Healthcare Compliance Programs in the United States and the Dominican Republic

Analysis of Legal Frameworks and Evidence with Recommendations for Adaptation

Revised October 20, 2026

Abstract

Healthcare compliance programs translate legal obligations and ethical commitments into everyday controls. Their value depends on their ability to detect problems, protect patients, and correct failures, alongside documenting policies. This essay argues that the Dominican Republic can adapt tools developed in the United States, but must build on its own healthcare, social security, data protection, and public procurement rules. Similar organizational structures do not mean that the laws of the two countries are equivalent.

This documentary study uses a qualitative, comparative approach to legal, institutional, and scientific sources. It examines healthcare compliance structures, the Dominican corporate criminal liability regime, and practical adaptation by institution type. The evidence supports attention to resources, staffing, audit and feedback, and implementation, while limiting causal claims about fraud prevention or patient outcomes. The analysis distinguishes binding rules, nonbinding guidance, research findings, and recommendations. It recognizes existing Dominican procurement compliance arrangements and the need for coordinated, proportionate institutional programs.

Introduction and Scope

Healthcare brings together clinical decisions, sensitive information, commercial relationships, and public and private resources. A billing error can affect financing; improper disclosure can violate privacy; and a purchasing decision influenced by private interests can undermine care. Compliance must therefore connect medical, administrative, financial, and technology functions.

The central question is which elements of the U.S. approach can strengthen compliance in Dominican institutions without automatically importing foreign rules. The essay examines providers, insurers, and organizations involved in care, with an emphasis on hospitals. It distinguishes binding laws and regulations, nonbinding guidance, and the essay's own recommendations. U.S. state laws, Dominican sector-specific resolutions, and special regulatory regimes require further review for each institution.

Methodology

This is documentary research with a qualitative, comparative approach. The purpose is to interpret the legal and organizational features of healthcare compliance in the United States and the Dominican Republic and identify practices that can be adapted to Dominican law. It combines legal analysis with a narrative review of scientific evidence; it is not a systematic review or an empirical evaluation of institutions.

Sources were selected for direct relevance to fraud prevention, patient rights and privacy, governance, procurement, and corporate criminal liability. Priority was given to laws, regulations, and official guidance, followed by scientific reviews located through PubMed and publisher or DOI records. News reporting was used to identify legislative proposals or implementation debates, without treating it as proof that a proposal had become law. Research began in August 2026, with updates on October 15 and 19 and a focused procurement review on October 20. Older foundational laws and studies were retained where relevant; no uniform publication-year cutoff was imposed.

The comparison examines legal force, institutional oversight, program components, sector risks, and evidence of effectiveness. Binding duties, voluntary guidance, empirical findings, and the author's implementation proposals are distinguished. Limitations include selective rather than exhaustive searching, heterogeneous and often indirect scientific evidence, limited Dominican comparative outcome data, and incomplete access to some live legislative records. No interviews, institutional inspections, or independent verification of operational performance were conducted. The findings support reasoned adaptation, not a ranking of national systems or proof that a program prevents crime.

The Purpose and Operation of a Compliance Program

A compliance program is a system of governance and risk management. It identifies applicable obligations, assigns responsibility, establishes controls, receives alerts, investigates facts, and verifies corrective action. It relates to patient safety and clinical ethics, although each function retains its own responsibilities. A clinical ethics committee, for example, does not replace billing audits or investigations of conflicts of interest. [1]

A program's quality should be assessed through its operation. An institution may train its entire workforce while recurring errors persist because no one examines their causes. It may also receive few reports because employees fear retaliation. Indicators must be interpreted in context, and leadership decisions must be examined to determine whether they support stated policies.

The U.S. Legal Framework

The civil False Claims Act, 31 U.S.C. sections 3729–3733, addresses false or fraudulent claims against the government. In healthcare, alignment among services, documentation, and billing is essential. The Anti-Kickback Statute, 42 U.S.C. section 1320a-7b(b), prohibits certain remuneration knowingly and willfully offered or received to induce or reward business financed by federal healthcare programs. The Physician Self-Referral Law, or Stark Law, 42 U.S.C. section 1395nn, restricts certain Medicare referrals for designated health services when a financial relationship exists, unless an exception applies. Their requirements and exceptions differ; a contract requires separate analysis under each relevant framework. [2]

Exclusion authorities and civil monetary penalties complement these mechanisms. The Office of Inspector General (OIG), Centers for Medicare & Medicaid Services (CMS), and Department of Justice have distinct oversight and enforcement roles. These mechanisms support institutional controls over credentials, financial relationships, and the engagement of excluded individuals or entities. A monetary recovery or settlement demonstrates enforcement activity, but does not by itself establish the causal effectiveness of internal programs. [2]

HIPAA and its privacy, security, and breach notification rules form another pillar. Their application depends on whether an organization qualifies as a covered entity or business associate; they do not automatically apply to every entity handling health information. Business associates may have contractual obligations and direct liability under certain provisions. In practice, access controls, risk management, and rules for sharing information are necessary. [3, 4, 5]

EMTALA establishes obligations for medical screening and, when appropriate, stabilization or appropriate transfer at Medicare-participating hospitals offering emergency services, regardless of a person's ability to pay. A hospital program should examine admission and transfer processes to identify barriers inconsistent with these obligations. [6]

For research involving human participants, 45 CFR part 46 includes the Common Rule and other protections. Institutions must determine applicability, institutional review board requirements, and applicable consent requirements or exceptions. Participant protection requires its own oversight process, coordinated with the institutional program. [7]

Guidance and Organizational Requirements

The OIG's General Compliance Program Guidance, published in 2023, is voluntary and nonbinding. It presents seven elements: written policies; compliance leadership and oversight; training; communication and reporting; enforcement of standards and incentives; risk assessment, auditing, and monitoring; and response and corrective action. It recommends adapting the program's structure to the entity's size and needs. [1]

The voluntary nature of guidance does not eliminate specific obligations. For nursing facilities subject to the relevant Medicare and Medicaid requirements, 42 CFR section 483.85 provides for compliance and ethics programs. It is therefore inaccurate to describe all U.S. programs as voluntary or to claim that an identical requirement applies to every healthcare organization. [8]

The Department of Justice assesses corporate programs through questions about their design, implementation, and practical operation. This approach provides a reference for examining autonomy, resources, and continuous improvement, although it is neither a healthcare certification nor a substitute for sector-specific obligations. [9]

Findings from the Research

Dunbar, Keyes, and Browne (2023) included 157 studies in a review of the determinants of regulatory compliance in health and social care. Many involved U.S. nursing homes. Favorable associations were observed with higher nursing staffing levels, lower staff turnover, and smaller facilities. Structural variables predominated, while qualitative studies of implementation were scarce. These associations do not establish that those factors independently cause compliance and cannot be automatically generalized to Dominican hospitals. [10]

Hussein and colleagues (2021) analyzed 76 empirical studies of hospital accreditation. They identified favorable findings for safety culture and process measures, but conflicting findings for mortality and infections. Methodological heterogeneity limits causal conclusions. The review provides evidence about

accreditation, an intervention related to quality that differs from a comprehensive anti-fraud and privacy compliance program. [11]

Araujo, Siqueira, and Malik (2020) reviewed 36 studies and identified possible accreditation benefits across several quality dimensions, alongside methodological limitations and gaps concerning access and equity. Together, these findings support measuring processes and outcomes and avoiding the use of accreditation as a substitute for compliance assessment. None of these reviews directly compares comprehensive U.S. and Dominican compliance programs. [12]

Additional Evidence and Implications for Program Design

Audit and Feedback Can Improve Practice but Effects Vary

The 2025 Cochrane review by Ivers and colleagues provides more direct evidence for a component of compliance management than accreditation studies alone. It included 292 randomized studies. Across 177 studies comparing audit and feedback with control conditions for dichotomous professional-practice outcomes, the median absolute improvement was 2.7 percentage points; the weighted meta-analysis estimated a mean improvement of 6.2 percentage points (95% confidence interval 4.1–8.2), with moderate-certainty evidence. These are different statistical summaries, not interchangeable estimates. Only 26 of the 292 studies were conducted in low- or middle-income countries. [13]

The review concerns professional practice, especially prescribing and test ordering, rather than corporate criminal liability or fraud reduction. It nevertheless supports testing a practical improvement cycle: measure a priority behavior, discuss feedback, agree on corrective action, and reassess. Exploratory findings suggest that benchmarks, interactive feedback, and support for action may help, but those design findings need confirmation. Dominican institutions should evaluate their own results rather than assume the review's average effect will apply locally. [13]

Managed Care Compliance Must Include Access to Care

On February 3, 2026, OIG issued its Medicare Advantage Industry Segment-Specific Compliance Program Guidance. Alongside billing and risk adjustment, it addresses access to care, provider networks and directories, prior authorization, marketing, quality, third parties, and vertically integrated organizations. The guidance is voluntary; CMS compliance program requirements for Medicare Advantage organizations remain mandatory. This is an important example of the distinction between a nonbinding guidance document and underlying legal duties. [14]

For the Dominican comparison, this supports a broader analytical lens for ARS and their provider relationships. As a proposed evaluation framework, compliance reviews should examine whether authorization rules, inaccurate directories, or unresolved network gaps obstruct covered care, as well as whether claims are accurate. The applicable coverage and procedural duties must be derived from Dominican law, resolutions, and contracts. Medicare Advantage rules do not become binding on an ARS through this comparison.

Screening Requires Attention to Data Quality and Ownership

OIG's September 2026 data brief A-02-24-01013 examined 1,017 revoked National Provider Identifiers absent from CMS's Preclusion List during 2022–2023. It identified $72 million in Part C and Part D payments

associated with 249 of those identifiers during 2022–2024, highlighting timing errors, ownership-related gaps, and regulatory limits affecting pharmacies. These are findings about vulnerabilities in a specific process, not a finding that every payment was fraudulent or recoverable. [15]

The comparative lesson is that a single database check may give incomplete assurance. As a management recommendation, a Dominican institution should verify the provider or supplier's identity, ownership where relevant, professional credentials, authorized services, and material changes through locally applicable records and requirements. It should record the source, date, reviewer, discrepancies, and resolution. U.S. exclusion and preclusion databases serve different legal purposes and should not be presented as universal Dominican screening requirements.

Privacy Controls Must Follow the Record and the Activity

The U.S. privacy analysis also requires attention to 42 CFR part 2, which protects records of federally assisted programs providing substance use disorder diagnosis, treatment, or referral. Some requirements extend to recipients of those records. Compliance with the 2024 final rule was required by February 16, 2026; relevant changes include breach notification, patient rights, and restrictions on uses in proceedings against patients. Part 2 has its own scope and is not simply another name for HIPAA. [16]

For Dominican healthcare organizations, the transferable management insight is to map information by origin, sensitivity, purpose, recipient, and legal basis. An institution should test its clinical, insurer, laboratory, and technology-provider information flows rather than treat a general confidentiality pledge as sufficient. Any direct application of U.S. requirements must be assessed separately; Dominican data obligations remain grounded in Laws 42-01 and 172-13 and other applicable rules. [17, 18]

October 2026 Developments in Disclosure and Billing Controls

On October 15, 2026, DOJ and HHS-OIG announced a coordinated policy for voluntary disclosure of potentially criminal healthcare conduct. Qualifying disclosure to DOJ's Health Care Fraud Section can receive the benefits of both DOJ's Corporate Enforcement Policy and OIG's Self-Disclosure Protocol without a duplicate OIG portal submission. Disclosure only to OIG generally does not qualify as voluntary disclosure to DOJ. Eligibility remains conditional; the policy does not resolve mandatory exclusion under 42 U.S.C. section 1320a-7(a) or create an enforceable right to a favorable outcome. [19]

This development strengthens the essay's focus on response procedures. An effective program should identify who assesses a report, preserves evidence, evaluates potentially criminal conduct, and decides the appropriate disclosure route. For Dominican companies, amended article 8 already gives legal significance to reporting and cooperation under specified conditions. The comparative lesson is to make that decision process operational; the U.S. disclosure route and benefits cannot be transferred to Dominican proceedings. [20, art. 3; 19]

A separate October 16, 2026 DOJ announcement provides a concrete laboratory-control example. A Connecticut physician and two practices agreed to pay $866,539 and accept three years of exclusion from federal healthcare programs to resolve False Claims Act allegations. The government alleged, among other matters, that tests were billed although required reagents were unavailable and the tests had not been performed. The announcement describes a civil settlement of allegations and should not be presented as a criminal conviction. [21]

For hospitals and laboratories, this supports a proposed control linking each billed test to its order, specimen, instrument or processing record, result, and required supplies. A missing result or a mismatch between testing volumes and reagent availability should trigger review before billing or prompt correction after detection. This is a practical inference from the case, not a universal statutory documentation formula. It also connects the Dominican Code's financial controls and documentary traceability criteria to daily clinical operations. [20, art. 3; 21]

The Dominican Framework and Institutional Obligations

General Health Law No. 42-01 is a foundation of Dominican healthcare law. It recognizes individual rights and provides for the confidentiality of information relating to medical records and stays in healthcare institutions, subject to legal exceptions. An institutional program must translate these rights into procedures for care, record management, and handling complaints. [17]

Law No. 87-01 establishes the Dominican Social Security System (SDSS). The National Social Security Council (CNSS) and the Superintendency of Health and Occupational Risks (SISALRIL) are part of its governance and oversight structure; their functions do not correspond exactly to those of CMS or OIG. Compliance by health risk administrators (ARS) and healthcare providers requires identifying obligations arising from their activities, contracts, and supplementary rules. SISALRIL describes protection of members and oversight of compliance within the system among its functions. [22, 23]

Regulation No. 1138-03 governs the licensing of healthcare establishments and services, known as habilitación. The Directorate for the Licensing of Healthcare Services and Establishments (DHSES) also publishes technical regulations, including the 2024 regulation for clinical, surgical, and diagnostic services. Licensing requirements should be integrated into monitoring authorized services, staffing, and technical conditions. Obtaining a license does not by itself demonstrate that other institutional risks are controlled. [24, 25]

Law No. 172-13 establishes personal data protection rules. Articles 76 and 78 must be read together: they provide special protection for health information and identify circumstances for healthcare-related processing subject to professional secrecy. It would therefore be inaccurate to require written consent for absolutely every clinical use of data or to equate this law with HIPAA. As a management recommendation, institutions should document the legal basis for each use, restrict access, and oversee technology providers. [18]

For entities subject to public procurement rules, Law No. 47-25 entered into force on January 28, 2026, and its implementing regulation was approved through Decree No. 52-26. The General Directorate of Public Procurement (DGCP) issued guidance on gradual implementation and transition for earlier proceedings. A public hospital's program should identify the rules applicable to each procurement proceeding, manage conflicts of interest, and preserve evidence supporting decisions. Presenting Law No. 340-06 as the sole current framework would overlook this transition. [26]

Background of Compliance in the Dominican Healthcare Sector

The Dominican healthcare sector has an institutional background on which broader compliance programs can build. One example is the DGCP regulatory compliance program for public procurement under Decree

36-21, which introduced compliance officers in participating public institutions, including healthcare bodies. This experience provides a general precedent for assigning oversight responsibilities and documenting controls; it should be coordinated with clinical, financial, privacy, and governance functions. [27, 28]

This background also illustrates the need to adapt compliance to institutional risks. Public hospitals require attention to procurement, state resources, separation of purchasing and payment functions, service licensing, and patient protection; their legal status also matters for the Criminal Code's public-entity exclusions. Private clinics face billing, commercial relationships, conflicts of interest, and credentialing risks. For ARS, authorizations, provider networks, and access to covered benefits are particularly relevant. Laboratories and suppliers require controls over testing records, inputs, deliveries, payments, and applicable authorizations. These are illustrative priorities, subject to each organization's applicable duties. [17, 24, 26, 20, 29, 22, 18, 14, 21]

Accordingly, this institutional experience is a starting point for proportionate programs suited to each entity's nature, size, activities, ownership, and risks, with defined responsibilities and controls. [20, art. 3]

The New Criminal Code and the November 2026 Corporate Liability Regime

Law No. 74-25, as amended by Law No. 44-26 of July 27, 2026, gives compliance programs express significance in the criminal liability regime for legal entities. Article 31 of Law 44-26 postpones the entry into force of Criminal Code articles 8, 9, 10, and 11 for three months from August 5, 2026, making November 5, 2026 the relevant date for these corporate liability provisions. This is a specific deferral, rather than the starting date for the entire Criminal Code. As of this essay's October 20, 2026 review date, companies have an additional preparation period for that regime. [20, art. 31]

Under amended article 8, an entity may be criminally responsible for punishable acts or omissions of its organs, representatives, or subordinates committed in its representation when those acts or omissions also result from failures of direction, control, or supervision. The provision also addresses negligence, imprudence, inadvertence, noncompliance with regulations, and breach of the duty of care. Article 9 preserves the separate responsibility of individuals who incur their own liability. Accordingly, corporate liability does not automatically mean that every director is criminally responsible. [20, art. 3; 29, arts. 8–9]

Article 11, as amended, addresses a controlling legal entity where specified involvement or organizational failures are established, including ordering, authorizing, tolerating, knowingly benefiting from, or creating a serious organizational defect that facilitated the offense. Healthcare groups should therefore examine the allocation of oversight across parent companies and subsidiaries. Article 13 exempts specified public entities from the preceding corporate liability provisions; the legal status of a public healthcare institution must be checked before applying the private-company analysis. Those exclusions do not eliminate other applicable obligations or individual liability. [20, art. 4; 29, arts. 11, 13]

Proposed Extension Requires Legislative Monitoring

On October 19, 2026, Acento reported that ANJE requested urgent consideration of a bill amending article 31 of Law 44-26 to extend the corporate liability adjustment period, citing the burden on businesses, particularly Mipymes. This is a reported legislative request, not evidence of an enacted extension. For this update, November 5, 2026 remains the preparation date supported by the statutory text examined;

companies should monitor official legislative and promulgation records and continue implementation rather than assume a postponement. [20, art. 31; 30]

How a Compliance Program Can Affect Liability

Amended article 8, paragraph III, permits mitigation in specified circumstances. These include proving that a genuine, effective, measurable, updated program appropriate to the entity existed and operated before the conduct; subsequently implementing real prevention and remediation measures where a program was incomplete or partly effective; repairing harm in public-action cases; voluntarily reporting before formal knowledge of an investigation; and effective cooperation in preserving or delivering evidence and identifying those involved. These are statutory grounds for assessment, not guaranteed outcomes. [20, art. 3]

Paragraph IV establishes a conditional basis for nonliability where both statutory circumstances are met: the entity objectively proves adoption and implementation of a relevant program that was fraudulently circumvented, with reporting to the competent authority if management becomes aware; and a subordinate or person outside management fraudulently violated the measures in a way that prevented management from detecting the conduct. Paragraph V separately addresses offenses committed exclusively against the entity without direct or indirect benefit, and specified reparation cases. A purchased manual, training certificate, or ISO certification alone does not establish these conditions. [20, art. 3]

The Eleven Statutory Program Elements

Article 8, paragraph VI, identifies the following minimum contents for a program under this regime, adapted to the entity's nature, size, activity, and risks. These are statutory program criteria; the practical implementation examples that follow are recommendations. [20, art. 3]

1. A clear policy or code of conduct defining the prevention and detection obligations of the entity's organs, representatives, and employees.

2. Express identification of areas of criminal risk associated with the entity's activities.

3. Risk controls appropriate to preventing offenses.

4. Appropriate, continuing training and awareness on human rights, inclusion, respect, equality, nondiscrimination, and the prevention and detection of offenses.

5. A body or department with autonomous powers to control or supervise implementation.

6. Financial and accounting procedures intended to prevent unlawful payments, transactions, or benefits.

7. A response protocol for detecting criminal risks, including disciplinary measures for breaches of the program and consequences for offenses.

8. Internal anonymous reporting channels, whistleblower protection, and rules against retaliation.

9. Clear, efficient procedures for investigating reports.

10. Periodic review and modification when the organization or its requirements change.

11. Documentary traceability.

Paragraph VII allows the management body of qualifying micro, small, and medium-sized enterprises (Mipymes) to perform the compliance oversight function directly. It provides for scaled, differentiated prevention, due diligence, and supervision proportionate to the entity's nature, business volume, and risk. A small clinic should determine whether it legally qualifies for this treatment and document the arrangement; small size does not remove the need for functioning controls. [20, art. 3]

Comparison and Limits of Transfer

Both countries require institutions to connect care, financing, and patient rights. The United States provides OIG guidance alongside specific legal requirements and specialized enforcement mechanisms. The Dominican Republic combines healthcare, social security, data, and procurement obligations with an amended Criminal Code that expressly identifies minimum compliance program contents and their potential relevance to corporate criminal liability. The November 5, 2026 corporate regime makes the comparison more than a transfer of voluntary practices: Dominican companies must evaluate how their existing controls meet domestic statutory criteria. [20, 29]

This difference should not be interpreted as evidence that all U.S. institutions have effective programs or that Dominican institutions lack controls. The information examined also does not establish that one system achieves superior compliance outcomes. Such a conclusion would require comparable data on violations, detection, resources, remediation, and harm, adjusted for institutional size and risk.

Dimension	United States	Dominican Republic
Organization	OIG guidance and specific requirements [1, 8]	Sector rules and Criminal Code program criteria [17, 22, 23, 24, 25, 18, 26, 20, 29]
Privacy	HIPAA by entity and activity [3]	Laws 42-01 and 172-13 [17, 18]
Financing	Federal anti-fraud controls [2]	SDSS and relevant oversight [22, 23]
Quality	Oversight and accreditation with distinct scopes [8, 11]	Licensing and technical regulations [24, 25]

The matrix summarizes comparable functions; it does not establish legal equivalence.

Practical Implementation and Verification Plan

For entities within the corporate liability regime, November 5, 2026 remains the preparation date supported by the legal text examined, subject to an officially enacted change. The following internal milestones are recommendations, not additional statutory deadlines. Public healthcare bodies must apply the plan according to their own legal status and obligations.

First, confirm legal scope and the institution's risk profile; approve the program, designate accountable leadership, and provide appropriate authority and resources. By October 22, identify urgent patient,

financial, and criminal risks and map existing policies against the eleven statutory elements. Coordinate existing procurement compliance functions with institutional oversight. [20, art. 3; 27, 28]

Second, implement priority controls and test them by October 29. Training should address role-specific scenarios and the human rights topics required by article 8. Test anonymous reporting, nonretaliation safeguards, investigation responsibilities, evidence preservation, and escalation decisions. For clinical and billing controls, select samples appropriate to the institution's risks rather than rely only on attendance records or policy acknowledgments. [20, art. 3; 13]

Third, by November 4 review unresolved findings, verify corrective action, and approve ongoing monitoring. Maintain a traceable chain from each risk and legal basis to its control owner, operating records, test results, and follow-up. Records should reflect actual dates and activity. A program's relevance to mitigation or nonliability remains subject to the legal conditions explained above; documentation supports that assessment without replacing effective execution. [20, art. 3]

Performance monitoring should combine training comprehension, sampled error rates, investigation quality and time, and recurrence after remediation. Fix definitions and denominators before comparison, establish a baseline, and interpret report volumes in context. Future Dominican research should compare institutions with similar risk profiles and combine documentary analysis, interviews, and outcome measures to distinguish increased detection from increased misconduct. [13]

Conclusion

The comparison supports a common governance approach with controls tailored to institutional risks. Scientific evidence favors testing practice changes and corrective action, but does not establish that one national system is superior or that an organizational model guarantees crime prevention. Dominican adaptation should build on existing procurement compliance and connect it with clinical, financial, and privacy responsibilities.

The amended Criminal Code adds specific legal significance to program design and execution for entities within its scope. A differentiated implementation plan therefore serves both institutional governance and preparation for the corporate provisions, while preserving the distinction between statutory duties, proposed internal milestones, and pending legislative changes. [20, 29]

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