level deficiencies had actually existed," says Mazer. "This is because if CMS rejects the allegations of compliance and correction and seeks to impose penalties and the laboratory files an administrative appeal, the lab will have to prove that each finding of a condition-level deficiency had been incorrect. The lab cannot avoid penalties imposed by the agency by contesting CMS' determination, rejecting a so-called 'credible allegation of compliance.'"

Takeaway: Theranos continues to face scrutiny from federal regulators as it reiterates its commitment to work with those regulators to achieve approvals for its testing technologies. G2

What Every Lab and Pathology Practice Needs to Know About "At-Will" Employment

What does at-will employment mean? It means that either the employer or the employee can end the relationship at any time and for any reason or for no reason at all—unless there is a contract for a term of employment. So why should a manager or compliance officer be concerned about that?

Because most states say yes, there can be an implied contract of employment and no, that contract doesn't have to be written or even expressed and yes, it can negate the at-will employment. If the employment is not at-will, the employer can terminate someone only for good cause. Terminations of employees you thought were at-will but really were protected by even an implied employment contract can create risks of wrongful termination lawsuits and hefty damage awards.

What creates an implied contract?

Some very common circumstances, says Denise I. Murphy, a labor and employment attorney with Rubin & Rudman in Boston. And labs and pathology groups need to make sure they don't fall into them.

From probation to contract

One danger area is the probationary period for new hires.

It's common practice, Murphy says. Many employers set a 60- or 90-day period before employment becomes final, the logic being that if the person doesn't work out, there's a simple good-bye with no firing. But the risk is that the process of making it through a probation period to full-scale employee can be seen as an implied contract of employment. And if there's a contract, the employer can't fire at will.

Another danger comes from simply having an employee handbook. People have argued that a handbook is evidence that there is an implied contract.

The simple solution is to do away with any probationary period the lab or practice now has.

What if there is a wait period before a newcomer can be given health insurance coverage? Does that create a probationary period?

No, she says. But for safety, make it clear to each new employee that such is not the case.

Add a statement to the handbook that "there's a waiting period for eligibility to obtain benefits" but that it "has no impact on anybody's employment status, which is at-will at all times."

Clad the handbook in iron

Another danger comes from simply having an employee handbook. People have argued that a handbook is evidence that there is an implied contract.

To void that argument, Murphy says, put a statement at the very beginning of the book that "this handbook is in no way a contract of employment" and that employment is at-will at all times.

Then for safety, reinforce it. Require the employees to sign a statement saying they have received and read the handbook, that they understand the contents, and that they acknowledge the employment status is at-will. And "restate the definition" of at-will employment.

More protection in the discipline

The at-will statement also needs to appear in a spot few employers ever think about, and that is on any document outlining a disciplinary policy or procedure. Without the at-will statement, it can be argued that the lab or pathology practice has to follow the disciplinary procedure before it can terminate any employee.

All the statement needs to say is that "nothing in this policy alters your status as an at-will employee. We reserve the right to terminate your employment at any time."

And with any updates to disciplinary procedures, repeat the statement so no one can say the new policy negates it.

Another safety point here is to put the same statement at the end of any written warnings an employee gets. That prevents a fired staffer from claiming the manager was supposed to go through the full disciplinary procedure before firing.

Come to work – but on our terms

Be careful too of negating at-will status in letters offering employment. Along with the basics of salary, benefits, and paid days off, there needs to be a

statement referencing at-will status: "This offer outlines the general conditions of employment. It does not form a contract. Your employment with us is employment at will and can be terminated at any time."

Give compliments, yes. But to sidestep risky statements, make each one "specific to the act," such as "you have done a fine job on this project."

In addition, don't state the pay amount in terms of "annual salary." Phrase it that way, and somebody can argue it implies a guaranteed one-year employment.

Instead, if it's an hourly employee, say "your hourly rate is $X." Or if the job is a salaried position, "you will be paid monthly at $3,000, annualized at $36,000."

Recruiting is also risky

Also, Murphy says, don't try to win over a candidate by saying that working for your lab or pathology practice can be a lasting career.

That's a common mistake. A top candidate comes in and gets a sales pitch of "people never leave here" or "most of our staff have been with us for 10 years or more."

Those remarks may make the employer look like a great place to work, "but they also suggest that longevity is guaranteed."

Say the same thing, but say it in different words such as "our staff enjoy working here."

And if a candidate asks about turnover, say "As in every business, people come and go, but the people who are here right now seem content. I think you'll enjoy working here."

The same applies to job reviews, she cautions.

Don't tell a good performer "you're a great asset and you'll always have a job here" or "we don't want to lose you" or "you're in our long-term plans" or even "I don't know what we'd do without you."

The performance could take a nosedive the next day. Or the lab or practice could make business changes that don't include that person.

Give compliments, yes. But to sidestep risky statements, make each one "specific to the act," such as "you have done a fine job on this project." Don't give overall general praise lest the employee take it as a sign of guaranteed permanent employment.

Takeaway: Labs and pathology practices that want to maintain at-will employees should be careful to avoid traps that can contradict the at-will relationship. G2

G2 Compliance Corner

Know What's Really Going On

Most of the recent enforcement cases that we have discussed in *G2 Compliance Advisor* and our sister publications have developed out of whistleblower or *qui tam* claims. Often these whistleblowers worked for the organization that is the subject of the allegations. So it's a good idea "to promote internal reporting to identify and address compliance issues before they get out in the public or give rise to a *qui tam* action," warns health care attorney Charles C. Dunham IV, of Epstein, Becker & Green.

To do that, don't overlook the importance of one of the seven "fundamental elements" of an effective compliance program the Office of Inspector General highlighted back in its 1998 compliance program guidance for clinical laboratories—effective lines of communication. "It's important to take the initiative to know what is going on in your organization and that there are appropriate reporting structures in place," advises Kristin Carter, a health care lawyer with Ober Kaler in Baltimore.

"Lab staff with boots on the ground are going to see the issues and you want it to go up the ladder," Dunham agrees. While the message isn't new, with the number of whistleblower claims that continue to arise every year, it bears repeating. Let everyone know what your communication system is, how to submit a report of potential compliance issues, and regularly encourage them to do so. Remember, too, that the OIG guidance notes it's not just misconduct or problems you want getting reported but you also want to enable staff to seek clarification or answers "in the event of any confusion or question with regard to a laboratory policy or procedure."

G2 COMPLIANCE PERSPECTIVES

Focus Medical Necessity Efforts on Three Core Elements

Jane Pine Wood, Esq.
McDonald Hopkins

Last month in *G2 Compliance Advisor (GCA)*, *Compliance Perspectives* highlighted the top 10 compliance issues for 2016, cited by health care counsel for clinical laboratories and pathology groups. Medical necessity was the top issue named among those surveyed. Health care attorney, Jane Pine Wood, a member at McDonald Hopkins, indicated it is the "single biggest issue" currently arising in audits. Other sources we spoke with also indicated that this is not just a Medicare issue. Private commercial payers are increasingly focused on medical necessity of testing as well. Wood, who counsels laboratories and pathology groups, indicates that while 10 to 15 percent error rates are not uncommon, she has been seeing error rates as high as 85-90 per cent, or even 100 per cent in some cases, in recent medical necessity audits. "We are talking about a sea change," she says. *GCA* spoke with Wood about why medical necessity is such a hot button issue right now for some types of testing and what all laboratories and pathology groups can do to avoid problems.

"CMS is pushing personalized medicine and preventive care and keeping patients healthy. A lot of the promise of pharmacogenetic testing was to keep patients healthy. So there's a bit of a disconnect or conflict between the public policy message and behavior CMS wants physicians to implement and then the audit and payment side of things."

—Jane Pine Wood, Esq.

Problem areas – panels, pharmacogenetics, toxicology

Medicare requires that testing be reasonable, necessary and appropriate for purposes of evaluating, diagnosing and treating a patient's medical condition. The attorneys we spoke with indicate that medical necessity issues are particularly a problem right now for laboratories performing pharmacogenetic and toxicology testing as well as new startup operations. Wood emphasized that testing involving panels was particularly at risk for medical necessity issues. Panels are common in toxicology testing and Wood explains that when panels are used to test for multiple drugs at once, Medicare and payers are pushing back, asking if all those drugs really must be tested for each time.

She also notes that there is a disconnect between government policy and payer pricing and reimbursement practices when it comes to toxicology and pharmacogenetic testing. The opioid abuse problem has received significant attention and government funding and there is a need for drug testing to address opioid abuse, but at the same time, Medicare is cutting payment rates for that testing, she explains. In the pharmacogenetic testing area, "it appears there is a real push to deny coverage," Wood adds. The local coverage determinations for pharmacogenetic testing have very narrow ICD-10 codes and high denial rates on audits. This is contrary to government policy promoting the value of this type of testing, however. "CMS is pushing personalized medicine and preventive care and keeping patients healthy. A lot of the promise of pharmacogenetic testing was to keep patients healthy. So there's a bit of a disconnect or conflict between the public policy message and behavior CMS wants physicians to implement and then the audit and payment side of things," says Wood. That policy conflict becomes a financial reality in the form of medical necessity denials.

Mistakes to avoid

So why are pharmacogenetic and toxicology labs experiencing medical necessity issues? "None of this is new," Wood says, but many in the toxicology and pharmacogenetic testing sector may be new to laboratory billing. "There are a lot of new players in the laboratory space, particularly in the pharmacogenetics arena and they may come from science side rather than the billing side," she notes. Additionally, many start-up toxicology laboratories may have been started by individuals who have sales or other experience but have not dealt with billing for laboratory tests before. Many who are new to lab billing "truly and honestly don't understand that if there is a documentation error or lack of medical necessity on the physician's medical record, the laboratory still bears the cost. It's coming as a very nasty surprise," observes Wood.

Additionally, there are aspects unique to toxicology and pharmacogenetics that make them more susceptible to medical necessity issues.

Another mistake laboratories may make is responding to medical necessity audits or queries from payers without getting the right documentation first.

Pain clinics and substance abuse clinics often use standing orders or set policies or protocols that stipulate patients get tested at a specific interval for drug usage. If a clinic doesn't review those standing orders and protocols to ensure there is some individual assessment for each patient and test order, the clinic can run into trouble demonstrating medical necessity. Simply having someone glancing over the standard test order to see if anything is problematic is not the same as a physician reviewing it, says Wood.

In many cases, it is also simply a problem of the ordering physician not documenting that he or she reviewed the results. Wood notes that in some pain management clinics, the physicians claim that given the volume of testing, it would take too much time to document that they looked at every test result. Physicians often feel it is sufficient to review the results and document when there is a health problem revealed by the results and document the discussion with the patient, she says. Wood addresses this concern with clients by comparing the lab test to an MRI, "because everyone can agree that Medicare won't pay for an MRI without a signed order, documentation in the record regarding the symptoms and why the MRI is needed, and the physician's review of results and discussion with patients." "Medicare and payers are saying we expect the same with this testing," she warns. But unfortunately, it's not appearing in the record in many cases for toxicology and pharmacogenetic testing.

Another mistake laboratories may make is responding to medical necessity audits or queries from payers without getting the right documentation first. Wood notes that "a lot of newer labs may just send in their test requisitions to support the test order" and they are not typically signed. Without a signed requisition, the laboratory needs to go back to the ordering physician to get a signed attestation to support the order. In addition, the laboratory should submit documentation from the physician's patient record to support the medical necessity of the testing ordered.

Finally, as Wood noted in our article last month, lab requisitions for panels may not always provide a means to order the tests in the panel individually. Wood flagged this as a red flag for payers who will assume bad intent from such a requisition design. *Bottom line:* Make

sure your requisitions clearly offer the option to order the panel or to separately order each of the individual tests in that panel. Remember, the OIG's 1998 compliance program guidance for laboratories advised that laboratory requisitions should "promote the conscious ordering of tests" and ensure ordering providers make an "independent medical necessity decision with regard to each test the laboratory will bill."

Another way to educate and encourage physicians to document medical necessity is to perform internal audits to determine if physicians can provide the needed documentation.

Wood also reports that Novitas in particular is denying an entire panel if there is a lack of documentation for individual tests within that panel. She contends payers shouldn't be denying payment for the entire panel when documentation is lacking for some but not all of the individual tests and reports that some labs are pushing back, arguing medical necessity for tests in a panel should be individually assessed and reimbursement granted for tests that are properly supported.

Getting physician cooperation

Medical necessity isn't a big deal for just pharmacogenetics and toxicology testing, however. It's a timeless problem for laboratories. Proof that tests have been properly ordered in accord with Medicare requirements is critical for any lab to get reimbursed and thus all labs need to ensure that the medical record documents the reasons a test is medically necessary. The problem, says Wood, is that the physicians ordering the tests "don't have any skin in the game" because the lab is on the hook for the test.

The message she's been giving in sales and marketing training is "to the extent you can, remind and encourage physicians (because all you can really do is remind and encourage) to really be careful with documentation of testing." Specifically, with regard to panels, she advises that staff tell ordering physicians to ask themselves "do I need the entire panel or not?" and if the answer is yes, to be very careful to document why all the tests in the panel are needed.

Another way to educate and encourage physicians to document medical necessity is to perform internal audits to determine if physicians can provide the needed documentation. Wood suggests focusing those audits on three core elements.

Audit three core elements of medical necessity

Wood and other experts surveyed in *GCA*'s January *Compliance Perspectives* article suggested labs perform their own audits and challenge ordering physicians to make sure they can produce the records needed to support medical necessity. Do this before Medicare or a payer comes knocking on the door to do their own audit. Use the audit as an opportunity to challenge, educate and remind physicians about the importance of documenting medical necessity.

Wood recommends that laboratories conduct medical necessity audits that focus on the three core elements essential to medically necessary testing.

Core element #1: Documented test order

First, consider the evidence that documents the patient's treating physician has ordered the test. Wood advises "the required documentation can vary by payer and type of test/service." For example, Medicare does not require a signed order or requisition form for clinical laboratory tests. A signed written order is required for anatomic tests. Documentation that

you should have could include: a signed requisition, an electronic signature through e-mail, or signed documentation in the patient's chart, says Wood. When you do not have one of those three things, she instructs laboratories to obtain a signed attestation from the ordering physician documenting the test order. Such an attestation "may suffice in an audit, but it is not nearly as good" as the signed order. "This requirement extends to special stains—there must be a signed written order by pathologists," adds Wood.

> ***"Increasingly, payers want to see documentation of review and/or use of the information by the ordering physician."***
>
> **—Jane Pine Wood, Esq.**

Core element #2: Documented need for the test

The next core element is documentation that the test is medically necessary. The patient's medical record must contain information indicating why the test is necessary. For panels, as we've said, there should be documentation in the medical record that specifically supports the medical necessity of each test in the panel. "The OIG views automatic prepackaged panels as fraud and abuse," reiterates Wood.

She also cautions that simply putting a statement on your requisition forms that declares that the physician agrees that if he orders the test, it is medically necessary is not sufficient. "It's not the recitation of the sentence that's important, it's the reason why it's medically necessary," she explains.

Core element #3: Document use of test results

Finally, the third core element is documentation of the usage of the test results. "Increasingly, payers want to see documentation of review and/or use of the information by the ordering physician," explains Wood. She notes she has seen this with Medicare particularly for pharmacogenetic testing. If the record doesn't show that the ordering physician in fact reviewed the test results, there can be medical necessity issues. Essentially, Wood explains, Medicare is saying that "if you didn't need to review the test results and act on them, we don't see why it was medically necessary."

Conclusion

Unfortunately, as laboratories know, the ordering physician's cooperation is critical for laboratories to demonstrate medical necessity and get paid for the testing they perform. But labs also need to make sure they aren't sabotaging themselves. So make sure your lab does these four things to improve medical necessity compliance:

1. Have sales and other lab staff remind ordering physicians of the importance of documenting medical necessity.
2. Make sure your requisitions facilitate proper documentation of the test order and medical necessity for every test ordered.
3. Perform your own medical necessity audits to educate your ordering physicians and test their documentation before a payer does.
4. Don't respond to audits too hastily. Don't just submit the test requisition. Make sure you have proper authentication of the test order and its necessity—or get it from the provider if you don't—before submitting a response.

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7 Service Terms to Include in Your Patient Debt Collection Agency Services Contract, *from page 1*

2. Agency's Obligation to Report Collections Information

Problem: The key data for measuring collection agency performance are the reports the agency provides. But agencies may not provide you the information you need to measure their performance.

Solution: Although methods differ, medical debt collection agency quality review should measure timeliness of collection, documentation, accuracy in resolving accounts and appropriateness of patient interactions. Make sure your services agreement requires the agency to give you clear, timely, and comprehensible:

Although methods differ, medical debt collection agency quality review should measure timeliness of collection, documentation, accuracy in resolving accounts and appropriateness of patient interactions.

- Account status reports—indicate how often you want to receive status reports and in what electronic format (or in paper);
- Confirmation of placements;
- Inventories; and
- Remittance statements.

3. Agency's Obligation to Report Patient Contacts

Problem: You must monitor how the agency is dealing with your patients. Is it honoring its promise to refrain from abusive and deceptive tactics? Is it treating patients with the necessary dignity and respect?

Solution: Make the agency promise to furnish you regular reports on its contacts with patients, including copies of patient complaints, concerns, or questions, and patient contact logs documenting the date, time, duration, and nature of each attempt to contact the patient and a brief summary of the outcome.

4. How the Agency Is Paid

Problem: Medical debt collection agencies are typically paid a commission based on the percentage of accounts they collect. There are lots of different ways to structure that commission.

Solution: The agreement should address four aspects of the agency's payment:

1. Upfront fees—consider not only direct but indirect charges like your lab's obligation to buy account transmittals;
2. Commissions should be based on the amount of money the agency successfully recovers;
3. Commissions should reflect the effort required to recover. Standard agreements provide for three phases of collection

Phase—Effort Level	Collection Fee
Phase I: Letter only	Minimal fee
Phase II: Phone calls added to letter series	> Phase I but < Phase II fee
Phase III: After 90 days, accounts transferred to receive extensive, personal follow-up, and credit reporting	Up to 50%

4. The agency should bill you monthly rather than withhold its fee from the patient payments it remits.

5. How Patient Payments Are Remitted

Problem: Remittance of money recovered is another key business term to deal with.

Solution: The remittance clause should address three things:

1. *Timing:* Monthly remittance is fairly standard practice for medical debt collection, although you can always negotiate for a shorter cycle. For your protection, the agreement should require the agency to keep collected funds in an escrow or trust account until the remittance date arrives;
2. *Information Reported:* Each payment should be reported with the name, agency account number, payment receipt date, commission rate, and apportionment between you and the agency; and
3. *Remittance Amount Recovered:* Do not agree to a provision that lets the agency deduct its fee from the remittance amount. Although they do not affect the amount you receive, deductions from remitted collections create administrative and accounting headaches for your staff. So try to get the agency to send you a monthly bill instead.

6. Client Support Services

Problem: While most agencies recognize the importance of customer service, attitude and commitment may not be enough to deliver the service you want and expect.

Solution: In addition to laying the basis for a successful partnership, specifying the kind of client support you want makes life easier for both sides. Services you might want to include as part of the core services package, without additional charge:

1. Direct access to agency supervisors or managers if you have a question or concern;
2. A dedicated phone line that your employees or patients can use if they have any questions (assuming your account is big enough);

> **Model Language**
>
> Agency agrees to have in operation within five (5) days after the execution of this Services Agreement a toll free telephone number, which shall be without cost or expense to the caller, which will be staffed during regular business hours by an employee of Agency who will answer any questions regarding the debt or other services provided by Agency under this Services Agreement. The phone number shall be published on all statements sent by Agency in its collection efforts under this Services Agreement and Agency shall make all reasonable efforts to ensure that calls received after regular business hours be returned the next business day.

3. Support for your in-house debt collection efforts and maybe even seminars and training for your staff.

7. Termination of the Agreement

Problem: You need an exit strategy in case the arrangement does not work out.

Solution: The termination clause is the escape hatch. There are two things it should include:

1. Your right to terminate immediately and at any time for cause, including but not limited to agency violations of its compliance obligations under the services agreement, the HIPAA business associates contract (which we talked about in Part I) and other applicable laws; and
2. Your right to terminate without cause upon 30 days' notice.

Agencies should have little trouble accepting these terms as long as they are mutual. If the agency does give you a hard time, it should send up a red flag. G2

News at a Glance

Few Hospitals Planning for Precision Medicine. Except for academic medical centers, few hospital executives see personalized medicine playing a significant role at their organization, according to a new nationwide survey, conducted by the analytics firm Health Catalyst. The survey revealed that more than two-thirds (67 percent) of non-academic executives see precision medicine as having no role, a small role, or an average role in their organization in the next five years. By comparison, 71 percent of academic health care executives see precision medicine as playing a "significant" role in their organization in the next five years. The majority of the 60-plus respondents to the 2015 online survey were health care executives including chief information officers, and chief medical officers, data-warehousing and analytics firm Health Catalyst says. When asked about the relevance of DNA sequencing to the individual organization's patient treatment strategies, respondents' answers again revealed a divide between academic and non-academic institutions. Nearly 100 percent of academic respondents declared DNA sequencing results to be relevant or very relevant to patient treatment strategies, compared to only 39 percent of non-academic center respondents. Not surprisingly, academic centers are more active in making plans to incorporate genomic data into electronic medical records. Nearly two-thirds of academic respondents (64 percent) said such plans were underway, compared to only 29 percent of non-academic respondents.

CDC and White House Address Zika Diagnostics. Feb. 5, the CDC reported that it and Dallas County Health and Human Services confirmed the first case of the infection in the continental US involving an individual who hadn't traveled to a country experiencing an outbreak of the virus. In that case, the infection was sexually transmitted. The CDC also issued interim guidelines indicating Zika testing can be offered to pregnant women 2-12 weeks after returning from outbreak locations, regardless of whether they have symptoms. Testing for the Zika virus is currently being performed at the CDC and four state health department laboratories and the CDC says it is working to expand laboratory diagnostic testing to additional states. Testing can be complicated by the fact that cross-reacting antibodies for other viruses such as dengue and yellow fever viruses may lead to false positive results for Zika. As to lab safety, the CDC advised in a January memo that the virus is classified as a biological safety level (BSL) 2 pathogen and "should be handled in accordance with Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines and a risk assessment performed for each laboratory for the specific procedures utilized."

Funding Supports ACMG Medical Geneticist Training. Shire committed $1.65 million to support the ACMG Foundation for Genetic and Genomic Medicine training programs for medical geneticists during the next three years. "The partnership between Shire and the ACMG Foundation will help foster a generation of geneticists around the world who will play crucial roles in the diagnosis and care of patients with rare and common diseases." The funds will be used for 10 one- to two-year training fellowships for medical geneticists. "We have reached a critical juncture in terms of the integration of medical genetics into health care," said ACMG Foundation Executive Director, Michael S. Watson, PhD, FACMG. "Though geneticists are essential to the diagnosis and management of rare diseases and for the care of individuals with genetic conditions, we are faced with a significant deficit in the number of laboratory and clinical geneticists in the United States." G2

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