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Article

Governing Verification Risk in Outcome Based Payments for Gene Therapies

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Abstract: Outcome-based payment agreements for gene therapies depend on institutional decisions where clinical evidence acquires financial consequences. Digital systems coordinate this sequence, but their reliability does not establish who is authorised to interpret an outcome, allocate missing evidence consequences, or revise a completed settlement. This article develops a legal account of verification risk: the risk that available evidence cannot support a sufficiently reliable and authorised determination of a contractual outcome. It distinguishes this risk from therapeutic underperformance and payment-execution error. Using the United States Cell and Gene Therapy Access Model as its principal institutional setting, the article examines the relationship between federal programme authority, state rebate agreements, and the HIPAA Privacy Rule. It recognises that the Model's design provides for reconciliation and appeals; the question is how these arrangements connect to subsequent corrections of clinical evidence. The article argues for a rebuttable contractual presumption of review where a correction is material to an existing payment condition, coupled with safeguards against retrospective alteration. It proposes a responsibility framework covering evidence production, outcome determination, settlement, and correction, testing it against hypothetical scenarios. The resulting contribution is a bounded account of financial finality: settlement should remain dependable while identified errors in its evidentiary basis remain capable of proportionate review. These proposals are contractual and programme-design recommendations, rather than claims that existing federal law requires a uniform reopening procedure.

Keywords: gene therapy; health economics; clinical evidence; contract law; payment models

1. Introduction

A payment agreement can be performed exactly as programmed and still produce a financial decision that its evidentiary basis does not justify. Consider a hypothetical gene-therapy agreement under which a manufacturer owes a rebate if a defined clinical event occurs within an agreed observation period. The relevant event is recorded at a second hospital, but the record reaches the payment administrator after the rebate calculation has been accepted. The software has calculated the agreed formula correctly [1]. The question concerns whether the late record should alter the accepted outcome determination and, if so, who may initiate the resulting financial adjustment. That problem exposes the institutional work concealed by the apparently straightforward commitment to pay according to results.

Gene therapies make the problem consequential because payment may precede reliable knowledge of long-term benefit. Certain payment models spread expenditure over time, pool financial exposure, and condition payment on therapeutic performance. This distinction clarifies why instalments alone do not transfer the risk of inadequate clinical benefit. Once payment depends on outcomes, however, a further question arises: how should the parties allocate the consequences of being unable to establish the relevant outcome reliably? A system may reduce uncertainty about when money moves while leaving uncertainty about whether it should move [2].

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The United States Cell and Gene Therapy Access Model provides an institutional setting in which to examine this distinction. The Centers for Medicare & Medicaid Services negotiates key terms with manufacturers for adoption in participating states' agreements, with an initial focus on sickle cell disease; its role includes support for data collection and reconciliation. This arrangement links public purchasing, contractual obligations, and clinical information across institutions. It should not be assumed to involve blockchain, tokenisation or autonomous payment, and this article makes no such claim. Its relevance to financial technology lies in the digital administration of contingent financial obligations, rather than in a presumed classification as a regulated financial product [3].

This article asks how law and contract should allocate verification responsibilities when clinical evidence determines a gene-therapy payment, particularly where that evidence is incomplete, subject to clarification, or corrected after settlement. It argues that verification risk deserves separate treatment because a rule governing therapeutic failure does not necessarily resolve an inability to determine whether failure occurred [4]. It then develops a qualified presumption of review for material corrections, distinguishing errors in applying an existing condition from attempts to replace that condition retrospectively. The presumption concerns access to a review process; it does not predetermine the result or create an unlimited right to recover money.

The analysis proceeds through conceptual differentiation, reconstruction of the applicable legal functions, and evaluation of institutional design. It uses a targeted selection of published scholarship, federal legislation, official programme materials, and verified guidance documents dated as of 20 October 2026. It is a doctrinal and normative article, not a systematic review, evaluation of programme performance, or report of interviews. Public application documents are treated as evidence of published design, not as substitutes for executed participation agreements or state contracts. Three illustrative scenarios test the proposed framework without implying that those scenarios have occurred in the Model. This method permits a defensible contribution before confidential agreements or patient-level data become available, while limiting claims about actual implementation.

2. Outcome Verification as a Condition of Financial Risk Allocation

2.1. Therapeutic Performance and the Production of a Contractual Outcome

Performance-based pharmaceutical contracting has an established body of literature [5]. Prior work has identified good practices for designing, implementing, and evaluating risk-sharing arrangements, including the specification of outcomes and the organisation of evidence collection. Subsequent analyses have documented implementation challenges across negotiation frameworks, outcome definitions, data infrastructure, administrative capacity, and legal alignment. These contributions confirm that existing research has not overlooked core evidentiary or institutional dimensions. The narrower task here is to explain the legal consequences of separating the production of evidence from the authority to determine its contractual meaning.

A clinical event, a clinical record, and a contractual outcome occupy distinct positions in this process. A hospital records what occurred during care delivery. An agreement selects certain features of that event-along with a defined observation period and evidentiary criteria-as relevant to a rebate calculation. An authorised actor must then assess whether the evidence satisfies those criteria. Finally, a financial administrator applies the corresponding formula [6]. While a single organisation may perform several of these functions, organisational consolidation does not erase their legally distinct roles. Authority to maintain a clinical record does not, by itself, confer authority to bind payer and manufacturer to a contractual classification.

This distinction also safeguards against the unwarranted extension of financial definitions into clinical domains. A patient may experience meaningful clinical benefit while meeting a narrowly defined rebate condition-or conversely, experience persistent difficulties without satisfying that condition. Contracts may legitimately adopt limited

endpoints for pricing purposes, provided they comply with applicable regulatory and ethical standards; however, such endpoints cannot substitute for comprehensive clinical evaluation of treatment effectiveness. The proposed framework therefore requires financial notices to explicitly state their contractual purpose and to avoid presenting a rebate classification as an overall medical judgment [1].

2.2. Three Risks with Different Remedial Consequences

Therapeutic risk pertains to whether the treatment delivers or sustains the benefit specified in the agreement. Verification risk pertains to whether available evidence permits a sufficiently reliable and authorized determination of that condition. Execution risk pertains to whether a valid determination is accurately translated into calculation, instruction, and settlement. These are analytical categories developed within this article [6]. Although they may overlap, each highlights a distinct type of remedial response.

When reliable evidence confirms the agreed adverse outcome, the appropriate response is the contractual performance consequence. When an electronic instruction contains an incorrect account identifier, the issue is correction of execution. When evidence is absent or contradictory, applying the failure rebate immediately may assign verification risk to the manufacturer despite absence of confirmed treatment failure [2]. Conversely, interpreting silence as success may assign that risk to the payer. Either approach may be negotiated, but neither constitutes a neutral technical default; its justification must be evaluated with regard to control over information, the costs of acquiring it, and the interests of affected patients.

These categories retain analytical utility even when evidence remains incomplete. A contract must ultimately specify who bears residual uncertainty [6]. This argument does not require indefinite investigation nor prohibit all default provisions. It requires that any default be explicitly recognized as an allocation of uncertainty-not misrepresented as definitive proof of a clinical outcome. Such clarity renders the financial arrangement transparent and enables independent assessment of whether a party has failed to meet a reporting obligation.

3. The Contribution Beyond Implementation Frameworks

Recent work further narrows the space for a contribution. A framework connecting contracting problems to alternative payment models and implementation choices has been proposed. Implementation conditions have been examined through interviews conducted across Europe [7]. Global literature on managed-entry governance and operational frameworks has been synthesised. Design and implementation uncertainties within the CMS Model have been identified. A general call for better data infrastructure would add little to these accounts.

The present contribution is more specific. It identifies a sequence of legally distinct decisions, locates the consequences of evidentiary uncertainty within that sequence, and proposes a rule for reviewing settled decisions when their underlying evidence changes. The test of the proposal is whether it differentiates matters requiring record amendment, clinical reassessment, contractual interpretation, or financial correction. It would be unnecessary where an existing agreement already performs those functions adequately [6]. The article accordingly offers an evaluative framework for agreements, rather than an assertion that all existing arrangements contain the same defect.

4. The Legal Structure of the CMS Model

4.1. Programme Authority and Rebate Obligations

Section 1115A of the Social Security Act authorises testing of innovative payment and service-delivery models within its statutory purposes and conditions. Section 1927 establishes the Medicaid framework for covered outpatient drug rebates. These provisions serve distinct functions: the former confers authority to test models; the latter defines the rebate framework within which specific arrangements operate. Neither

provision, considered independently, determines the meaning of every negotiated outcome condition or confers an unconditional right to revise a particular rebate.

Legal analysis must first identify the governing instrument before assigning obligations. A requirement in a federal participation agreement, a commitment in a state rebate agreement, and a duty imposed on a health-information holder may differ in terms of affected parties, enforcement mechanisms, and scope. Characterising the overall arrangement as a public programme does not eliminate its contractual nature [8]. Likewise, describing the rebate mechanism as contractual does not exempt public actors from compliance with applicable statutory requirements. Determining whether a financial determination is subject to a specific administrative review process requires careful examination of both the decision itself and its underlying legal foundation.

This functional distinction has practical implications for regulatory technology. A platform may record the time of information transmission, but the legal effect of receipt depends on the deadline stipulated in the governing instrument [9]. A record may be accepted for programme monitoring without meeting the evidentiary standard required for rebate calculation. Contract administration must therefore maintain clear attribution of authority for each decision, ensuring that technical events recorded in shared systems are not automatically assigned legal significance.

4.2. Reconciliation Already Forms Part of the Published Design

The March 2024 manufacturer application document explicitly addresses rebate documentation and reconciliation. Section 2.5.7 specifies a 45-business-day review period, provisions for raising concerns regarding documentation or data accuracy, requests for supplementary information within applicable legal boundaries, and structured consultation leading to resolution through state-administered processes [10]. It further clarifies that such procedural reviews are distinct from modifications to the agreed rebate methodology, and notes that final reconciliation arrangements will be formalized in participation agreements. This constitutes a well-developed procedural framework; therefore, any claim that no review mechanism exists is not supportable.

The remaining consideration involves how financial review procedures interact with updates to clinical evidence that occur outside their standard schedule. A notice may be accepted before the originating institution rectifies an inaccurate date or classification. The publicly available design document does not, on its own, determine how each executed agreement handles such instances [11]. Its existence necessitates a targeted examination of the relevant contractual terms, rather than assuming that late correction is either universally allowed or categorically prohibited. The proposed presumption in Part VI is intended to address this contractual interface.

Distinguishing between errors in evidence and changes to methodology is especially useful. Correcting the date of a qualifying event affects the application of an existing condition, whereas adopting a new endpoint due to advances in scientific understanding alters the fundamental terms of the arrangement. Contractual finality carries greater weight against the latter than against objectively verifiable errors in applying the former [12]. Even this distinction requires careful interpretation when an endpoint includes clinical terminology whose meaning may shift over time. Accordingly, the version of the endpoint governing the assessment must be clearly identifiable alongside the underlying record.

5. European Experience as a Limited Institutional Comparator

Italian registry experience illustrates how evidence infrastructure can support pharmaceutical contracting. The development of national registries for managed-entry arrangements concerning orphan medicines demonstrates the relevance of registry design to the allocation of monitoring functions, but does not establish that all such registries incorporate outcomes-based rebates or that foreign regulatory frameworks govern agreements in other jurisdictions. Registry practice raises key institutional design

questions, including data entry responsibility, claim validation procedures, and authorisation mechanisms for financial consequences.

These arrangements have been examined within broader comparative analyses of managed-entry agreements and their practical constraints. The methodological insight is that international institutional experience may inform functional design without conferring domestic legal authority. The analysis therefore remains grounded in United States federal responsibilities and agreement-specific implementation, avoiding the application of external legal standards or assumptions about data governance frameworks determining public health rebate mechanisms.

6. Health Information Rules and Financial Consequences

6.1. Permission to Use Information and Authority to Determine Payment

Certain uses and disclosures of health information for treatment, payment, and health-care operations are permitted under applicable privacy regulations, subject to defined conditions and scope. Such permission must be assessed according to the role of the actor involved, the nature of the information, and the specific purpose; it does not constitute a blanket authorisation enabling all participants in pharmaceutical financing arrangements to access complete clinical records. Manufacturers, registries, and covered providers may hold distinct legal responsibilities. Contractual convenience cannot substitute for a valid legal basis for disclosure.

Where the minimum-necessary standard applies, the information requested must be strictly limited to what is essential for the stated purpose. The regulatory framework also includes specific exceptions-such as certain treatment-related disclosures-meaning this standard cannot be applied uniformly across all clinical information exchanges. A payment-verification design should explicitly specify which functional requirement corresponds to which data elements, rather than routinely accepting the entirety of a patient's clinical record as standard input [13].

Even when a disclosure complies with privacy requirements, it does not automatically satisfy the conditions for financial disbursement [9]. Privacy permissions govern access and use only; the contractual agreement and relevant programme instruments define the authority and criteria for financial decisions. An institution may lawfully receive a record that is ambiguous, incomplete, or falls outside the agreed observation period. Mere possession of such information does not rectify those deficiencies. The system architecture must therefore clearly separate the act of obtaining evidence from the process of interpreting and validating it against contractual terms.

6.2. Amendment Rights Already Extend Beyond the Originating Record

Individuals have the right to request amendment of protected health information within a designated record set, subject to specified conditions and permissible grounds for denial. When an amendment is accepted, the responsible entity must follow prescribed procedures regarding the record and notify relevant recipients-including those known to possess the information and who may have relied, or foreseeably could rely, on it to the individual's detriment. The regulatory framework also establishes formal processes for handling denials and expressions of disagreement [9]. Therefore, the amendment mechanism cannot be characterized as limited to an isolated, localized modification.

However, updating records following an amendment differs fundamentally from recalculating commercial or public rebates. The amendment provision does not establish a uniform methodology, materiality standard, or time window applicable to all outcome-based agreements. Recipients must assess whether the amendment impacts the contractual condition, whether such assessment falls within their authorized scope, and which procedural rules apply to any resulting adjustment. This interpretive point is narrowly drawn yet meaningful: the amendment pathway constitutes one component of a broader corrective framework, while financial consequences remain governed by the underlying legal arrangement [3].

This further differentiates correction of factual inaccuracies from differences in professional interpretation. For example, an erroneous patient identifier may be corrected without altering the definition or significance of a clinical endpoint [10]. Divergent clinical assessments may necessitate additional expert evaluation. A claim that a contract selected an unsuitable endpoint involves a distinct type of consideration. Applying a single data-editing process to all three scenarios would obscure the distinct decision-making authority required for each and could inadvertently assign responsibilities beyond those conferred by the agreement.

7. Patients and the Limits of Bilateral Financial Remedies

The payer and manufacturer have direct interests in the amount of the rebate. Patients may have different interests in the accuracy of records, the burden of follow-up, and the clinical interpretation associated with a financial label. Governance of health-data use requires attention to potential harms and shared responsibility beyond reliance on individual control alone. Applied here, this perspective supports examining consequences for individuals who may not be parties to the payment contract [2].

It does not follow that every patient must become a party to every rebate-related matter or receive confidential pricing terms. A narrower contractual safeguard would allow a patient or authorised representative to raise a relevant evidentiary concern through an accessible clinical or programme channel, receive confirmation that it has been directed to the appropriate team, and obtain information about any effect on their own record or care. Contractual recalculation can remain a matter for authorised parties. The governance objective is to prevent a bilateral financial process from becoming the sole mechanism for addressing an error with consequences for the patient.

8. Digital Administration and the Distribution of Decision Making Power

8.1. The Limits of Transferring Financial Regulatory Concepts

Financial and regulatory technologies have been examined for their potential to reshape the production and use of regulatory information [11]. Such analysis highlights the appeal of integrating evidence, rules, and oversight within a digital process. However, this analogy faces significant limitations in health care. Clinical evidence is typically generated for clinical care, interpreted by qualified professionals, and subsequently repurposed for financial applications. Its mere availability does not render its contractual meaning self-evident, and digitisation of the process does not imply applicability of financial-services legislation.

This article adopts a functional definition of regulatory technology, referring to tools that support monitoring and implementation of applicable legal obligations. It does not assert that any specific administrative body has adopted a particular technological architecture, nor does it categorise every registry as a regulatory technology system. The central legal question concerns whether an implementation maintains clear distinctions among recording information, interpreting a clinical or operational condition, and authorising a financial consequence. These distinctions remain legally salient regardless of whether the administrator employs a shared ledger, a conventional database, or manual review augmented by electronic records.

8.2. Reliable Execution Cannot Settle a Disputed Premise

Automated contractual performance remains inherently dependent on legal institutions and the availability of remedies. In the present setting, execution can be accurate even when clinical input has been misclassified. A digital signature may identify the submitter of an outcome determination; however, it does not verify whether the signatory possessed the requisite clinical competence or contractual authority. An audit trail may preserve a decision while leaving its substantive validity subject to review [3].

Contemporary analyses of algorithmic governance highlight how standards, monitoring mechanisms, and corrective actions shape institutional power distribution. In an outcome-based agreement, the specification of which missing-data status triggers

payment directly influences economic exposure prior to any formal review. Such design choices constitute part of the broader allocation of contractual risk. An administrator must be able to articulate both the rule applied and the basis of authority enabling its application.

The response represents a constrained form of automation. Systems may verify field completeness, confirm authorization for determinations, and validate calculation consistency with those determinations. Where clinical interpretation remains unresolved, the system should retain an indeterminate status and escalate the matter to a person or body vested with appropriate authority. The existence of a functional escalation pathway is more critical than the nominal involvement of a human reviewer lacking access to relevant evidence or decision-making power.

9. Data Restraint and Continuity of Responsibility

Financial verification should ordinarily rely on information sufficient for the specific decision. A payer may require an authenticated statement confirming whether the agreed event occurred, while the clinical source maintains more detailed records for appropriately controlled review. This functional separation must not serve as a means to withhold necessary evidence from an authorized challenger. The arrangement must clearly specify when supporting information may be requested and how legal restrictions on disclosure will be upheld.

Continuity is equally critical when the observation period extends beyond a service-provider contract. The parties must designate who retains responsibility for preserving essential records, maintaining relevant definitions, and processing corrections following changes in registry or administrative oversight [4, 8]. A historical log without an accountable successor may document that a decision was made but provide no effective mechanism for review. Retention and transition responsibilities must align with applicable privacy, security, and records management requirements; the proposal does not confer any independent right to retain identifiable clinical information indefinitely.

10. A Responsibility Framework for Verification and Correction

10.1. Assigning Functions According to Authority and Control

The framework begins by distinguishing four functions: production of evidence, determination of the contractual outcome, execution of the financial consequence, and review of correction requests [1]. Each function requires a named responsible actor or a clearly defined delegation pathway. The allocation must specify the scope of decision-making authority for each actor, the types of evidence it may lawfully obtain, and the parties entitled to formally contest its decisions. These functions need not be assigned to four distinct organisations; in smaller arrangements, separation of authorisation, review, and access controls may be more practical than institutional duplication.

Responsibility should align with control over the relevant risk and the practical capacity to mitigate it. A provider may be well positioned to correct its own records but ill-suited to bear the financial impact of a large pharmaceutical rebate. A manufacturer may fund verification infrastructure without holding authority to adjudicate its own contested financial obligations. A central administrator may coordinate data flows without possessing the mandate to reinterpret individual state-level agreements. Liability, reporting requirements, and decision-making authority must therefore be explicitly delineated-even when these elements intersect operationally [7].

The following matrix presents proposed contractual allocations. It serves as an analytical design tool, not a description of existing CMS agreements. References to suspension apply solely to the contested financial component; they do not permit interruption of clinically appropriate care or supersede statutory payment obligations

Table 1. Proposed Allocation of Responsibilities for Outcome Verification and Correction in Gene Therapy Payment Agreements

Function	Proposed responsibility	Trigger for escalation	Proposed response
Evidence production	Named source institution and reporting coordinator	Missing, inconsistent or misidentified record	Targeted correction or proportionate alternative evidence
Outcome determination	Actor authorised under the governing agreement	Dispute over evidence or endpoint application	Reasoned determination with appropriate clinical input
Financial execution	Designated rebate or payment administrator	Calculation or instruction differs from approval	Correct the instruction and reconcile affected amount
Review after correction	Designated reviewer with power to revise or refer	Credible correction potentially material to settlement	Admissibility decision followed by bounded review
Continuity	Accountable principal and appointed successor	Provider, registry or administrator exit	Preserve lawful access and transfer unresolved responsibilities

10.2. A Procedure for Incomplete Evidence

An agreement should distinguish an incomplete record from a confirmed failure to satisfy the clinical condition. Upon identifying incompleteness, the administrator should document the known reason, notify the responsible institution, and request the minimal additional evidence required to resolve the question. A missed visit, failed transmission, or inconsistent assessment should not be treated uniformly. Their evidentiary weight and the appropriate responding entities differ.

The procedure must have a defined conclusion. At the end of a proportionate remediation period, the authorized decision maker should either apply the clinical condition based on the available evidence or implement an expressly agreed rule for unresolved uncertainty. Such a rule may allocate the unsettled amount between the involved parties, provide a limited adjustment, or adopt another mutually accepted resolution. Its validity depends on the terms of the agreement, applicable law, and operational context [1]. The rule must clarify that it addresses the allocation of unresolved financial risk-not that missing information implies a specific clinical outcome.

Responsibility for the missing evidence must be distinguished from the immediate financial consequence. A reporting breach may trigger a separate contractual remedy without determining the clinical endpoint [11]. Conversely, an agreed allocation for unresolved uncertainty may apply even in the absence of any wrongful conduct. Maintaining this distinction enables the contract to achieve a financial resolution without asserting an unwarranted clinical conclusion or requiring attribution of fault where the parties intentionally allocated uncertainty on a no-fault basis.

10.3. A Qualified Presumption of Review After Material Correction

Where credible new information corrects the evidentiary basis of a completed outcome determination, the agreement should presumptively permit an admissibility review if the correction could materially affect the amount or entitlement under the condition applicable at the original decision. This is a proposed contractual starting point. It can be implemented through negotiated terms or authorised programme requirements; it is not presented as a free-standing rule of current federal law.

The requesting party should identify the original determination, the corrected fact or record, its source and its potential effect on the outcome. A designated reviewer should first decide whether the request concerns an existing condition and is sufficiently credible and material to warrant substantive review. Materiality means a plausible difference to the applicable entitlement or calculation, rather than any alteration in the patient's history [12]. The initial test should not require the requester to prove the ultimate financial result before gaining access to the review needed to establish it.

Substantive review should use the definition and observation period applicable to the original determination. It should give affected financial parties a fair opportunity to respond, subject to lawful access restrictions, and produce reasons identifying what changed and why. If the clinical record was amended but the contractual outcome remains the same, the reviewer should close the request without recalculation. If the outcome changes, an authorised actor must then determine the permissible adjustment under the agreement and applicable law [11]. Review thus contains two decisions: whether the premise was materially affected and whether a financial remedy follows.

The presumption should be bounded by an agreed ordinary correction period and a narrower route for exceptional cases, including instances involving serious procedural error where applicable law permits [4]. Notice periods, evidentiary retention and the scale of the contested amount should inform those limits. An outer limit may remain appropriate even where factual uncertainty persists. The proposal rejects both an unqualified veto based on technical settlement and a perpetual obligation to reopen every historical decision. Its purpose is to make the terms of finality explicit before any formal resolution process begins.

10.4. Financial Adjustment without Retrospective Rewriting

Finality has several dimensions. The execution of a transfer may be operationally complete; the rebate calculation may still be contractually reviewable; the underlying clinical record may remain subject to a lawful amendment request. An agreement should clarify the relationship among these positions [3]. A completed transfer need not be technically reversed to permit a later compensating payment or credit. Such an adjustment must be grounded in legal authority and comply with applicable public-accounting standards, rebate provisions, and contractual terms.

Correction must be clearly distinguished from modifying the original allocation. A newly discovered event occurring within the original observation period may affect the application of the condition. A clinically significant event occurring after that period does not acquire financial relevance solely because it is important to the patient's care. Similarly, advances in medical understanding regarding appropriate success criteria do not automatically justify substituting the contractual endpoint for prior settlements. Prospective renegotiation and retrospective error correction must follow distinct approval pathways and version-control protocols [5].

This distinction supports both innovation incentives and budgetary integrity. Parties can reliably price an agreed exposure only if its substantive boundaries remain sufficiently stable. At the same time, stability in the governing rule does not preclude addressing demonstrable errors in its application. A well-defined correction mechanism operationalizes this balance and reduces incentives to influence outcomes through strategic timing or classification of evidence.

11. Testing the Framework through Hypothetical Disputes

11.1. A Missing Visit Following a Change of Care Provider

Assume an agreement requires a clinical observation at a specified point, but the patient has relocated and no record appears in the original registry. Under a default rule treating missing evidence as treatment failure, the manufacturer bears the financial liability even if the patient is clinically stable. Under a default rule treating it as success, the payer may forgo a rebate despite occurrence of a qualifying adverse event. Neither conclusion logically follows from the absence of the entry alone.

The framework first assesses whether the visit occurred at another site, whether data transmission failed, or whether the required observation was not performed. An authorized coordinator would seek proportionate substitute evidence where permitted by law and supported by clinical relevance. If uncertainty remains after the designated resolution period, the pre-agreed residual rule governs the financial outcome [2]. The patient must not bear financial responsibility solely due to administrative complications arising from relocation, and any additional monitoring requested exclusively for rebate verification must be clinically justified and funded under the arrangement. These are proposed procedural safeguards, not characterizations of current Model practice.

This scenario also illustrates why a blanket requirement for complete follow-up can distort accountability. A hospital may lack access to records held by other providers, and a patient may lack the means or authority to facilitate inter-institutional data sharing. Reporting obligations must therefore clearly define what information each party can reasonably obtain and assign responsibility for coordination. Otherwise, the actor with the least operational control may be unfairly tasked with ensuring outcome observability, while financially interested parties retain the benefits of the arrangement [11].

11.2. Conflicting Clinical Assessments of the Same Event

Assume two clinicians agree that an admission occurred but differ in their clinical evaluation of whether its cause meets the contractual endpoint definition. Improved interoperability will transmit both evaluations more efficiently, yet cannot resolve differences in professional interpretation. The source institution may correct a coding error; it should not be required to revise a clinically justified assessment solely to align the financial record with the administrator's preferred classification [10].

The appropriate resolution pathway depends on the nature of the difference. If the difference arises from clinical judgment, the agreement should provide for independent review by appropriately qualified professionals, with any relevant professional affiliations fully disclosed [11]. If the difference concerns the interpretation of the contractual endpoint, the designated contractual review mechanism should determine the outcome, incorporating clinical expertise as needed. The party financially affected by a particular classification may present supporting rationale, but must not unilaterally control the review process. The final determination must explicitly state whether it addresses a factual finding, a clinical assessment, or the contractual meaning of the endpoint.

This scenario also underscores the limited utility of mandating routine human review for all such differences. A reviewer lacking requisite expertise or decisional authority may simply reaffirm the initial assessment. Instead, the framework precisely defines the function under review, specifies the evidentiary requirements, and clarifies the authority responsible for implementing the resolution [10]. This ensures procedural rigor can be objectively evaluated and allows existing institutional review mechanisms to satisfy the requirement where they already meet these functional criteria.

11.3. A Corrected Record After Acceptance of the Rebate Calculation

Assume the parties accepted a calculation indicating no rebate, and a later verified correction reveals that an event occurred within the agreed observation period. Under the proposed presumption, the designated reviewer assesses credibility, timeliness, and potential materiality before determining whether to reopen the outcome. If the existing conditions are satisfied, the parties apply an authorised financial adjustment. If the corrected event falls outside the observation period, the record may be updated while the rebate remains unchanged [10, 13].

Now consider an altered fact: the record was accurate at settlement, but a subsequent contractual amendment adopts a broader endpoint for future cohorts. The proposed correction rule does not apply retroactively. This distinction is decisive-the first case involves a mistaken application of an existing rule, whereas the second introduces a new rule for a risk already allocated. The framework thus provides a rationale for reviewing one settlement while preserving the other, treating finality as context-dependent rather than absolute.

These scenarios illustrate internal coherence rather than empirical superiority. They clarify which questions a contract must address and where the proposed rule alters analytical reasoning [7]. They do not indicate the frequency of such events, the cost of review, or whether a particular Model participant already employs an adequate procedure. Such matters require subsequent empirical investigation and access to the operative contractual instruments.

12. Objections and the Limits of Procedural Protection

12.1. Review Can Consume the Value Created by Contingent Payment

The strongest objection is economic. Additional investigation, professional assessment, and retention may incur costs exceeding the expected improvement in rebate accuracy. A complex procedure may also delay agreement and reduce the willingness of states or manufacturers to participate. Existing implementation research already prioritizes feasibility when selecting a payment mechanism. A legal framework that disregards such costs would replicate the administrative challenge it aims to resolve.

The response is to calibrate verification according to the significance of the issue involved [3, 9]. Routine corrections may be handled by the administrator, while substantial clinical matters require specialist evaluation. Shared procedures can minimize duplication, and appropriate aggregation may lower transaction costs where permitted by the agreement. However, aggregation cannot guarantee fair distribution of missing observations or fully mitigate individual-record impacts. The costs and remaining inaccuracies associated with each design remain essential considerations in determining whether an outcomes-based condition is justified.

A simpler discount or alternative payment arrangement may be more appropriate when the outcome is difficult to observe, interpretation lacks stability, and the anticipated benefit from correction is limited. This constitutes a substantive constraint on the recommendation. The framework assesses whether contingent payment can be administered responsibly; it does not presume that the most information-intensive agreement yields optimal access or value.

12.2. Contractual Finality Supports Public and Private Planning

Manufacturers require predictable liability exposure, and public payers must finalize accounts and allocate resources efficiently. A correction right lacking a defined timeframe may create an unquantifiable contingent liability. The appropriate response is a transparent, publicly disclosed timetable, a clearly specified materiality threshold, and a narrowly defined exceptional pathway. Under this framework, ordinary finality functions as a mutually agreed allocation of residual risk following a reasonable opportunity to detect material errors.

This rationale does not imply that contractual finality validates the original classification [1]. A financial determination may remain settled while clinical documentation is updated and subsequent care decisions reflect newly available information. Maintaining this functional separation safeguards the integrity of the closing rule and ensures that financial settlement does not impede clinically appropriate record corrections.

13. Existing Law and Agreements May Already Provide Adequate Remedies

An institution-specific review may find that current reconciliation provisions, amendment procedures, and resolution mechanisms already integrate the relevant

functions. In that case, the proposal supports formalizing and applying those existing mechanisms, rather than establishing a separate adjudicative body. A documented deficiency in accessibility, scope of authority, or effectiveness would warrant targeted refinement [8]. A conceptual distinction alone does not indicate a regulatory gap.

Similarly, not every procedural limitation necessitates new statutory requirements at the federal level. Enhanced clarity in model instruments, intergovernmental agreements, data governance frameworks, or administrative mandates may suffice-depending on the origin of the issue and the applicable legal basis. Formal legislative action would require evidence that more focused instruments are inadequate to ensure required safeguards. This hierarchical approach ensures recommendations remain appropriately calibrated, without importing proportionality as a freestanding legal standard.

14. Contractual and Regulatory Implications

14.1. Specify the Interface between Evidence Correction and Reconciliation

Programme designers and contracting parties must clarify whether a correction to clinical evidence triggers a financial review, which party is responsible for initiating and receiving such review, and the applicable deadlines. A general obligation to maintain accurate records is insufficient to resolve these operational questions. Where a model agreement already addresses these points, its provisions should be fully integrated into the administrator's procedural framework. Where gaps exist, a precisely drafted clause can align evidence correction with reconciliation processes without necessitating revision of the entire payment methodology.

The clause must clearly differentiate the observation period, the reporting deadline, the standard objection period, and the absolute deadline for corrections. Conflating these temporal elements risks treating a late report of an in-period event identically to an event occurring outside the observation window. The former relates to evidentiary timing; the latter pertains to the substantive scope of the contractual arrangement. Financial consequences for each scenario must be explicitly defined in the agreement.

14.2. Require Reasons and Lawful Evidentiary Access for Material Decisions

A material outcome determination should specify the applicable contractual version, the evidence relied upon, the approved classification, and the authorized decision-maker. An affected party requires sufficient information to comprehend and seek review of the decision, consistent with applicable privacy and confidentiality requirements. Full clinical disclosure is not always required, but a binary result lacking supporting rationale may be inadequate when its underlying basis is subject to credible technical challenge.

Providing clear reasons also supports accurate attribution of responsibility. It enables differentiation among potential sources of error-for example, an inaccurate source record versus a correct record misinterpreted due to application of an incorrect processing rule, or a valid determination incorrectly implemented through a flawed instruction. This precision allows remedies to be directed at the specific contributing act, thereby reducing the tendency to attribute systemic outcomes solely to the institution maintaining the most prominent database.

14.3. Protect Clinical Independence and Fund Verification Duties

Reporting and review obligations must be supported by adequate resources and a transparent allocation of administrative costs [5]. Payers and manufacturers should not presume that standard clinical workflows can accommodate all additional observations mandated by financial agreements. While clinical safety follow-up and payment verification follow-up may overlap in practice, their distinct purposes and funding sources must remain clearly delineated.

Patient-facing safeguards should mitigate foreseeable burdens without assigning patients responsibility for rebate administration. A dedicated channel for raising concerns, facilitating accurate information routing, and maintaining strict separation between financial matters and clinical decision-making helps mitigate this risk. These measures are

intended to complement existing statutory rights and programme protections, and must not contravene any applicable legal prohibitions.

14.4. Evaluate Technology through Legally Meaningful Performance

Technology should be assessed based on whether an authorised determination can be traced, understood, challenged, and corrected within the applicable legal and regulatory framework. Useful criteria include identification of the governing endpoint version, preservation of source provenance, controlled access to supporting materials, and continuity of administrative oversight upon personnel transition. Such criteria may be satisfied using conventional infrastructure; adoption of novel technical mechanisms does not, by itself, indicate improved governance.

Evaluation must also document the resource costs associated with producing these assurances and explicitly identify instances where the process fails to yield a determinable outcome. A platform reporting high automated completion rates may obscure how frequently incomplete evidence is assigned to default categories. The legally relevant question concerns whether the resulting allocation was both authorised and substantively justified-including its impact on affected individuals and its alignment with governing agreements. These criteria are proposed for future empirical investigation rather than reflecting currently measured attributes of existing platforms.

15. Limitations and Directions for Further Research

The article's principal limitation is access to operative instruments. Published programme materials establish important design features but cannot resolve every state-specific term, later amendment or contested practice. The framework would need to be applied to executed agreements and governing state law before identifying an enforceable entitlement in a particular matter. It does not provide an exhaustive account of Medicaid beneficiary appeals, state contract remedies, anti-kickback rules, information-security obligations or public-accounting requirements. Those bodies of law may affect implementation and require focused analysis.

The normative proposal also rests on an unquantified trade-off [6]. Material review may improve accuracy and legitimacy, but its cost, duration and distributional effects remain to be established. Future research could analyse a defined sample of public and voluntarily disclosed agreements, map the relevant authority at each stage and interview practitioners about specific hypothetical matters. Interviews would clarify institutional considerations; they would not establish the meaning of law by professional consensus. Patient-level information would not be necessary to begin that investigation.

A further empirical test should examine whether missingness is associated with barriers to access or continuity of care. A neutral-looking default could distribute financial consequences unevenly if some populations are harder to follow through the required evidence infrastructure. That possibility is a research hypothesis, not a finding of this article. Demonstrating it would require appropriate data, ethics approval and a design capable of distinguishing documentation patterns from actual therapeutic outcomes.

Finally, transferability is functional rather than system-wide. Other health systems may allocate registry authority, reimbursement and patient rights differently. The useful comparative question is which institution performs each function and how correction acquires financial effect. The specific answer for the CMS Model cannot be transferred merely because another system also uses outcomes-based payment [6].

16. Conclusion

Outcome-based payment depends on an institutional process through which evidence becomes an authorised financial determination. Distinguishing therapeutic, verification, and execution risks makes that process legally visible. It clarifies why a missing record is not necessarily a failed treatment, why lawful access does not determine a rebate, and why a corrected clinical premise does not automatically trigger a financial adjustment.

The CMS Model's published reconciliation and resolution arrangements provide an existing foundation for this inquiry. The remaining design task is to connect those arrangements to the correction of relevant evidence, with attention to the instruments actually governing each relationship. A qualified presumption of review can make that connection where the corrected information is credible, timely, and potentially material to an existing payment condition. Defined limits and separate procedures for methodological change preserve the stability needed to price and administer the agreement.

The resulting account of finality is bounded. It permits a financial decision to close under known rules while preserving a proportionate route for addressing qualifying errors and supporting the integrity of clinical correction. For financial and regulatory technology scholarship, the broader contribution is to locate accountability in the authority and reviewability of the decision that precedes execution. For gene-therapy policy, it supplies a framework for deciding whether the promised transfer of therapeutic risk is supported by a workable allocation of verification responsibility.

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