# Turning Employees into Compliance Assets:

## *Managing and Preventing Claims Based on Failed OBRA '90 and USP <800> Compliance*

**KEYWORDS:**
OBRA '90
Counseling
DUR
UPS <800>
Compounding pharmacies
Hazardous drugs
Compliance programs
Employee reports
Exposure and liability due to non-compliance
Internal reporting
Whistleblower
False claims
Audits and recoupments
Investigations
Remediation
Whistleblower retaliation
Employee protection laws
False Claims Act retaliation
Qui tam
Risk management
Compliance training

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A strong compliance program requires attention, engagement, and active monitoring of pharmacists and pharmacy professionals. Done well, compliance is routine, consistent, even mundane. Yet these very characteristics can create a culture of complacency that pharmacies must actively guard against. This potential risk is only compounded by the wide range of regulatory and contractual rules that bind the practice of pharmacy. Compliance involves tracking everything from state and federal laws—each state's pharmacy act, the Federal Controlled Substances Act, Stark and anti-kickback statute requirements, to name a few—to USP and accreditation standards, and even to government and commercial payor requirements and restrictions. The sheer scope and complexity of regulatory demands can be overwhelming.

While pharmacies are watchful for liability warning signs like false claims, kickbacks, and controlled substance risks, inadequate attention to other regulatory requirements can also result in substantial liability to the pharmacy. This article examines two compliance areas that present unique challenges in compounding: USP <800> and OBRA '90. It addresses the potential liabilities and risks of noncompliance associated with each; how pharmacies can effectively leverage employees as compliance assets; and what to do if an employee blows the whistle about alleged violations of USP <800> or OBRA '90.

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# I. A Quick Refresher: What Do USP <800> and OBRA '90 Require?

This section provides an abbreviated summary of the general framework of USP <800> and OBRA '90. Although not a thorough review of these complex regulatory regimes, it sets forth important context for pharmacies and their compliance departments to more effectively identify and evaluate potential risks.

## OBRA '90

The Omnibus Budget Reconciliation Act of 1990 ("OBRA '90") imposes duties on pharmacies filling prescriptions for Medicaid patients.[1] In particular, for each eligible Medicaid patient, OBRA '90 requires the dispensing pharmacist:

1.) To make a reasonable effort to obtain, record, and maintain a patient medication record ("PMR");

2.) To examine the PMR and to conduct a prospective drug use review ("ProDUR") when filling a prescription; and

3.) To counsel the patient regarding the drug being dispensed.

While OBRA '90's is a federal statute, its application to Medicaid claims as well as its adoption—or the adoption of analogous requirements—by state pharmacy acts effectively imposes these requirements on all pharmacies for all prescriptions dispensed. In addition to expanding the scope of claims this applies to, some of these analogous regulations expand on the requirements outlined in OBRA '90. For example, federal regulations require Medicare Part D sponsors to include as part of their quality assurance measures *concurrent drug utilization systems*, that must include the same types of considerations as a ProDUR, but are performed "before **each** prescription is dispensed."[2] Consequently, the maintenance of PMRs, the performance of drug utilization reviews ("DURs")—including prospective, retrospective, and concurrent utilization reviews—and the counseling of patients has effectively become a practice standard for pharmacists.

## USP CHAPTER <800>

USP Chapter <800> ("USP <800>") is developed and promulgated by the United States Pharmacopeia ("USP"), a "private, non-profit scientific organization that develops standards and science-based solutions" for the pharmaceutical industry.[3] While the USP is a private organization, the standards it promulgates related to compounding and the handling of hazardous drugs (HDs) set the industry standard. Both the federal government and most states have effectively adopted a version of USP Chapters <795>, <797>, and <800>.

Developed "with the goal of protecting the health and safety of healthcare workers and patients who may be exposed" to hazardous drugs ("HDs"), USP <800> specifically applies to the "handling of hazardous drugs (HDs) where there is a risk of exposure to patients, healthcare workers, and the environment."[4] To mitigate the risks inherent in handling HDs, USP <800> requirements target the parts of the process with the highest risk: handling, compounding, and dispensing HDs.

## II. Why This Matters (and Not Just Administratively): Three Parallel Risk Channels Compounding Pharmacies Must Manage

In part because they are part of the regular practice of pharmacy, the risks of noncompliance with OBRA'90 and USP <800> are seldom a point of sustained focus. However, the very nature of compounding heightens the dangers of a lax compliance process. The regular and mundane nature of a standard compliance process risks reduction to a checkbox operation. But especially for compounding pharmacies, negligent compliance can lead to significant harms and associated liabilities. Consider the specifics of these two sets of standards:

OBRA '90's requirements include, but are not limited to the following criteria:

*The regular and mundane nature of a standard compliance process risks reduction to a checkbox operation. But especially for compounding pharmacies, negligent compliance can lead to significant harms and associated liabilities.*

## OBRA '90 REQUIREMENT: CRITERIA

### PMR

The PMR contains the patient's drug profile, pharmacist comments, chronic conditions, allergies, and drug reactions.

### ProDUR

The pharmacy's ProDUR includes the following considerations: over/under utilization; therapeutic duplication; drug-disease, drug-drug, and drug-pregnancy interactions; incorrect dosage or duration of treatment; drug-allergy interactions; clinical abuse-misuse; ingredient duplication; and drug-age contraindications.

### Counseling

The pharmacist counsels the patient in the following areas, when applicable: intended use and expected action; route, dosage form, dosage and administration schedule; special directions for preparation, proper storage; special directions for administration, precautions to be observed during administration; common side effects that may be encountered, including their avoidance and the action required if they occur; techniques for self-monitoring of drug therapy; and potential drug-drug or drug-food interactions or other therapeutic contraindications.

With respect to USP <800>, given the risks inherent in the handling, dispensing, and administration of HDs, its requirements target specific areas to mitigate these risks, including: proper facilities and engineering controls; personal protective equipment (PPE); hazard communication program; personnel training; hazardous material handling including receiving, labeling, packaging, transport, and disposal; compounding; documentation and standard operating procedures; and medical surveillance.

While all pharmacies are subject to counseling and DUR requirements, because compounding is by its nature specialized and customized, examination of how the various components of a compounded drug product will interact with a patient is frequently more narrowly tailored to specific patient needs and for that reason inherently riskier than dispensing off-the shelf FDA-approved products. Confirmation of the prescription details—including dosage, components, route of administration, etc.—and counseling the patient on the compounded drug's use, while always crucial to compliant pharmacy practice, requires elevated vigilance when the drug product is customized. This is more than a token step. Failures in DURs, interaction screening, or counseling/documentation can lead to actual patient harm and regulatory and contractual non-compliance. What's good for patients is good for business.

Similarly, while other pharmacies may handle and dispense HDs,[5] USP <800> outlines substantial requirements that compounding pharmacies must satisfy when engaged in the compounding of HDs or drug products containing HD components, including measures to safeguard both the pharmacists and technicians involved in the compounding and the patients to whom these HDs are dispensed or administered. The danger inherent in HDs increases the risk of harm to employees and patients that can result from errors, mistakes, or other accidents.

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When the potential for harm resulting from mistakes is elevated, so too are the risks of non-compliance. These risks expose compounding pharmacies to different sources of liability.

## A. CIVIL LIABILITY EXPOSURE

Civil liability—the risk associated with litigation—is a fact of life for compounding pharmacies. Any harm, whether to patients or employees, can result in civil liability. Inadequate DURs can result in adverse patient events. Improperly calculated strength or dosage instructions can result in a toxic dose. Similarly, HDs, by their nature, are hazardous, not only to patients to whom they are dispensed, but also to employees exposed to HDs in the course of their employment. When a compounding pharmacy's compliance program and associated safeguards fail, and as a result someone is injured, that injured person can sue for damages.

## B. ADMINISTRATIVE/ REGULATORY EXPOSURE

Compliance failures—specifically of administrative and regulatory requirements—open a pharmacy up to administrative actions. For compounding pharmacies, violations of USP <800 > and OBRA '90 are typically policed by the state board of pharmacy, and in certain instances may be subject to action by the FDA. Regulatory infractions seldom remain confined to the regulatory body that first identifies a problem. Most regulatory agencies require licensed entities to self-report actions by other agencies. Final disciplinary actions are usually also reported to either the NABP and/or the NPDB for disclosure to other participants—e.g., state boards—in the industry. For facilities with licensure in multiple states, an infraction in one state may be treated as a separate infraction in other states of licensure.

## C. CONTRACTUAL/PAYER EXPOSURE

Potentially less obvious are the risks presented from payors. Payor requirements are often obscure or even opaque, but noncompliance can lead to substantial financial risk. Pharmacies should pay close attention to pharmacy benefits manager (PBM) claim submission standards. Pharmacies that regularly fail to perform DURs or to counsel patients risk investigation or even audit recoupment. Worse, a pattern of failures in these areas could open a pharmacy up to federal False Claims Act ("FCA") liability under certain conditions. In fact, both OBRA '90 and the regulations governing Medicare Plan D sponsors require, in addition to prospective DURs, retrospective DURs of drug claims "in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care."[6] If the Government establishes that compliance in these areas is a material condition of payment such that non-compliance violates the compounding pharmacy's implied certification under *Escobar*,[7] then False Claims Act ("FCA") suits may be initiated by private individuals ("relators")—often employees—on behalf of the government. Relator actions are highly incentivized by potential statutory awards ranging from 15-30% of any recovery.

The government and relators have pursued False Claims Act ("FCA") claims against health care providers targeting more general standard of care and regulatory compliance issues such as billing for drugs that were not properly prescribed, medically necessary, or compliant with governing pharmacy and long-term care requirements, including in the following examples:

- In 2025, a jury found a long-term care pharmacy liable for submitting over three million false claims to Medicare, Medicaid, and TRICARE by dispensing drugs without valid prescriptions in long-term care facilities, resulting in $135.6 million in damages, and a total judgment of approximately $948.8 million after trebling and statutory penalties.[8] The verdict rested on the finding that the pharmacy's claims implied compliance with medication use and pharmacist oversight requirements, which the jury found were violated on a systematic basis.[9]
- In 2025, DOJ resolved a $3.61 million FCA matter involving skilled nursing facilities accused of billing Medicare and Medicaid for grossly substandard care, where the government alleged that claims for reimbursement implied compliance with Nursing Home Reform Act quality-of-care and medication-management standards that were violated through unnecessary, inappropriate, and poorly monitored drug regimens.[10]
- In 2025, DOJ announced a $300M settlement to resolve allegations that a national pharmacy chain illegally filled millions of invalid controlled substance prescriptions and then billed Medicare and other federal programs in violation of the FCA.[11]

Here again, it is virtually impossible to silo risk. Self-reporting is typically required for all actions taken against a pharmacy for compliance failures. An administrative action can result in a payor audit; an action by one state board can result in sister state action; and concerns at the payor level can be escalated to the relevant regulatory bodies.

## III. Pre Incident Prevention: Make Employees a Compliance Force Multiplier

Many of the government's enforcement mechanisms rely on employees reporting suspicious behavior. In sufficiently egregious cases the government incentivizes these reports.[12] Financial incentives allow the government to weaponize employees against their employer. The reason for this is obvious: Employees are often the first to spot compliance problems.[13] For the same reason, pharmacies should encourage internal reporting. Giving employees opportunities to provide feedback on matters of compliance and showcasing how that feedback can result in the review, revision, and implementation of new policies and procedures can drive organizational improvement. This kind of virtuous circle can also reinforce compliance basics: Increasing common employee oversight and responsibility over compliance can help reduce the risk that violations occur or continue unnoticed.

### A. CODIFY A REAL OBRA '90 PROGRAM (APPLIES TO *ALL* PATIENTS IN MANY STATES).

Many of the OBRA '90 requirements are operationalized through Medicare and other payor provider manuals, pharmacy contracts, and DUR boards. Failure to comply with DUR requirements may be enforced at the federal level by CMS through mechanisms such as audits, corrective action plans, and other penalties. At the state level, boards of pharmacy may enforce DUR requirements via disciplinary actions including citations, fines, probation, suspension or revocation of pharmacist or pharmacy licenses, and other administrative sanctions under state pharmacy practice acts.

Pharmacies should ensure they have written policies addressing the three components of the DUR mandated by OBRA '90: prospective drug utilization review, record-keeping, and counseling. These policies and procedures should define DUR screening criteria, integrate real-time clinical decision support into dispensing workflows, document pharmacist interventions and patient counseling, and provide ongoing staff training to ensure consistent compliance with both federal OBRA '90 mandates and applicable state law. Pharmacies should also explore additional operational safeguards—for example, software alerts and overrides—that further enforce and reinforce these requirements.

### B. EMPLOYEES AS ASSETS IN ACHIEVING AND MAINTAINING USP <800> READINESS.

Similarly, because they face the greatest regular risk of harm in the event of improper handling, employees directly involved in handling and compounding with HDs are most likely to be aware of matters of compliance risk. Their voices should be heard, and their concerns and expertise should be given great weight. The particular policies in place will vary depending on the circumstances, but ensuring that these employees have direct and open lines of communication with those in charge of HDs and the compounding of HDs is critical. Similarly, especially for larger operations, maintaining a process for conveying these concerns from the compounding floor to the compliance department and executive leadership is crucial to an effective compliance program.

Similarly, to the extent policies can be enforced by concrete operational safeguards—regular PPE checks, procedure checklists, etc.—these should be encouraged. Regular training of employees as well as periodic testing on and reviews of the policies and procedures provide the pharmacy with natural opportunities to solicit feedback and leverage employee knowledge to sustain a safer working environment and more effective compliance program.

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### C. PROACTIVE WORKFORCE ENGAGEMENT.

So, what does pharmacy with a strong culture of compliance look like? Does your pharmacy have a compliance policy, compliance officer, open door policy, investigation procedure, or anonymous reporting hotline? Does your pharmacy provide regular compliance training, including recurring USP/OBRA drills and competency checks? Does your pharmacy elicit employee feedback? Does your pharmacy ask employees at exit interviews whether they have any concerns to report? These practices can both improve compliance skills and allow management to address and remedy potential compliance violations before an employee reports to an outside agency or attorney.

Conversely, where communication fails, fear is its own liability. Fear of retaliation often drives employees to report externally, rather than trusting that pharmacy leadership will promptly address reported issues.[14] Whether their own or that of their peers, employees see the effects of their feedback. Policies should expressly prohibit retaliation and provide a safe mechanism for employees to report retaliation concerns. The reporting of suspected noncompliance is often a legally protected activity. Employer retaliation is prohibited and may result in additional civil liability.

## IV. When a Whistleblower Surfaces: A Do/Don't Field Guide

Despite even the most diligent of efforts, employees sometimes blow the whistle. What now?

### A. DO NOT RETALIATE.

Once an employee raises a concern, even internally, retaliation risk attaches.[15] Subsequent adverse actions – including termination, suspension, demotion, reduced hours, reassignment, or hostile treatment – may give rise to retaliation claims, even if the underlying compliance concern is ultimately unsubstantiated. Potential exposure may include claims under the federal False Claims Act (31 U.S.C. § 3730(h)), OSHA whistleblower statutes,[16] state false claims or healthcare worker protection laws (which vary by jurisdiction),[17] and wrongful termination in violation of public policy,[18] among others – often with significant damages.

Because internal reporting is itself frequently a protected activity, employment decisions following a report should be carefully evaluated, coordinated with the investigation, and made in consultation with legal counsel where appropriate.

### B. ACKNOWLEDGE AND OPEN A PROMPT, DOCUMENTED INVESTIGATION.

Early engagement has a practical human resources effect: employees who see their concerns taken seriously, investigated, and addressed internally are far less likely to seek outside counsel or report directly to government agencies. In short, a prompt,

thorough, and remedial response—when necessary—reduces the likelihood that an internal concern escalates into a whistleblower-initiated enforcement action.

Documentation is critical because a contemporaneous investigative record demonstrates good faith compliance, preserves the basis for tolling the overpayment repayment period, and provides objective evidence that the organization acted promptly, reasonably, and without retaliatory intent. This evidence may be invaluable to defend your organization against possible future regulatory action.

Time is crucial to investigations. For example, under the Medicare and Medicaid 60-day overpayment rule, the repayment clock generally begins when an overpayment is identified—i.e., when the entity knowingly receives or retains an overpayment. While the rule allows for some extensions, failing to act timely and in good faith to investigate and act has its own set of repercussions.[19] Similarly, other oversight bodies—such as boards of pharmacy—are typically inclined to treat a pharmacy that promptly responds to a compliance concern with more leniency than a pharmacy that allows compliance issues to linger.

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### C. PRESERVE EVIDENCE; ENGAGE COUNSEL EARLY.

Because time is material to investigations, it is critical to take immediate action to implement litigation holds to key employees to preserve evidence, and to promptly route employee interviews, document review, and any root-cause analysis through counsel where appropriate to preserve privilege. Where the investigation identifies credible evidence of potential fraud or violations subject to civil monetary penalties, evaluate whether voluntary disclosure through the HHS OIG Self Disclosure Protocol or a claim reversal is warranted.

## D. INTERIM MEASURES (PAID LEAVE > UNPAID; SAFETY FIRST).

During an internal investigation, it is often advisable to maintain employees on the payroll—even where they are alleged to have engaged in misconduct—to ensure continued access to crucial witnesses and information. In many cases, placing an employee on paid administrative leave strikes an appropriate balance between preserving the integrity of the investigation and avoiding premature employment action.

Where temporary separation from duties is necessary to prevent further potential wrongdoing—such as to protect patient safety, records, or operational integrity—paid administrative leave is also generally recommended, and the business rationale for the leave should be clearly documented. However, because employment actions in the course of an investigation carry the risk of retaliation, employment decisions during an investigation should be made in consultation with counsel and tailored to the specific situation.

## E. REMEDIATE QUICKLY — EVEN IF CAUSATION IS UNCLEAR.

It is commonly thought that remedial action inevitably amounts to an admission of some violation or deficiency. From a strictly legal perspective, this is not necessarily true.[20] But even—or especially!—when it is, failing to remediate can compound existing liabilities. Postponing remedial action not only exposes the pharmacy to ongoing liability but signals to employees that compliance is not a priority and that employee concerns will not be addressed. Conversely, when a pharmacy seriously reviews reports, promptly takes any needed remedial action, and (where feasible) encourages continuous employee participation in remedial efforts, this both encourages employee buy-in and reduces the risk of additional fallout.

## F. COMMUNICATE OUTCOMES INTERNALLY (AND CAREFULLY).

Where appropriate, close the loop with the reporting employee by acknowledging the issues reviewed and thanking them for raising the concern. Without disclosing confidential personnel, patient, or investigative details, reinforce that compliance is a priority and that the concern was taken seriously and

addressed. This type of feedback fosters trust in the reporting process and helps prevent unnecessary escalation outside of the organization.

## X. WRAPPING IT ALL UP: WHERE TO GO FROM HERE?

What does this look like, practically, from a leadership perspective? Here are some suggestions:

### DO

- Create and implement a strong compliance program taking into consideration the specifics of the compliance areas being addressed.
- Provide regular training on compliance and the internal reporting process.
- Request employee feedback on compliance programs and trainings.
- Route complaints to your compliance team and/or counsel.
- Acknowledge receipt of any reports.
- Open a documented investigation immediately.
- Take interim non retaliatory measures with the employees involved (such as providing paid leave and/or duty modifications during the pendency of an internal investigation as recommended by counsel in the circumstances).
- Promptly correct compliance gaps. If billing is touched, quantify and return overpayments within timelines.
- Consult with counsel before making employment decisions.
- Close the loop with the reporter and thank them for coming forward.

### DON'T

- Ignore, put-off, or offend the reporter or minimize the report. These are the reporters who seek outside counsel or report to enforcement agencies.
- Terminate, demote, or take any other action that might chill the reporter; this invites the reporter to seek outside counsel (both from attorneys and/or the government) and opens the company up to liability for a variety of retaliation claims. Make sure to consult with counsel before making employment decisions.
- Fail to implement policies and procedures. Well drafted compliance policies if not implemented or followed can be Exhibit 1 in a lawsuit or other action as evidence of the pharmacies willful disregard for these compliance issues.

*And never forget that well-trained employees who know their concerns will be heard are frequently the backbone of a pharmacy's compliance program.*

While a regular and frequently mundane part of pharmacy life, a well-honed compliance program is never mindless or a mere afterthought. While compliance programs are usually developed to protect employees, patients, and the public in general, ultimately, they protect your business too. So, pay attention. And never forget that well-trained employees who know their concerns will be heard are frequently the backbone of a pharmacy's compliance program. Do not let inertia, negligence, or fear turn your greatest compliance asset into a ticking time bomb.

## References


1. Section 4401 of the Omnibus Budget Reconciliation Act of 1990 codified at 42 USC 1396r-8(g)(1)(A) and 2(A)(ii).
2. 42 CFR. § 423.153(c)(2).
3. United States Pharmacopeia, About the *Unite States Pharmacopeia (USP)*, https://www.usp.org/about (last visited March 21, 2026).
4. United States Pharmacopeia, *USP <800> FAQs (Updated: November 1, 2023)*, https://go.usp.org/l/323321/2020-06-26/3flhxs/323321/111087/USP_FAQs_on_GC_800.pdf.
5. USP <800> Section 12 specifically addresses this scenario.
6. 42 USC 1396r-8(g)(B). *See also* 42 CFR 423.153(c)(3) requiring Part D plan sponsors to include as part of their quality assurance measures "[r]etrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees."
7. *See Universal Health Servs. v. United States ex rel. Escobar,* 579 U.S. 176, 136 S. Ct. 1989 (2016). Under *Escobar*, when a provider's misrepresentation about a statutory, regulatory, or contract requirement is material to the government's payment decision, such misrepresentation may give rise to FCA liability.
8. *Statement of U.S. Attorney Jay Clayton on the Verdict in U.S. Omnicare and CVS Health Corporation,* U.D. DEP'T OF JUSTICE (Apr. 29, 2025), available at: Southern District of New York | Statement Of U.S. Attorney Jay Clayton On The Verdict In U.S. V. Omnicare And CVS Health Corporation | United States Department of Justice; United States ex rel. Bassan v. Omnicare, Inc., 2025 U.S. Dist. LEXIS 128455 (S.D.N.Y. July 7, 2025).
9. *Bassan*, 2025 U.S. Dist. LEXIS 128455, at *14-15 ("The Government ended up using taxpayer funds to pay for drugs for which it had no obligation to pay, because those drugs were not legally prescribed.") ("[T]he violations in this case were both deliberate and egregious. Omnicare was aware for years of the problems posed by its dispensing practices; it was warned again and again, both by employees and by outside (State) regulators" but "did not follow the rules.").
10. *Ohio-Based Nonprofit and Affiliated Nursing Homes Agree to Pay $3.61 Million to Resolve False Claims Act Liability,* U.S. DEP'T OF JUST. (June 3, 2025), *available at:* https://www.justice.gov/opa/pr/ohio-based-nonprofit-and-affiliated-nursing-homes-agree-pay-361m-resolve-false-claims-act.
11. *Walgreens Agrees to Pay Up to $350M for Illegally Filling Unlawful Opioid Prescriptions and for Submitting False Claims to the Federal Government,* U.S. DEP'T OF JUST. (Apr. 21, 2025), available at: Office of Public Affairs | Walgreens Agrees to Pay Up to $350M for Illegally Filling Unlawful Opioid Prescriptions and for Submitting False Claims to the Federal Government | United States Department of Justice.
12. That dynamic is unmistakable: for example, in its Jan. 16, 2026, report, the Department of Justice recorded a record $6.8 billion in FY 2025 FCA recoveries—$5.3 billion of which (approximately 78%) was from earlier filed whistleblower matters. Health care comprised roughly 84% ($5.7 billion) and a record 1,297 qui tam filings (around 32% more than FY 2024). In sum, pharmacies face heightened exposure in this whistleblower driven environment, where internal personnel issues can rapidly escalate into investigations, federal or otherwise, absent robust HR compliance controls. *See 31 U.S.C. § 3730(d)(1)–(2); see also, False Claims Act Settlements and Judgments Exceed $6.8B in Fiscal Year 2025*, U.S. DEP'T OF JUST. (Jan. 16, 2026), available at: Office of Public Affairs | False Claims Act Settlements and Judgments Exceed $6.8B in Fiscal Year 2025 | United States Department of Justice.

13. *See, e.g., HHS OIG, Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731, 23,734–37 (May 5, 2003), *available at*: https://oig.hhs.gov/documents/compliance-guidance/799/050503FRCPGPharmac.pdf (noting companies should maintain mechanisms that allow employees and agents to report potential compliance issues without fear of retaliation, recommending "a process, such as a hotline, to receive complaints and questions from employees and others regarding potential compliance issues.")
14. DOJ — *Evaluation of Corporate Compliance Programs, at p. 5 (Updated March 2023), available at:* justice.gov (noting: "Prosecutors should assess whether the company's complaint-handling process includes proactive measures to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers.").
15. *See, e.g., Vaughn v. Harris Cnty. Hosp. Dist.*, No. 4:17-cv-02749, 2022 U.S. Dist. LEXIS 72247, *4-5, 2022 WL 1165146 (S.D. Tex. Apr. 20, 2022) (FCA retaliation claim was based upon raising internal concerns about a funding scheme); *Jamison v. Fluor Fed. Sols., LLC*, No. 3:16-CV-0441-B, 2017 U.S. Dist. LEXIS 118580, *22-23, 2017 WL 3215289 (N.D. Tex. July 28, 2017) (an internal report can put the company on notice under the FCA, and no "magic words" such as "illegal" or "unlawful" are required).
16. Statutes enforced by OSHA contain anti-retaliation provisions protecting healthcare employees who report. *See, e.g.,* OSHA, Whistleblower Protection Program, *available at*: https://whistleblowers.gov/statutes.
17. *See, e.g.*, C.R.S. § 24-31-1204 (prohibiting retaliation because of a Colorado False Claims Act-related protected activity, mirroring the federal FCA's anti-retaliation framework); C.R.S. § 8-2-123 (prohibiting disciplinary action taken in retaliation for a protected report or disclosure, applying to registered healthcare workers including pharmacists and other licensed professionals). *See also,* TEX. HEALTH & SAFETY CODE § 161.134 (prohibiting retaliation against an employee of a hospital, mental health facility, or treatment facility who reports unlawful conduct); TEX. HEALTH & SAFETY CODE § 161.135 (prohibiting retaliation by a hospital, mental health facility, or treatment facility against a non-employee who reports unlawful conduct).
18. Reporting conduct that would violate regulatory requirements tied to public welfare can provide a basis for a claim for wrongful termination in violation of public policy under Colorado law, for example. *See, e.g., Rocky Mountain Hosp. & Med. Serv. v. Mariani,* 916 P.2d 519 (Colo. 1996) (professional standards and regulatory duties designed to ensure accurate reporting and protect the public may provide a public policy basis for a wrongful discharge claim when a healthcare employee is terminated for raising compliance concerns).
19. CMS regulations expressly allow the 60-day deadline to be suspended while a provider conducts a timely, good-faith investigation to determine the scope of related overpayments arising from the same issue. Failing to act promptly – or worse, ignoring a reported issue – could transform a compliance concern into "reverse false claim" exposure, because knowingly retaining an overpayment beyond the regulatory deadline constitutes an "obligation" under the False Claims Act. *see*, 31 U.S.C. § 3729(a)(1)(G).
20. For example, Rule 407 of the Federal Rules of Evidence states that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove...culpable conduct."

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