Huron Life Sciences

Government Programs for the Compliance Office
A Focus on Pricing – Considerations as Scrutiny Heats up

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Agenda

Abstract

Overview and Recent GP Settlements, how it informs us, and where the Government Focus will Be

The CMS AMP Final Rule

A Focus on BFSF/FMV, and other Critical Areas

Benchmarks of GP Compliance and the Elements of a Compliance Program

Evaluating your GP Compliance

Abstract

- In the 2003 OIG guidance, "Compliance Program Guidance for Pharmaceutical Manufacturers," Medicaid Program Integrity was identified as one of the key risk areas.
- Since then, as Medicaid and Medicare spending at the federal and state level has continued to grow, scrutiny on program integrity has only increased.
- While Government Program Compliance for pharmaceutical manufacturers is for critical, there is also a lack of clear authoritative guidance, and manufacturers are required to make reasonable assumptions to apply available guidance to their business.
  The recent CMS AMP Final Rule reinforces the important reliance in reasonable assumptions.
- CMS guidance also requires CEO or CFO level certification of the accuracy of the reported statutory pricing calculations.
- As such, it is important for manufacturers to have a strong GP compliance program and infrastructure, and in the event of an audit be able to demonstrate compliance and accuracy in its reported statutory pricing calculations.
- It is critical therefore to integrate GP compliance in to the Corporate Compliance and Legal functions. Manufacturers should be able demonstrate that decisions within highly scrutinized areas, such as bona fide service fees and fair market value, are independent and objective, and that they are Compliance driven functions, and have appropriate documentation in place on reasonable assumptions and approaches.

Key Questions

- What should the Compliance and Legal offices be thinking about with Government Program compliance?
- What does the AMP Rule mean for an organization?
- Why is the government focusing on ASP and FMV?
- Where is the focus on drug pricing and transparency going?
- How should we think about GP within our compliance program?
- What is the best way to get educated on the complexities of GP?

Overview and Recent GP Settlements, How it Informs Us and Where the Government Focus Will Be

Recent GP Settlement

GP Enforcement – Accurate Information and Timeliness

In March 2015, the OIG announced the newest of the settlements related to GP and the Medicare Part B Program.

- Allegedly misrepresented the ASP data to CMS
- Company to certify that the company has established a GP compliance program

How does this inform us on the Government's evolving view of a GP Compliance Program?

The settlement includes

> "a certification by the company that it has established a government pricing compliance program.."

GP Compliance Program

Recent Settlement

The Settlement provides a view of the OIG's perspectives of a robust GP Compliance Program, and where we have seen the Compliance Program structures evolve to with independent oversight. Required Certifications in the Settlement:

A Government Pricing Compliance Director

A Government Pricing Compliance Committee

Dedicated departmental liaisons knowledgeable in Government Pricing Policies for each relevant business function

A Code of Conduct and US Supplement (related to federal health care programs)

Government Pricing Policies

An annual GP training program

A GP audit program

A GP Disclosure program

HHS OIG Workplan, FY 2016

Where is the OIG focusing, and what may it mean for you?

- Comparison of average sales prices to average manufacturer prices
- Part B payments for drugs purchased under the 340B Program
- Increase in prices for brand-name drugs under Part D
- States' collection of rebates on physician-administered drugs
- States' collection of rebates for drugs dispensed to Medicaid MCO enrollees
- Manufacturer rebates–Federal share of rebates
- Analysis of generic price increases compared to price index
- Manufacturer compliance with AMP reporting requirements
- Treatment of authorized generic drugs
- Specialty drug pricing and reimbursement in Medicaid
- HRSA—duplicate discounts for 340B-purchased drugs

http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf

Evaluating GP Compliance

- In today's sub regulatory environment, there is not always a "right or wrong."
- GP Compliance:
  - Can you show that you have evaluated available guidance, applied the guidance to your business, developed methodologies, and made reasonable assumptions?
  - Do you have written polices and procedures that guide your day-to-day procedures?
  - Can you demonstrate that the data you use in your calculations is complete and accurate?
  - Have you performed assessments/audits to demonstrate that your people, processes, and systems are adhering to your written documentation, are auditable, and repeatable?
- Be able to demonstrate good faith effort, that you have done your best to evaluate the guidance, made appropriate reasonable assumptions, and made determinations on methodology and policy in an independent and objective manner.

Compliance Driven Functions

- Make activities like BFSF reviews "Compliance Functions," with involvement and oversight by Compliance and Legal
  - Have policies in place for the process and decision making
  - Be able to demonstrate an independent and objective review
  - Have documentation of the approach, methodology and findings
  - Gain visibility in the compliance committee where appropriate

The CMS AMP Final Rule

The CMS AMP Final Rule

- After a six year wait, CMS finally published the Covered Outpatient Drug Final Rule for the Medicaid Drug Rebate Program. The Final Rule provides important regulatory interpretations touching almost every aspect of the Medicaid Drug Rebate Program ("MDRP") under the Affordable Care Act legislation of 2010.
- The Rule will have a significant impact on manufacturers, including the business, contracting strategies, compliance, and operations, and should be evaluated broadly across the organization to evaluate what it will mean, what the risks are, and how to implement it.
- The Compliance Office should have a core role in the evaluation of the Final Rule, as Government Program (GP) Compliance is a high risk area, and relies on a significant level of reasonable assumptions around key areas where the organization has to determine policies and approaches, especially in areas that can significantly impact Statutory Price reporting, which establishes pricing across Medicaid, Medicare and the PHS Programs.
- Organizations should be able to demonstrate that decisions and approaches in these areas, and the evaluation of risks, are consistent with compliance obligations in this highly regulated industry.

https://www.federalregister.gov/articles/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs

Note: Final Rule provisions are fairly close to those of the Proposed Rule with a few exceptions

Final Rule - Key Elements

Inclusion of US Territories in the MDRP

Standard AMP: Presumed Inclusion Maintained

COT - Definition of Retail Community Pharmacy (RCP)

Smoothing of AMP Pricing Components

Authorized Generic (AG) Drugs in AMP

5i AMP: Clarification of Not Generally Dispensed

Baseline AMP Restatement

Line extension product identification and rebate calculation

Bona Fide Service Fees (BFSFs)

Drug Classification Issues

Reimbursement Considerations

The CMS AMP Final Rule

(Effective April 1, 2016)

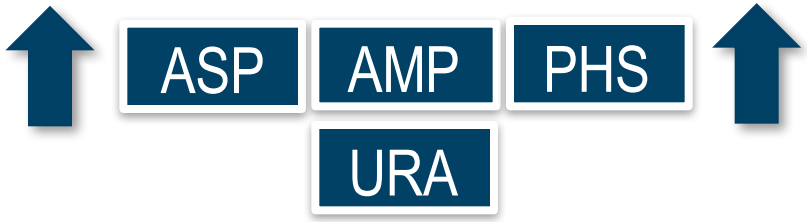
The Final Rule Addresses multiple areas that will impact pharmaceutical manufacturers, their rights and obligations in the MDRP, and how their products will be reimbursed in the Medicaid market.

1. Provides a regulatory definition of Average Manufacturer Price, or "AMP" (used historically for the determination of Medicaid rebate amounts, but now to be used for FUL), and other rebate program standards
   - Significant impacts across legal, policy, contracting, methodology, systems, finance and operations
   - Also used to calculate the Public Health Service, or "340B" Price
2. Changes how drugs will be reimbursed in the market
   - Each state must establish a mechanism to develop Actual Acquisition Cost (AAC) for how they will reimburse pharmacies for Medicaid utilization.
     - Where will there be standards, where will there be volatility?
     - What will be the changes for our your drugs are purchased and reimbursed?
   - The Federal Upper Limit (FUL) for multi-source drugs will be established based on Manufacturer submitted AMPs.
     - AMPs across multiple products will be weighted and aggregated for a published quarterly FUL
     - How will this shift purchasing and reimbursement trends for your products?

The Final Rule Consistently References "Reasonable Assumptions"

Can you defend you calculation methodologies and assumptions?

- Manufacturers must evaluate statutory and regulatory language that is not prescriptive and from it determine policy, approach and methodology.
  - The rationale must be evaluated independently of the financial impact, reviewed by legal counsel where appropriate, and well documented.
- The meat of the Rule is in the Preamble.
  - Have to evaluate what level of "guidance" a CMS response constitutes, and how to draw conclusions from narrative language not articulated in the provisions of the actual regulations
- Manufactures cannot universally revert to what may be perceived as "Conservative," Conservative in one program may be viewed as Aggressive in another
  - Example – Treatment of an agreement as an excludable BFSF would drive all price points higher, which could be "conservative" for AMP with a potential higher URA, but also a higher ASP and higher PHS price, which could be perceived as "aggressive"



Service Fees and FMV

The Final Rule reinforces the importance of BFSF and FMV. Have you conducted an appropriate Bona Fide Service Fee evaluation, do you have sufficient documentation of your rationale?

The Final Rule reiterates several key points:

- Manufacturers are affirmatively obliged to subject all fees paid to AMP and BP eligible entities to the BFSF test and to document their conclusions at the time the agreement pay the fee is made.
- CMS will not define FMV, that burden is on the manufacturer
- CMS will require each manufacturer to make FMV determinations, and to document the rationale used
  - Any changes to test?
  - Are there any safe Harbors?
  - How should we interpret adequate documentation ?
  - FMV any change to methodology
- Fees cannot be excluded categorically, i.e. GPO Admin Fees
- Pass Through Assumption
  - Manufacturers may assume that there is not a pass through if they do not have notice or evidence of a pass through.

Bundling – Still the Hardest Part of GP to Implement

Does your organization evaluate agreements for potential bundling (contingent) arrangements, are you aware of the potential impact of bundling on statutory pricing, and do you have the appropriate touch points between contracting and the GP function?

- The Final Rule provides some clarification on potential bundling arrangements, to where there are price concessions contingent on purchase or performance requirements. The area remains very complex without clear guidance
  - It is often unclear as to whether a bundled sale exists.
  - The business does not always have the GP expertise to identify potential bundles and may establish agreements that have bundles without awareness of the impact.
  - Most government price calculation systems cannot "unbundle" certain bundled arrangements.

Expansion to the Territories

Extending Medicaid to the Territories opens a wide array of challenges across the organization, including contracting relationships, pricing, Medicaid Best Price impact, data integrity, as well as the financial impact of extending the Medicaid Rebate. Has your organization evaluated the risks, and the ability to implement this change?

The Final Rule extends Medicaid to five Territories: Puerto Rico, US Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

- Although this does not take effect until 2017, manufacturers have to start collecting data in May for smoothing
- Territory data will need to be included in the calculations
- Contracting strategies and sales to the Territories may be very different from those in the US.
- Contracting and Service Fees probably have not been evaluated for BFSF/FMV treatment
- Manufacturers must invest time and attention now to be prepared for Territorial expansion:

Authorized Generics

Authorized Generic relationships can have a significant impact on the Medicaid AMP calculations for the Primary Manufacturer, as well as an indirect PHS pricing impact. The burden will be on manufacturers to make reasonable assumptions on the relationship, and to determine an approach to data and treatment

- Branded manufactures have to determine if their secondary manufacturers are "engaged in the wholesale distribution of drugs to RCPs."
- Will have to evaluate the data points available, and what assumptions to make
- Can dramatically impact AMP and may undermine the profitability of the entire AG arrangement

Class of Trade and Specialty Pharmacy

The Final Rule states that Specialty Pharmacy is not by definition a Retail Community Pharmacy (RCP) Entity, but is considered RCP a if they meet the definition of a RCP. The treatment one way or another can dramatically impact the calculations. This places the burden on the manufacturer to determine an approach and make reasonable assumptions on whether their Specialty Pharmacy Customers are RCP.

- Whether a specialty pharmacy is an RCP is critical to (a) calculating standard AMP and (b) determining if infused, implanted, inhaled, instilled, or injected products use an alternative 5iAMP methodology
- Entities (including SPs) are RCPs if they:
  - Do not distribute primarily through the mail AND
  - Are independent, chain, supermarket, or mass merchandizer pharmacies AND
  - Are licensed AND
  - Dispense to the general public at retail prices
- Requires a policy and reasonable assumption, each manufacturer may vary in how/how they sell

BaseAMP Restatement

Manufacturers have an established "BaseAMP" for the first full quarter of sales of a branded drug. The Base AMP component can result in a "penalty" which raises the Medicaid rebate payment, and can dramatically reduce the PHS/340B Price (the penalty is based upon price increases compared to the rate of inflation). The problem is that new methodologies under the Final Rule can be a different methodology than the original Base AMP period. The Final Rule provides an option, on a product by product basis to restate the Base AMP. How do you evaluate whether you can or should explore this option?

- Manufactures are given the opportunity to restate BaseAMP, the critically important metric in determining the inflation penalty portion of the Medicaid URA.
- We may restate until May 30, 2017.
- Actual and verifiable data must underlie all BaseAMP restates. Is that actual data available for old or acquired products?
- How does the organization make the determination, on a product by product basis, can you, should you, look to BaseAMP Restatement

Patient Assistance Programs and Coupons

PAPs and Coupons cannot be categorically excluded from the pricing calculation by what they are called. Has your organization evaluated the programs to see if they appropriately meet the criteria for an excludable program under CMS guidance?

- The Final Rule provided clarification around language as to what constitutes an excludable Coupon or PAP under Medicaid
- The Final Rule brings consistency to the treatment of patient assistance across programs and price types.
  - Generally, excludable patient assistance (a) benefits the patient directly and (b) intermediates receive no part of the payment other than a *bona fide* service or administration fee.
- Outside of the GP function, important to evaluate/audit the programs and ensure GP is given appropriate direction
- This looks to be an area of increased focus of the OIG

Bona Fide Service Fees and Other Key Risk Areas

Key Treatment of Bona Fide Service Fees

1. "The fee paid must be for a *bona fide*, itemized service that is actually performed on behalf of the manufacturer."
2. "Manufacturer would contract for the service in the absence of the arrangement."
3. "The fee is not passed on in whole or in part to a client or customer of the service provider."
4. "The fee represents FMV for the services rendered."

Increasing Regulatory Scrutiny

- The Addendum to the Corporate Integrity Agreement for Novartis Pharmaceuticals Corporation (issued November 19) notes that to ensure compliance with the Anti-Kickback Statute, pharmaceutical companies should establish and implement:

> "A written review and approval process for all arrangements…that includes at least the following…a process for specifying the business need or business rationale for each service provided under the FFS arrangement and determining and documenting the fair market value of the remuneration specified in the FFS arrangement;"

Recommended Documentation

Contracts

Policies and procedures

FMV range and methodology

Expected volume assumptions (if not addressed by valuation advisor)

A “business plan” for the services to document need and that the expected value arising from the service is greater than FMV

Document receipt of service and other factors supporting transaction legitimacy

Streck Case, July 2012

A way of looking at “GP Compliance”

The lack of regulatory guidance meant that manufacturers had to make good faith interpretations of AMP historically, which makes it difficult to suggest that a manufacturer knowingly falsified AMP if they made good faith attempts to correctly understand AMP.

Key Questions

- Are you making a good faith effort?
- Are you demonstrating effective due diligence?
- Have you documented your reasonable assumptions?
- Is Compliance and Legal appropriately involved, especially in more qualitative and subjective areas?

An Increased Focus on ASP

- A published pricing metric
- Higher ASP can be perceived to be favorable to the manufacturer
  - Creates a focus on BFSF Treatment
- Hard for manufacturer to evaluate ASP related reimbursement
- Complicated to mitigate historical ASP calculation issues
- Limited awareness by the OIG of the difference between ASP and AMP

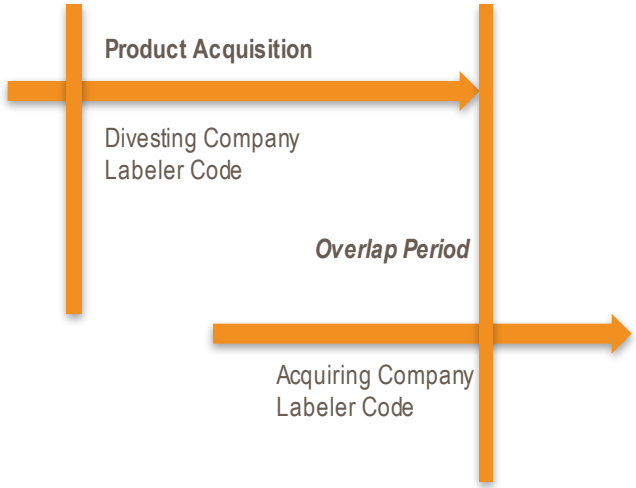
Will published AMP-based FULs have similar scrutiny?

The New Generic Drug Inflation Penalty

- There has been very public scrutiny on drug pricing, including congressional scrutiny on Generic Drugs
  - "The prices of more than 1,200 generic medications increased an average of 448 percent between July 2013 and July 2014"
    - Bernie Sanders, Congressional Hearing, November 2015
  - New CMS Guidance establishes that beginning in January 2017, Generic Manufactures will be subject to an inflation penalty, similar to the inflation penalty that has been in place for branded drugs

M&A Activity

- Acquisition/Divesture always have significant GP impact
- The GP Function is usually not involved pre-deal, and have to assess impact post deal
- There is often minimal pre-deal analysis of risks
- Post deal risk mitigation can require significant mitigation
- An acquiring company inherits compliance history, including potential FCA exposure
- GP Compliance aspects and operational responsibilities between companies are often not incorporated in to the agreements, i.e. overlapping Labeler Codes and Medicaid



Increasing Focus on Pricing Transparency

- Pubic perception, questioning of drug pricing
- Oregon, California and Mass. North Carolina, Pennsylvania Initiatives, focusing on the pricing of pharmaceutical products
  - Massachusetts S. 1048
    - Maximum Allowable Price
    - A health policy commission will "review and consider all data reported to the commission and the center and determine whether the price of the prescription drug is significantly high given: (i) the prescription drug's medical benefits, (ii) the cost to develop and manufacture the prescription drug, and (iii) the prices charged by the manufacturer in other countries."

      "If the commission determines that a prescription drug is significantly high, then the commission may set the maximum allowable price that the manufacturer can charge for that prescription drug that is sold for use in the commonwealth…"
- Could require significant data reporting requirements

What Does This All Mean For Compliance?

Make activities like BFSF reviews "Compliance Functions," with involvement by Compliance and Legal

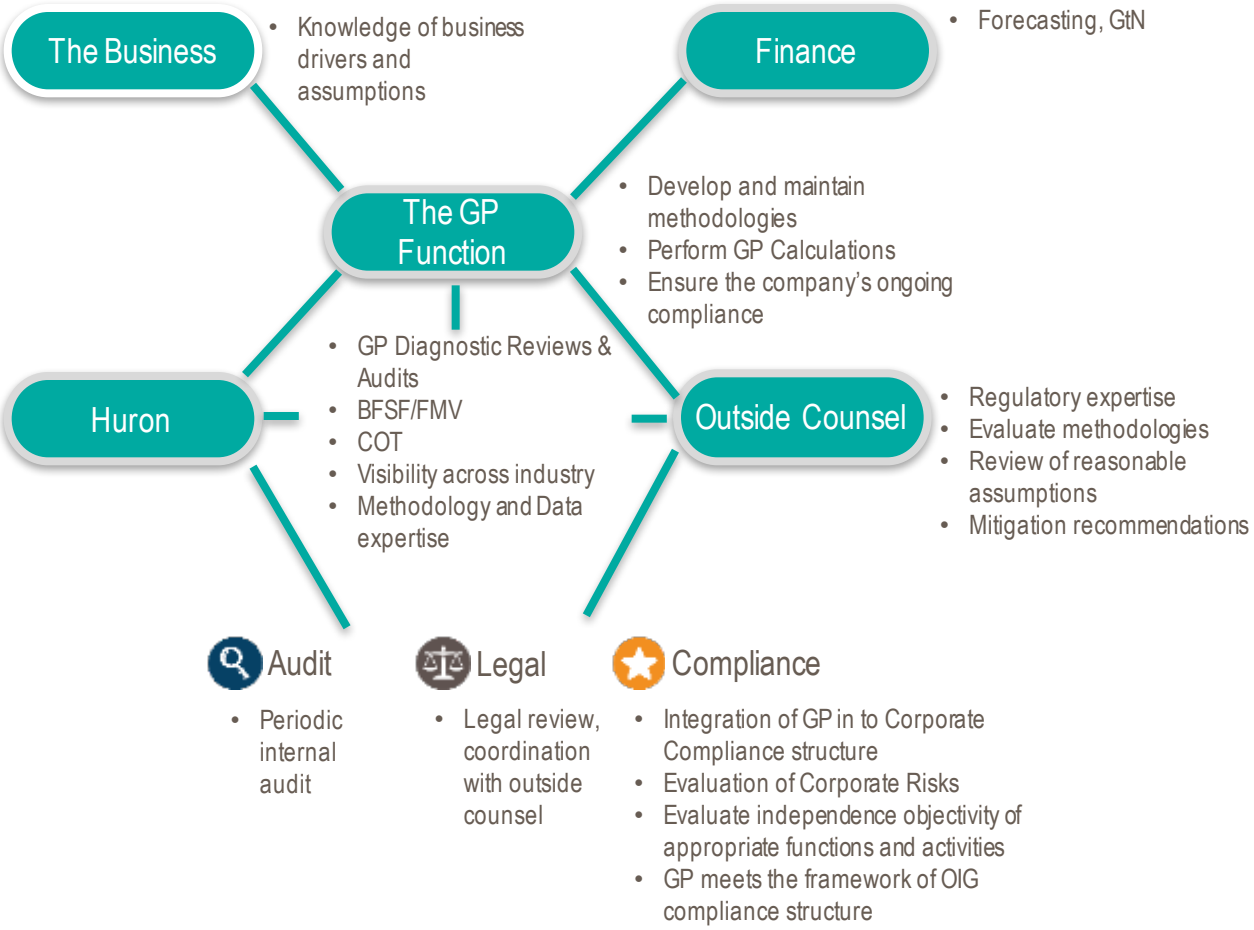
Have policies in place for the process and decision making

Be able to demonstrate an independent and objective review

Have documentation of the approach, methodology and findings

Gain visibility in the compliance committee where appropriate

Roles Across the Stakeholders



GP Benchmarks of Compliance & The Elements of a Compliance Program

GP Compliance:

In today's sub regulatory environment, there is not always a "right or wrong."

- GP Compliance – Are you audit ready?
  - Can you show that you have evaluated available guidance, applied the guidance to your business, developed methodologies, and made reasonable assumptions?
  - Do you have written polices and procedures that guide your day-to-day procedures?
  - Can you demonstrate that the data you use in your calculations is complete and accurate?
  - Have you performed assessments/audits to demonstrate that your people, processes, and systems are adhering to your written documentation, are auditable, and repeatable?

OIG Seven Elements of an Effective Compliance Program

- We looked at GP compliance within the context of the seven main elements outlined by HHS OIG. These have been widely considered and recognized as fundamental to an effective compliance program.
- Key GP compliance benchmark considerations for each elements have been identified.

[1] OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Department of Health and Human Services, Office of Inspector General. *Federal Register* / Vol. 68, No. 86. May 5, 2003.

Implementing written policies and procedures

Written policies and procedures which outline the regulatory guidance, the company's interpretation, and process instruction. This includes:

- Demonstrate GP compliance with relevant laws, regulations, and contract terms and conditions for all of the government programs; MDRP, Medicare Part B, PHS, and FSS
- Describe current business practices on how each of the GP calculations are performed as well as other key underlying processes that support them
- Maintain other documentation, including assumption memos outlining the company's positions on issues not clearly described in regulations for each of the government programs

Designating a compliance officer and committee

A compliance officer and compliance committee provide oversight needed to help ensure compliance across the company.

- Having a compliance officer, function, and committee that ensures that the GP function has established relevant policies and procedures

Developing effective lines of communication

Proper education and training of employees and officers to ensure expectations are understood and proper GP procedures are being executed. This includes:

- Having a GP training curriculum in place (consider annual training updates, and appropriate training and education to various functions)
- Ensuring resources have skill sets that include a strong knowledge base of GP
- Adequate staff training on relevant GP documentation including policies and procedures
- Regular assessment of staffing size to ensure it is sufficient to meet the current demands of GP

Conducting effective training and education

Establishing and maintaining a culture that encourages ethical conduct and commitment to compliance with the law. This includes:

- Pricing committee to discuss new contracts, pricing, price reporting impacts to URA, etc.
- Open and transparent communication across functions around items that may affect or impact GP function

Conducting internal monitoring and auditing

Monitoring and auditing around the implementation as well as an on-going evaluation of current processes. This includes:

- A parallel independent price calculation of historical reported values to assess if the documented policy matches what was submitted to the various government agencies

Enforcing standards through well-publicized disciplinary guidelines

Sets forth clear, disciplinary consequences of violating the law and what actions need to be taken. This includes:

- A compliance program training and/or employee handbook that mentions importance of GP

Responding promptly to detected problems, undertaking corrective action

Failure to comply with applicable federal or state law can threaten the company's participation in these government programs. This includes:

- A process to assess any suspected non-compliance within the GP function

Evaluating your GP Compliance Program

Understand Current Processes and Procedures	Assess Current Methodology and Operations	Perform an Independent Price Calculation	Prepare Findings Report
• Identify key stakeholders within GP function and/or an outside vendor • Request, collect, and review relevant GP policies and procedures for all price types • Collect and review all other documents (e.g. CoT Schema, Transaction Type, etc.) • Conduct workshops/ interviews with key personnel to ensure accurate interpretation of documents	• Assess overall GP processes including the data collection and validation, calculations, review, and submission • Review GP calculations methodology used by GP function and/or the outsource vendor • Validate and confirm methodologies to perform independent GP calculations	• Collect and review sales data for direct sales, chargebacks, rebates, and other transactions • Perform sample testing of customer master data • Perform an independent calculation for a sample of NDCs and one quarter • Review results against historical calculations • Identify key drivers of any variances	• Develop a summary level report documenting observations, findings, and gaps of the current state of GP function • Document specific findings related to the independent price calculations • Develop recommendations or roadmaps to address any gaps, if applicable • Coordinate with counsel on direction and legal review • Evaluate both prospective and retroactive impacts • Map out the complexities of mitigation across programs

Effective GP Compliance Program

Core Components to Evaluate Your GP Function

Diagnostic Assessment vs. Audit

Diagnostic Assessment

- Often the initial evaluation
- Provides opportunity for corrective action and mitigation to be “Audit Ready”

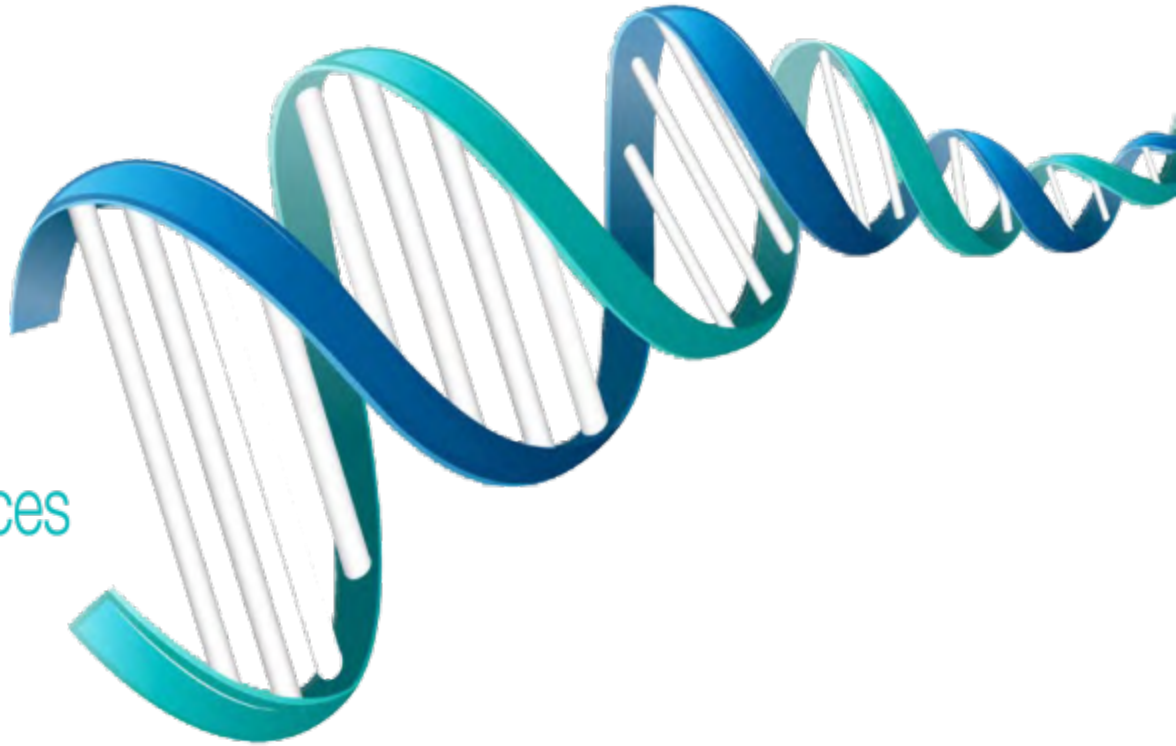
Audit

- Follows more formal audit protocols
- Tends to be deeper dive

How Can Huron Help?

- *Bona fide* service fee and FMV
- Diagnostic Assessments and Audit
- Support with the CMS Final Rule
- M& A Support
  Company acquisition and assumption of historical risks
- Harmonization of methodologies
- Bundled arrangements
- Data and Methodology errors, prospective and historical impacts
- PHS Diagnostics & Risks, such as Duplicate Discounts and Orphan Drug provisions
- ASP reimbursement
- Product Launch and Base AMP analysis
- Complexities of replacement programs, free goods
- Potential impact of AMP-based FULs

Questions



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Thank You

Please contact us if you have any additional questions or would like to reach out to us regarding this presentation.

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