

HOW TO PREPARE YOUR ORGANIZATION FOR GOVERNMENT PROGRAM COMPLIANCE

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CHRIS COBOURN,
MANAGING DIRECTOR

As Medicaid and Medicare spending at the federal and state level continues to grow, scrutiny surrounding an organization’s program integrity will likely increase.

In the following Q&A, Chris Cobourn, Huron managing director, and John Moose, Huron director, provide practical information about preparing an organization for Government Program (GP) compliance from the top, down.

Q: AT A HIGH LEVEL, WHAT ARE THE TOP ISSUES ORGANIZATIONS FACE REGARDING GP COMPLIANCE?

A : **Chris:** There is a lot of scrutiny on what organizations currently do, yet not a lot of clarification. This is particularly true regarding determination of treatment of fees, bona fide service fees, and fair market value.

John: Many companies underestimate the amount of effort required in order to implement an appropriate and proper system to support bona fide service fees. This path needs to be integrated within the practices and negotiations.

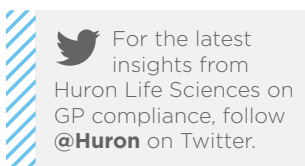
Q: WHAT GUIDANCE DO YOU GENERALLY PROVIDE ORGANIZATIONS CONCERNED ABOUT GP COMPLIANCE?

A : **Chris:** The government is not looking at these things in terms of materiality—the government is looking to see that organizations are compliant. So each company needs to be able to understand these programs, apply it to their product-distribution model, contracting strategies, and determine its risk profile.

Q: HOW WILL THIS GUIDANCE IMPACT THE C-SUITE, AND WHY SHOULD THEY CARE?

A : **Chris:** When you take a look at an organization’s impact—whether it’s current guidance or future guidance—organizations are asking: What’s it going to take to implement, and what are the financial impacts?

From a leadership perspective, the biggest risk is not being informed. The C-Suite doesn’t have to be GP experts, but they need to know, for instance, if Medicaid is extended to Puerto Rico and the territories, and what that would mean for the company.



Q: WHAT ARE SOME PRACTICAL WAYS ORGANIZATIONS CAN INTEGRATE GP COMPLIANCE INTO THEIR CORPORATE AND LEGAL FUNCTIONS?

A : Chris: First, it's important to have appropriate oversight outside of the GP function, making sure you are showing calculations that are correct and that you have the ability to mitigate any issues.

Make sure your documentation, policies, and procedures are in motion. Conduct a monitoring audit and ensure you have the expertise to do so.

Q: WHAT ARE THE TOP CONCERNS YOU FIND ORGANIZATIONS MOST OFTEN EXPRESS REGARDING GP COMPLIANCE?

A : Chris: It varies by the size and type of organization. The government market is bigger than it used to be, so whether you're a small biotech or large one, there will be issues in that area presenting problems within your key market.

You also have to consider the government customer, who are Americans that benefit from a publicly funded program—Medicaid, Medicare Part B, etc.

Even if Medicaid is a small part of your customer base, it's still not worth risking non-compliance in that area. And if it is a big part of your customer base, then you need to make sure you're upholding compliant practices.

John: From a bona fide service fee perspective, some top concerns are not just in the government pricing space; they are focused on achieving compliance across a number of different entities.

WHITEPAPER: TIME TO VALIDATE YOUR COMPANY'S OPEN PAYMENT SUBMISSION DATA

Federal regulators are stepping up scrutiny in the relationships between healthcare providers and pharmaceutical and medical device industries. The following Huron white paper details the importance of proactively planning for upcoming changes.

Download and read the white paper here:
<http://www.huronconsultinggroup.com/openpayments>

These entities can reach into contracting and market access, as well as managed markets to get them to conform to what is ultimately going to be reported for government pricing.

If you're considering a GP compliance program, Huron can help. You can learn more about our services, and contact us, by visiting:
www.huronconsultinggroup.com/lifesciences

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