

# September 2024 OIG Work Plan Updates



**CJ Wolf** MD, CHC, CPC, CCEP, CIA

September 2024 only saw three new items added to the OIG's Work Plan. Let's take a closer look at what they have added.



## SAFETY RISKS OF DRUGS AND THE FDA

The Food and Drug Administration (FDA) plays a crucial role in ensuring drug safety. After drugs are released to the market, the agency analyzes reports of adverse drug events and other relevant data to identify what it refers to as "potential signals of serious risk," known as safety signals. These signals indicate there may be a public health risk associated with a drug's use. The FDA carefully assesses each safety signal to evaluate the level of risk and may take regulatory or compliance actions if necessary, such as requesting updates to the drug's safety label or issuing public safety alerts.

This OIG Work Plan item will focus on the FDA's post-market assessments of safety signals, examining both the timeliness of responses and the actions taken to safeguard public health. OIG plans to analyze case files and summary data pertaining to safety signal evaluations over the past decade and conduct interviews with FDA leadership and staff regarding their decision-making processes.

CMS regulations require hospitals to make their prices readily available for consumers. Many hospitals have been fined for allegedly violating this rule. In fact, one hospital in Florida was fined nearly \$1 million dollars.



## MEDICAID AND REMITTANCE REQUIREMENTS

The Centers for Medicare & Medicaid Services (CMS) implemented medical loss ratios (MLRs) in Medicaid managed care to ensure that managed care plans allocate the majority of their revenue to services that benefit the health of their enrollees, thus restricting the amount spent on administrative costs and retain as profit. During the capitation rate setting process, federal regulations mandate that states establish capitation rates for their plans that allow them to reasonably achieve MLRs of at least 85 percent. Additionally, states have the option to require their managed care plans to make payments if they do not meet the minimum MLR established by the state.

The OIG will review states and managed care plans with contract provisions that require remittances from managed care plans if a minimum MLR is not met. They will determine whether the remittances the MCOs reported to states were correctly calculated and whether the Federal share of remittances that states received was returned to the Federal Government.





## HOSPITAL PRICE TRANSPARENCY

CMS regulations require hospitals to make their prices readily available for consumers. This is called the Hospital Price Transparency (HPT) rule. Many hospitals have been fined for allegedly violating this rule. In fact, one hospital in Florida was fined nearly \$1 million dollars.

CMS believes that the HPT rule will lead to increased market competition and drive down the cost of health care services. One of the requirements of the rule is for hospitals to make public all negotiated charges with third-party payers.

The OIG plans to examine and conduct an analysis to compare the pricing information published by the hospitals to the amounts that Medicare paid. Specifically, they will evaluate how much Medicare pays in comparison to the third-party payer negotiated charges and the minimum negotiated charges.

## CONCLUSION

The wise compliance professional will consider these newly announced areas of scrutiny and determine if their organization should proactively review the same issues.



CJ Wolf

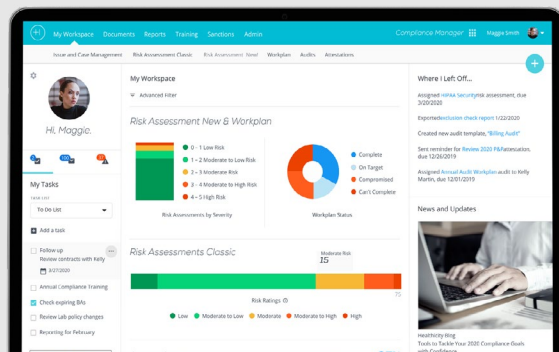
MD, CHC, CPC, CCEP, CIA

CJ Wolf is a healthcare professional with more than 25 years of experience in hospital and physician revenue cycle, practice management, compliance, coding, billing, and client services. He has provided healthcare consulting and solution services to hospitals and physician organizations throughout the country.



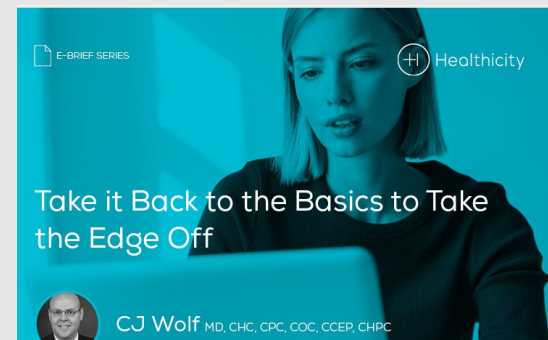
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