A R C L I G H T I N S I G H T S ™

Policy White Paper

Due Process Denied:

Medicare Appeals, Wound Care, and the Right to a Meaningful Hearing

A Case Study in Rationale Drift, Episode Fragmentation, and the No-Rebuttal Ratchet

Important Notice

This white paper is prepared for policy analysis, legal theory development, and administrative reform discussion. It does not constitute legal advice. The patient case study has been anonymized. Patient names, Medicare identifiers, addresses, and other protected health information have been removed or generalized.

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AUDIENCE: Congressional Offices | CMS | Industry Stakeholders | Healthcare Policy Organizations

Executive Summary

Medicare's audit and appeals system offers providers multiple levels of review. Those levels can create the appearance of due process while withholding its substance.

Consider what a coherent regulatory process looks like for a business facing related billing disputes arising from the same customer, the same service model, the same contract, and the same course of performance over several weeks. A rational process would group those related disputes before one adjudicator using one factual record. It would not send each invoice or each day's work to a different decisionmaker, allow the government's theory to change at each stage, and require the business to rebuild the same factual record every time. Yet that is precisely how Medicare wound-care appeals can function. Same patient. Same wound. Same care plan. Same product. Multiple claims, multiple appeal numbers, multiple reviewers, multiple judges, and shifting denial theories at every level, with no consistent mechanism to ensure the episode is evaluated as an episode.

Three overlapping defects drive this failure.

Rationale drift and the no-rebuttal ratchet. The operative basis for denial shifts across appeal levels. A documentation denial from the program integrity contractor becomes a product-evidence denial at the MAC, then a categorical Q-code investigational theory at the QIC. At each level the provider responds to the theory it received. At the next level a new theory appears in the decision. The provider has no mechanism to respond to that new theory at the same level where it was introduced. The only option is to escalate. This is the no-rebuttal ratchet: the process always moves forward, the theory keeps shifting, and the provider chases a moving target at its own expense while recoupment continues.

Episode fragmentation. Wound care is longitudinal. A course of treatment for a complex wound depends on conservative-care history, wound response, infection monitoring, serial measurements, graft-sizing rationale, and healing trajectory. Medicare's appeals architecture is transactional. The same clinical story must be defended before different adjudicators, under potentially different legal theories, with no requirement for consistent outcomes across the treatment episode. A provider should not have to prove the same wound-care episode multiple times on multiple fronts unless a clinically material difference distinguishes each date of service.

Recoupment before meaningful review. Medicare contractors may resume recoupment after QIC action and maintain it through ALJ hearing, Medicare Appeals Council review, and federal court. When the QIC decision is the first place the dispositive denial theory appears, the provider has not had a genuine opportunity to contest the theory before financial recovery begins. For a small practice, the gap between QIC decision and ALJ resolution commonly spans more than a year. Recoupment running during that period can threaten practice survival before any adjudicator reaches the clinical merits.

Three additional features compound the core problem. The documentation-only trap means a provider submitting thousands of pages of records has no structured mechanism to guide reviewer attention, clarify context, or correct a factual error before denial issues. A recent Victory Wound Care audit required submission of 4,587 pages of documents. A process of that volume, with no opportunity for dialogue, produces predictable errors. Q-code fair-notice failure occurs when contractors convert an administrative billing code into retroactive proof of noncoverage, requiring providers to litigate inter-agency ambiguity they did not create. And the contractor accountability gap means that upstream errors reversed downstream impose costs

on providers, OMHA, and taxpayers with no transparent consequence for the contractor whose findings drove the cascade.

The legal foundation is well established. Mathews v. Eldridge requires courts to weigh the private interest affected, the risk of erroneous deprivation, and the government's burden of providing additional safeguards. All three factors support targeted reform here. FCC v. Fox holds that regulated parties must know what is required of them before enforcement proceeds. SEC v. Chenery establishes that agency action must be judged on the grounds the agency actually invoked. Medicare wound-care appeals test all three principles and come up short.

Victory Wound Care's experience with a single patient illustrates what failure looks like in practice. Several dates of service from one wound-care episode reached ALJ merits review and resulted in fully favorable decisions. Related dates in the same clinical episode were dismissed without merits review because the procedural path was different. Same patient. Same wound. Same clinical record. Different outcomes because the claims traveled different procedural routes.

The reforms proposed here are modest and administratively feasible. Episode-of-care docketing, QIC claim maps, Material Issues Notices, pre-denial reviewer conferences, rationale ledgers, automatic good cause for consolidation ambiguity, same-episode adjudicator assignment, and recoupment stays after rationale drift would each improve procedural coherence without changing Medicare's substantive coverage standards. They would not require Medicare to pay improper claims. They would require Medicare to give providers a fair, organized, and meaningful chance to defend themselves.

Core Finding

Medicare's appeals process is organized around claims. Wound care is organized around patients.

A provider should not have to prove the same wound-care episode multiple times on multiple fronts unless a clinically material difference distinguishes the dates of service at issue. De novo review should mean independent review of the relevant clinical episode. Claim-level atomization produces incoherence when the medical question depends on a longitudinal course of care.

Governance Map

The table below identifies each procedural defect, how it appears in Medicare wound-care appeals, the due-process harm it causes, and the proposed reform.

Procedural Defect	How It Appears	Due-Process Harm	Reform
Rationale drift	Documentation denial becomes product-evidence denial, MPIM theory, or Q-code investigational theory across levels.	Provider responds to one theory while the decision turns on another.	Material Issues Notice and rationale ledger.
No-rebuttal ratchet	Reviewer introduces a new rationale in the decision itself.	Provider can only respond by escalating; no same-level response available.	Same-level response window before new dispositive rationale is finalized.
Evidence front-loading	Provider must submit all evidence before QIC decision while QIC may raise new issues.	Provider cannot anticipate undisclosed theories; new-evidence burdens apply on escalation.	Automatic good cause for evidence responsive to new theories.
Episode fragmentation	Same patient, same wound, same care plan split across multiple claims, judges, and appeal numbers.	Provider relitigates the same clinical history before different adjudicators.	Episode-of-care docketing.
Documentation-only trap	Provider submits thousands of pages with no structured chance to guide attention or correct misunderstandings.	Key evidence is overlooked; erroneous denials multiply into avoidable appeals.	Pre-denial reviewer conference for high-volume audits.
Opaque consolidation	QIC consolidates claims without finality and deadline tables.	Provider loses appeal rights despite diligent pursuit.	Mandatory QIC claim map and finality table.
Q-code fair notice failure	Contractors infer investigational status from administrative billing code classification.	Provider must litigate CMS/FDA coding ambiguity rather than clinical necessity.	CMS guidance clarifying HCPCS status is not a coverage determination.
Recoupment pressure	Recoupment resumes after QIC action, including when QIC introduced the operative theory for the first time.	Provider may face practice-ending financial pressure before meaningful merits review.	Recoupment stay after rationale drift or appeal-scope ambiguity.
Contractor accountability gap	Upstream findings reversed downstream with no transparent performance consequence.	Error costs shift permanently to providers, OMHA, and taxpayers.	Contractor accuracy metrics tied to appeal outcomes and rationale reversals.

I. Introduction: When Multiple Appeals Don’t Equal Meaningful Process

Medicare post-payment audits serve a legitimate and necessary function. The Medicare Trust Funds must be protected from fraud, waste, abuse, and improper payment. Effective program integrity also requires accurate initial determinations, stable rationale across review levels, and procedures that give legitimate providers a genuine opportunity to defend medically necessary care.

The current system frequently fails that third requirement in wound-care audits.

Consider what it would mean to face related billing disputes in a functioning regulatory process. The disputes arise from one customer, one service model, one contract, and one disputed interpretation of the applicable rules over several weeks or months. The same witnesses, the same documents, and the same performance sequence are relevant at every proceeding. No rational regulatory body would assign each disputed invoice to a different decisionmaker, permit the government to change its legal theory between hearings, and require the business to rebuild the same factual record from scratch each time. That structure increases the chance of inconsistent outcomes and rewards procedural endurance over truth.

Medicare wound-care appeals can operate in precisely that way.

The same patient. The same wound. The same care plan. The same product. The same clinical history. Multiple claims, multiple appeal numbers, multiple reviewers, multiple judges, shifting rationales at every level, and no consistent mechanism to ensure the episode is evaluated as an episode.

Due process requires more than a sequence of proceedings labeled ‘appeal.’ It requires a meaningful opportunity to understand and answer the actual basis for deprivation. In the Medicare audit context, that means the provider must know what theory it needs to defeat, have a realistic opportunity to respond to that specific theory at the level where it first appears, and receive review organized around the clinical reality of the service being examined.

Wound care exposes this defect clearly because wound treatment is inherently longitudinal. Serial skin substitute applications cannot be fairly evaluated in isolation from each other. Each application depends on the prior course of conservative care, wound response, infection status, serial measurements, product-selection rationale, and healing trajectory. A claim-by-claim appeals system misses the logic of the care plan even when the record contains the complete clinical story.

II. The Legal Frame: Due Process Requires Practical Fairness

The leading procedural due-process framework comes from Mathews v. Eldridge, 424 U.S. 319 (1976). Courts applying that test weigh three factors: the private interest affected by the government action, the risk of erroneous deprivation under existing procedures and the value of additional safeguards, and the government's interest in maintaining current procedures, including administrative and fiscal burden.

Applied to Medicare wound-care audits, each factor points toward targeted reform.

The private interest is substantial. Post-payment audits generate overpayment demands that can reach hundreds of thousands of dollars. Recoupment takes effect during appeals and continues running. The timeline from a UPIC determination to an ALJ decision commonly spans eleven to seventeen months, with administrative burden measured in staff hours, legal fees, and consultant costs throughout. A mobile wound-care operation works on narrow margins. Recoupment pressure across a multi-year appeal can end the practice before any adjudicator reaches the merits, leaving patients without access to care that subsequent review may find was medically reasonable and necessary.

The risk of erroneous deprivation is elevated by several features of the current system acting together. Rationale shifts require entirely different evidentiary responses. Evidence front-loading rules require submission before the operative theory is known. Documentary-only review allows factual misunderstandings to harden into denials without a correction mechanism. Claim fragmentation means one clinical episode may reach inconsistent outcomes depending solely on which procedural path each date of service travels. Each of these features independently increases the probability of error. Together, they create a compounding effect.

The value of additional safeguards is high relative to their cost. A Material Issues Notice before a QIC rationale shift costs little to implement and would allow same-level response to new theories. A pre-denial reviewer conference for high-volume audits would reduce erroneous denials and avoidable appeals. A rationale ledger tracking theory changes across levels would make drift visible and auditable. Episode-of-care docketing would reduce duplicative adjudication of the same clinical history. None of these reforms change what Medicare covers. They improve the accuracy and coherence of how Medicare measures it.

The government's fiscal and administrative interest is also served by these reforms. A system that drives legitimate providers into multi-level, multi-front litigation over shifting theories imposes systemic costs through OMHA docket growth, contractor rework, avoidable appeals, and provider insolvency that eliminates access to care. Procedural clarity upfront reduces those downstream costs.

FCC v. Fox Television Stations, 567 U.S. 239 (2012), reinforces the fair-notice dimension. The Court explained that regulated parties must know what is required so they may act accordingly, and that imprecise standards create conditions for arbitrary enforcement. Medicare providers operate in a dense regulatory environment. They rely on CMS coding assignments, LCD coverage criteria, FDA pathway determinations, MAC billing articles, and Medicare payment history to determine which products may be billed and under what clinical circumstances. When contractors later treat those same signals as proof of noncoverage, the regulatory foundation the provider reasonably relied upon becomes the instrument of the denial.

SEC v. Chenery Corp., 318 U.S. 80 (1943), holds that agency action must be judged on the grounds the agency actually invoked. Medicare's de novo review structure complicates a strict Chenery claim, since QICs and ALJs review independently rather than affirming prior decisions

on stated grounds. The underlying principle still matters. A provider must be able to identify and mount a defense against the actual operative basis for adverse action. When that basis changes at every level, coherent defense becomes structurally impossible.

III. Program Integrity Without Process Integrity Fails Both Goals

Program integrity and procedural fairness are not competing values. They are mutually dependent.

Medicare program integrity depends on accurate determinations. A process that permits shifting theories, fragments clinical episodes, externalizes contractor error costs, and substitutes documentary volume for substantive review does not protect the Trust Funds efficiently. It converts program integrity review into provider endurance. The provider who can sustain multi-level litigation across shifting theories survives. The provider who cannot may close, leaving patients without care that subsequent ALJ review might have found appropriate.

Strong due process is not a barrier to program integrity. It is a condition of program integrity. Accurate initial determinations conserve public money by reducing avoidable appeals. Clear and stable rationale reduces downstream adjudication. Contractor accountability creates incentives for accuracy upstream rather than waiting for correction at ALJ. Pre-denial dialogue reduces erroneous denials before they become multi-year contests. Each of those process improvements serves both goals simultaneously.

The current system's most serious program integrity failure is not that providers sometimes win on appeal. It is that the error rate is not being measured in a way that attributes responsibility to the point of origin. When a UPIC or MAC determination is reversed at ALJ, the reversal may be recorded as the provider's success without any systematic analysis of whether the initial determination was a contractor error, a process design failure, or a genuine provider deficiency. That measurement gap insulates contractors from performance consequences and perpetuates the conditions that generate avoidable appeals. The contractor accountability reforms in Tier 3 of this paper's recommendations directly address that structural failure.

IV. The Regulatory Architecture That Creates the Problem

Understanding the due-process defect requires understanding the specific rules that shape each level of Medicare appeals.

At redetermination, the Medicare Administrative Contractor reviews the initial determination. The provider may submit evidence and arguments. The MAC may affirm, modify, or reverse.

At reconsideration, the Qualified Independent Contractor conducts an independent, on-the-record review. Under 42 CFR section 405.968, the QIC may obtain evidence on its own initiative and may raise new issues not raised at redetermination. When medical necessity under Section 1862(a)(1)(A) is at issue, the QIC must convene a panel of physicians or appropriate health care professionals. The QIC is not bound by LCDs or CMS program guidance, although it should give substantial deference to applicable policies and explain any departure. It has broad authority to apply a different policy framework than the one used at redetermination.

That authority is the structural problem. The regulation permits QICs to depart from the framework used below and raise new issues, but it does not provide a matching same-level notice-and-response mechanism for the provider. The defect is not simply that the QIC changed the rationale. The defect is that the system permits the change after the provider has already

submitted its appeal evidence and without giving the provider a same-level opportunity to respond before the decision issues.

The provider faces an asymmetric evidence burden throughout. Under 42 CFR section 405.966, a party filing a reconsideration request should present all relevant evidence before the QIC decides. Absent good cause, evidence not submitted before the QIC decision may be precluded at ALJ. Under 42 CFR section 405.1018, new evidence submitted by a provider at ALJ that was not presented at the QIC must include a written explanation for the omission, or it will not be considered. CMS and its contractors are not subject to the same new-evidence restriction in the same way. A QIC may introduce a new theory in its decision; the provider must then escalate and explain why it could not have anticipated and responded to that theory at an earlier stage.

These rules together create the no-rebuttal ratchet. The provider submits its full evidence before the QIC decides. The QIC may introduce a new theory in the decision. The provider learns the new theory when the decision arrives. The provider cannot respond at the QIC level. Escalation to ALJ is the only path, and the journey takes months while recoupment continues.

Recoupment rules make the timing problem acute. Under 42 CFR section 405.379, contractors must cease recoupment during a timely redetermination and reconsideration request. After the QIC issues its decision, contractors may resume or initiate recoupment. Recoupment then remains in effect through ALJ hearing, Medicare Appeals Council review, and federal court. When the QIC decision is the first disclosure of the operative denial theory, the provider faces recoupment for a debt it has never had a fair opportunity to dispute on the actual basis for the demand.

Medicare's consolidated proceedings rule already recognizes the efficiency of grouping related disputes. Under 42 CFR section 405.1044, ALJs may hold consolidated hearings when common issues overlap across pending appeals. That efficiency logic should be applied upstream and systematically when serial wound-care claims involve the same patient, wound, product, and care plan.

V. The De Novo Problem: Independence at the Wrong Unit

De novo review is a genuine protection. Each adjudicator reviews the claim independently, without deference to prior levels. That independence matters.

In serial wound care, de novo review produces incoherence when applied to individual claim fragments rather than to the clinical episode. Claim-level atomization is especially costly when combined with the no-rebuttal ratchet: each fragment may be reviewed under a shifting theory before a different adjudicator, with no mechanism to reconcile outcomes or ensure consistent standards across the episode.

The medical question in skin substitute therapy is not whether one application on one date satisfied abstract criteria in isolation. The medical question is whether the patient's wound-care course, taken as a whole, supported initiating and continuing that therapy. Answering that question requires the full clinical sequence: what conservative care was tried, how the wound responded, whether infection was controlled, whether measurements showed progress, why the product was selected, and whether continued treatment remained clinically justified.

De novo review applied claim by claim treats each date of service as a freestanding clinical universe. The fifth application cannot be evaluated fairly without the context of the first four. An adjudicator reviewing a single date sees a partial picture even when the full record is submitted, because the relevance of each piece of evidence depends on understanding the treatment arc.

Episode-level de novo review would preserve genuine independence while reducing incoherence. Each adjudicator would still reach an independent conclusion about coverage. The evidentiary unit would be the treatment episode rather than the claim fragment. A prior favorable finding for the same patient, wound, and care plan would not automatically bind subsequent adjudicators, but any materially inconsistent outcome would require an explanation identifying the clinical, evidentiary, legal, or procedural distinction driving the different result. That approach is more faithful to clinical reality and more efficient for OMHA.

VI. Eight Legal Theories Supporting Reform

1. Rationale Drift and Fair Notice

A provider's defense is built around the theory it must defeat. When the operative denial theory changes across appeal levels, a provider who constructed a careful rebuttal to the disclosed theory finds itself answering a different case at the next level.

Rationale drift takes three forms in Medicare wound-care audits. Category drift occurs when the type of denial changes, such as from documentation deficiency to categorical product noncoverage. Policy framework drift occurs when the legal basis shifts, such as from an applicable LCD to MPIM general guidance. Evidentiary standard drift occurs when the type of proof required changes, such as from clinical documentation to peer-reviewed product literature.

All three forms appeared in Patient A's record. Qlarant's initial findings focused on documentation: wound-onset date, four weeks of conservative care, wound management planning, comorbidity and infection documentation, product quantity relative to wound size, and post-application documentation. Victory responded with a clinical timeline, conservative-care explanation, infection-management chronology, product-utilization rationale, wound-measurement analysis, and photographic documentation.

The QIC later acknowledged that the medical records supported the procedure, baseline assessment, trialed conservative treatment, wound measurements, and amount of product used and wasted. It then denied payment because Q4205 was experimental and investigational as denoted by Q-code status nomenclature, and because MPIM Chapter 3, Section 3.6.2.2 was the correct policy rather than LCD L35041. A documentation case had become a categorical product-coverage case. A patient-record defense had become a scientific, coding, and policy dispute.

The deeper problem is where that shift placed the burden. Providers do not create HCPCS codes. Providers do not control FDA pathways or write billing articles. They rely on that regulatory infrastructure to make coverage decisions. When the theory becomes a Q-code investigational theory, Victory is no longer being asked to prove that its care was appropriate for one patient. It is being asked to refute the Medicare and FDA systems it relied upon to determine what products were available, which had undergone appropriate regulatory review, and which Medicare signaled as potentially payable. A bedside provider should not bear the burden of resolving ambiguity created by the government's own coding, coverage, and payment systems.

2. The No-Rebuttal Ratchet

Rationale drift would be manageable if the provider had a same-level opportunity to respond before the new theory became final. In Medicare appeals, that mechanism does not exist.

When the QIC introduces a new rationale in its decision, the provider's option is to appeal to ALJ. That means months of additional delay, continued recoupment, additional legal and administrative cost, and no opportunity to speak with anyone at the QIC who could evaluate a direct response. There is no mechanism to request that the QIC reconsider the new theory, no pre-decision conference, and no way to determine whether the QIC understood the provider's prior arguments before changing the framework.

The result is a ratchet. Each review level may change the theory. The provider responds by escalating. The theory may change again. The provider escalates again. The financial clock runs throughout. Even a provider who ultimately prevails at ALJ may have spent years and substantial resources litigating theories it never had a fair chance to address at the level where they first appeared.

3. Episode Fragmentation

The same wound-care episode can move through Medicare appeals across different claim numbers, different appeal numbers, different QIC groupings, and different ALJ assignments. When it does, the provider defends the same clinical story before adjudicators who may reach inconsistent conclusions through no fault of either party.

Patient A's post-surgical abdominal wound dehiscence required a course of skin substitute therapy. The clinical history supporting each application was largely the same: the same surgical origin, the same conservative-care course, the same comorbidities, the same infection management, the same wound trajectory, and the same product rationale. Three dates of service reached ALJ merits review and resulted in fully favorable decisions. Related dates within the same episode were consolidated under one QIC appeal number and then dismissed at ALJ on timeliness grounds after the provider argued that consolidation ambiguity had obscured the applicable deadline.

This is not a scheduling inconvenience. It is a structural failure. A provider who wins three favorable ALJ decisions in a wound-care episode cannot use those wins to protect related dates in the same episode from procedural elimination. There is no episode-level reconciliation mechanism, no same-episode assignment rule, and no requirement that later adjudicators explain inconsistent outcomes on closely related dates.

4. The Documentation-Only Trap

Medicare wound-care appeals are conducted entirely through paper submissions. A provider cannot guide a reviewer through a complex record, flag where a key document appears among hundreds of pages, or correct a factual misunderstanding before it hardens into a denial.

Victory's second Qlarant audit required submission of 4,587 pages of medical records and supporting documentation. No process of that volume, operating without dialogue, produces reliable results. Reviewers working through that record without any mechanism for clarification will miss things. A wound-number designation may appear inconsistent until the provider explains that it references a different anatomical site. A product quantity may seem excessive until the provider explains that tunneling, undermining, and depth required a larger application surface than two-dimensional wound measurements suggest. A wound-onset date may conflict with another record until the provider explains the difference between the surgical origin date and the home health start-of-care date.

None of these clarifications require argument or advocacy. They require a brief exchange that the current process does not allow. A structured pre-denial conference would not transform audits into negotiations. It would be limited, documented, and focused on issue clarification. The

contractor identifies preliminary concerns. The provider identifies where the record addresses each concern and provides relevant context. The contractor documents which issues remain unresolved. This exchange would reduce erroneous denials, reduce avoidable appeals, reduce OMHA docket burden, and improve the quality of the record that travels to higher review levels.

5. Q-Code Fair Notice and Inter-Agency Ambiguity

Q-codes are administrative billing codes assigned by CMS on a temporary basis to products and services that do not yet have a permanent HCPCS code. They are billing placeholders. They tell a provider how to submit a claim. They do not determine whether an item is covered, investigational, or experimental.

The QIC's theory in Patient A's case inverted that logic. It treated Q4205's status as a Q-code as evidence that the product was investigational and therefore noncovered. ALJ Grace found this reasoning confusing and inconsistent with Novitas's own billing article, which stated that Q-codes representing skin substitutes are covered when administered consistently with the related LCD and billed with application codes. ALJ Wells reached the same conclusion, accepting that Q-code status does not make an item experimental or investigational, and finding Q4205 was FDA approved and medically reasonable and necessary for this patient.

Two ALJs independently reviewed the Q-code investigational theory and rejected it. The QIC applied it anyway. Victory spent two levels of appeal defeating a theory that neither the applicable billing guidance nor the adjudicators who examined the evidence supported. CMS should issue prospective guidance stating that HCPCS Q-code classification is an administrative coding designation and does not establish investigational, experimental, or noncovered status.

6. Recoupment Before Meaningful Review

Medicare contractors may resume recoupment after QIC action and continue collecting through ALJ hearing, Medicare Appeals Council review, and federal court. The policy rationale is that the QIC provides meaningful intermediate review, making indefinite stays of collection impractical.

That rationale holds when the QIC decision addressed the same theory the provider had a full opportunity to contest. It does not hold when the QIC decision is the first time the dispositive theory appears. A provider who received a documentation denial from UPIC, responded during MAC redetermination, and then received a Q-code investigational theory for the first time in the QIC decision has not had a meaningful opportunity to contest the operative basis for the demand before recoupment begins.

Recoupment should be stayed when the QIC introduces a materially new rationale for the first time in its decision, when consolidation creates reasonable ambiguity about what has been finally decided, or when a related date in the same patient episode has already received a favorable ALJ finding. These targeted stays would protect providers from insolvency caused by procedural circumstances rather than clinical deficiency, while preserving Medicare's ability to collect after coherent review.

7. Contractor Accountability as Root Cause

Contractor accountability sits at the root of every other defect described in this paper. It is not one recommendation among many. It is the structural condition that makes all other failures self-perpetuating.

The appeals system acts as the error-correction mechanism for upstream contractor determinations. But the cost of correction is externalized entirely away from the entity that created the error. When Qlarant or a MAC issues a determination that is later reversed at ALJ, the provider bears the administrative and financial cost across two or more years of appeals. OMHA bears the adjudicatory cost. The Medicare Trust Fund bears the systemic cost of avoidable escalation. The contractor's accuracy rate for the reversed determinations may remain largely invisible in its performance metrics.

That structure creates a system with no learning mechanism at the point of origin. A contractor whose Q-code investigational theory is rejected by two ALJs as inconsistent with existing guidance faces no apparent adjustment to its interpretive approach. A contractor whose documentation findings are overturned at a high rate faces no evident performance consequence. CMS should evaluate contractors using downstream appeal outcomes: ALJ reversal rates by service category and contractor, rationale reversal rates, frequency of QIC theory substitution, same-episode inconsistency rates, and avoidable appeal rates. Contractors with repeated patterns of downstream correction should face contract performance consequences proportionate to the systemic costs their errors impose.

8. Government-Induced Reliance and the Fair-Notice Obligation

Government-induced reliance and retroactive enforcement shock present a compelling fair-notice argument in the skin substitute market.

Medicare spending on skin substitutes grew from approximately $256 million in 2019 to over $10 billion in 2024. That figure appears in the ALJ decisions for Patient A, citing a CMS press release from October 2025. The spending increase reflected decisions made by CMS about coding assignments, pricing methodologies, payment rates, and coverage criteria. Providers did not design that architecture. They relied on it.

When CMS assigns a Q-code, publishes a payment rate, creates an LCD permitting coverage when clinical criteria are met, and processes payment for thousands of claims over several years, providers reasonably understand those signals as evidence that the product category is potentially payable for appropriate patients. Aggressive audit enforcement that retroactively treats the same product category as categorically investigational, without clear prospective notice of that interpretation, imposes an enforcement shock on providers who made decisions based on the government's own signals. The appropriate response is prospective clarity: stable coverage criteria, unambiguous Q-code guidance, transparent product-evidence standards, and payment reform designed before enforcement becomes the primary correction mechanism.

VII. The Documentation-Only Trap: Volume Without Understanding

A process that substitutes volume for dialogue does not serve accuracy. It serves paper trails.

When a reviewer examines a wound-care audit record without any ability to ask questions, the record's complexity works against the provider. The wound-care notes must be understood in relation to home health agency documentation, hospital discharge summaries, surgical operative reports, laboratory values, specialist consultations, and product documentation. Each piece gains meaning from its context within the full clinical sequence. A reviewer who cannot ask a clarifying question may misread that context entirely.

In Patient A's case, a QIC decision described the patient as presenting for advanced wound therapy for a non-healing pressure ulcer. The full clinical record consistently describes a post-

surgical abdominal wound dehiscence following a May 2024 bypass procedure. These are not interchangeable wound types.

Case Study Error: Wrong Wound Type

The QIC described Patient A's wound as a non-healing pressure ulcer. The record described a post-surgical abdominal wound dehiscence following bypass surgery in May 2024. These are distinct wound types. A pressure ulcer arises from sustained mechanical pressure causing tissue ischemia, typically over bony prominences. A post-surgical dehiscence is a failure of a wound to heal after a surgical incision, often involving infection, tissue necrosis, and disruption of sutured layers. The difference matters clinically and legally: different etiologies, different conservative-care expectations, different documentation requirements, different policy analyses. A five-minute clarification with the provider would have corrected this error before the denial became final. A documentation-only process allowed a basic factual mistake to enter the operative decision and travel through two more review levels before an ALJ corrected it.

That mischaracterization did not arise from bad faith. It arose because a reviewer working through a complex record, without any structured mechanism for clarification, misidentified the wound type. The mischaracterization then shaped the coverage analysis applied in the denial and required multiple levels of appeal to correct.

The pre-denial conference proposed in Recommendation 4 is not a negotiation. It is an information exchange. The contractor identifies what it cannot resolve from the record. The provider identifies where the record addresses each concern. The contractor documents whether the issue remains open. The process is brief, recorded, and limited to factual clarification. The benefit is proportionate: fewer erroneous denials, fewer avoidable appeals, and a cleaner record at every subsequent level.

VIII. Case Study: Patient A and the Appeals System in Practice

A. The Clinical Episode

Patient A received serial skin substitute applications for a complex post-surgical abdominal wound dehiscence following bypass surgery in May 2024. Victory's records documented the surgical origin, the course of conservative care, hospitalization and debridement, infection monitoring, negative pressure wound therapy, serial wound measurements, and the clinical rationale for initiating skin substitute therapy after conservative treatment stalled over thirty days. The clinical question was episode-level: did this patient's wound-care course, taken as a whole, support the use of skin substitute therapy?

The appeals process converted that episode-level question into a sequence of disconnected claim-level disputes.

B. The UPIC Findings

Qlarant reviewed 20 claims across 11 beneficiaries, allowing 4 and denying 16, producing an 80% claims error rate. For Patient A specifically, Qlarant identified concerns involving wound-onset documentation, conservative care, wound management planning, comorbidity and infection documentation, product quantity relative to wound size, and post-application wound description. Victory's rebuttal responded directly to each concern with a clinical timeline, surgical-origin explanation, conservative-care history, infection management chronology, wound-measurement analysis, product-sizing rationale, and photographic documentation.

C. The Shifting Denial Theory

The following table illustrates how the denial theory changed at each level and what each shift required Victory to defend.

Review Level	What the Reviewer Focused On	What Victory Had to Defend
UPIC / Qlarant	Documentation and medical necessity: wound onset, conservative care, treatment plan, comorbidities, infection control, product quantity, and post-application description.	Patient record, wound timeline, conservative-care history, infection management, wound measurements, and product-utilization rationale.
MAC / Novitas	Product literature, FDA pathway, homologous use, and whether the product provides scaffolding for skin growth versus serving as a wound covering.	Product science, FDA 361 HCT/P regulatory classification, homologous-use definition under 21 CFR § 1271.3c, and published peer-reviewed literature.
QIC / C2C	Q-code status as proof of investigational classification; MPIM Chapter 3, Section 3.6.2.2 rather than LCD L35041.	The meaning of CMS HCPCS administrative coding, FDA pathway inter-agency ambiguity, and the distinction between investigational classification and code assignment.
ALJ	De novo merits review of the full clinical and regulatory record.	Full clinical and regulatory context: LCD L35041 applicability, Q-code guidance, product documentation, wound measurements, conservative-care history, and healing trajectory.

At the UPIC level, the dispute was about whether Victory's documentation supported the care delivered. By the time the QIC issued its decision, the dispute had become one of administrative coding classification and inter-agency regulatory ambiguity. Victory was no longer being asked to prove that it treated a patient appropriately. It was being asked to litigate the meaning of a CMS-assigned HCPCS code.

D. The QIC Decision

The QIC decision for Patient A's July 2024 date of service acknowledged that the medical records supported the procedure, baseline assessment, trialed conservative treatment, wound measurements, and amount of product used and wasted. It then denied payment because Q4205 was experimental and investigational as denoted by Q-code status nomenclature, and because MPIM Chapter 3, Section 3.6.2.2 was the correct policy rather than LCD L35041. The QIC decision for the consolidated group of Patient A claims directed multiple claims and dates of service to a complete decision under one lead claim number and denied on the same Q-code investigational theory.

This is the core case study fact. The medical-record dispute became a product-category dispute. The patient-level clinical analysis was effectively set aside in favor of an administrative coding argument.

E. ALJ Merits Decisions: Favorable Outcomes When the Record Was Heard

Three Patient A dates reached ALJ merits review. All resulted in fully favorable decisions. ALJ Grace found the QIC's reasoning confusing and inconsistent with Novitas guidance. The decision rejected the QIC's substitution of MPIM Section 3.6.2.2 for LCD L35041 without adequate explanation, finding the LCD directly applicable and MPIM general guidance

applicable only when no LCD addresses the service at issue. The decision also rejected the Q-code investigational theory as contradicted by the July 2020 revision to Billing Article A54117, which removed Q-code-specific restrictions and confirmed that Q-code skin substitutes are covered when administered consistently with the related LCD and billed with application codes.

ALJ Wells issued fully favorable decisions for two later Patient A dates, rejecting the Q-code investigational theory, finding Q4205 used as a recognized homologous wound covering, determining the product was FDA approved under Section 361, and concluding the treatment was medically reasonable and necessary. ALJ Wells also noted that Victory uses skin substitute products in fewer than 10% of its cases and employs data-driven protocols to assess candidacy and track progress.

When adjudicators reached the merits, Victory prevailed. Two ALJs, reviewing the same product and the same denial theories independently, found the theories inconsistent with existing guidance and unsupported by the clinical record.

F. Consolidated Claims and the Procedural Break Point

The related Patient A consolidated claims never reached merits review. Victory argued that the QIC had grouped multiple claims and dates of service under one Medicare Appeal Number, directed them to a complete decision under a lead claim number, and that this structure created reasonable ambiguity about which dates had been finally decided and which remained pending. Victory also received subsequent QIC correspondence under the same appeal number addressing additional claims, which it understood as confirmation that the reconsideration remained active.

The ALJ dismissed the request for hearing as untimely, finding that the July 2025 QIC reconsideration triggered the 60-day filing window and that Victory's December 2025 ALJ request arrived outside that window. Good cause was denied.

The result was that the same patient episode produced fully favorable ALJ decisions on three dates and no merits review on closely related dates because the claims traveled different procedural paths. That outcome is the due-process problem made visible. Not a close clinical question. Not a weak record. A procedural divergence that allowed some dates to be heard on the merits and eliminated others before any adjudicator reached the clinical case.

IX. What the Record Shows

The Patient A record demonstrates systemic failure, not individual error.

The denial theory changed at every level. Documentation concerns became product-literature and FDA-pathway arguments, which became categorical Q-code investigational theory. The required defense changed each time. The no-rebuttal ratchet operated throughout. Each new theory appeared in a decision that could not be contested at that level. Escalation was the only response, and escalation takes months while recoupment continues.

A critical factual error, the pressure ulcer mischaracterization, persisted through the QIC level because the process contained no mechanism for clarification before decision. The same clinical episode split across procedural paths. Dates that reached ALJ merits review produced fully favorable decisions. Dates that traveled through QIC consolidation were eliminated on timeliness grounds without any adjudicator considering the clinical record.

When adjudicators reached the merits, Victory won. Two ALJs, reviewing the same product and the same denial theories, reached the same conclusion: the theories were inconsistent with existing guidance, the clinical record supported the care, and the patient's wound improved significantly during treatment. The system produced enough process to say an appeal existed. It did not produce enough coherence to ensure the episode received a meaningful hearing.

X. Policy Recommendations

The twelve recommendations below are organized in three tiers reflecting implementation complexity and urgency. Tier 1 reforms require no new rulemaking. Tier 2 reforms involve OMHA and Council process changes. Tier 3 reforms address contractor accountability and financial protection.

#	Reform	What It Does
Tier 1 — Immediate Administrative Fixes (No Rulemaking Required)		
1	**Material Issues Notice**	Before finalizing a reconsideration on a materially different rationale, the QIC provides written notice of the new theory and a defined response window. Providers receive fair notice at the level where the theory first appears.
2	**QIC Claim Map and Finality Table**	Every multi-claim QIC decision includes a claim-level table showing decision status, ALJ deadline, lead-claim incorporation, and pending claims. Eliminates deadline ambiguity created by consolidation.
3	**Rationale Ledger**	Each appeal record tracks the denial basis at every level, the policy cited, and the evidence required. Makes rationale drift visible and auditable.
4	**Pre-Denial Reviewer Conference**	For high-volume audits, a short structured exchange between contractor and provider occurs after preliminary findings. Limited to record clarification and factual correction before denial issues. Reduces erroneous denials and avoidable appeals.
5	**Good Cause Presumption for Contractor-Created Ambiguity**	Good cause for late filing is presumed when contractor consolidation, lead-claim incorporation, claim-number changes, delayed notice, or subsequent same-appeal-number correspondence reasonably obscured the applicable deadline.
Tier 2 — OMHA and Council Process Reforms		
6	**Episode-of-Care Docketing**	Serial wound-care claims involving the same patient, wound site, provider, product, and treatment window are grouped and assigned to the same adjudicator. Individual payment determinations may still issue. The evidentiary record reflects the clinical episode.
7	**Same-Patient Adjudicator Assignment**	OMHA assigns related wound-care appeals to the same ALJ or attorney adjudicator when feasible. Extends the existing consolidated-proceedings rule upstream to the intake stage.
8	**Explain-Departure Rule**	When a prior ALJ decision found services payable in the same patient episode, a subsequent adjudicator reviewing a related date explains any materially different outcome by identifying the clinical, evidentiary, legal, or procedural distinction.
9	**Medicare Appeals Council Episode Reconciliation**	The Council has explicit authority to identify and reconcile inconsistent ALJ outcomes within the same patient episode and to remand for consolidated episode-level consideration when procedural splitting produced incomplete adjudication.
Tier 3 — Accountability and Financial Protection Reforms		

10	**Contractor Accuracy Feedback Loop**	CMS evaluates contractors using downstream appeal outcomes: ALJ reversal rates, rationale reversal rates, QIC theory-substitution frequency, same-episode inconsistency rates, and avoidable appeal rates. Repeated patterns of downstream correction carry contract performance consequences.
11	**CMS Q-Code Guidance**	CMS issues clear guidance that HCPCS Q-code classification is an administrative billing designation and does not establish investigational, experimental, or noncovered status. Guidance specifies how Q-code products are evaluated under LCDs, billing articles, FDA pathway determinations, and reasonable-and-necessary analysis.
12	**Recoupment Stay After Rationale Drift or Appeal-Scope Ambiguity**	Recoupment is stayed when the QIC introduces a materially new rationale for the first time, when consolidation creates reasonable finality ambiguity, or when a related date in the same patient episode has already received a favorable ALJ decision.

XI. Draft Regulatory Language

The following draft provisions operationalize the core recommendations. They are offered as starting points for regulatory and sub-regulatory action.

Provision	Draft Language
A. Episode-of-Care Docketing	For claims involving serial wound-care services furnished to the same beneficiary for the same wound or wound site during a clinically related treatment period, CMS contractors and OMHA shall identify and process the claims as a related episode of care for purposes of appeal tracking, evidence review, and adjudicator assignment, unless the contractor or adjudicator explains in writing why separate adjudication is clinically or legally necessary.
B. Material Issues Notice	When a Qualified Independent Contractor determines that its reconsideration will be resolved on a materially different basis than the rationale stated in the redetermination decision, the QIC shall provide the appellant a written Material Issues Notice identifying the new issue, the policy authority at issue, and the category of evidence relevant to the new issue. The appellant shall have a defined response period before the reconsideration decision is issued.
C. QIC Claim Map and Finality Table	Any QIC reconsideration decision involving more than one claim, date of service, internal control number, appeal number, or lead claim incorporation shall include a claim-level finality table identifying each claim addressed, the decision status for each claim, the applicable ALJ filing deadline for each claim, and any claims remaining pending under the same appeal number.
D. Good Cause Presumption	Good cause for late filing shall be presumed when a provider demonstrates that contractor consolidation, claim-number changes, lead-claim incorporation, delayed notice, or subsequent contractor correspondence under the same appeal number reasonably obscured the finality date or applicable filing deadline.
E. Pre-Denial Reviewer Conference	In post-payment audits meeting defined thresholds of volume or complexity, the contractor shall provide the provider an opportunity for a structured pre-denial conference after preliminary findings are issued and before a final overpayment determination. The conference shall be limited to clarification of the record, identification of relevant evidence, and correction of factual misunderstandings. The contractor shall prepare a written summary of unresolved issues following the conference.
F. Explain-Departure Rule	When a Medicare adjudicator reaches a conclusion materially inconsistent with a prior favorable decision involving the same provider, beneficiary, wound site, product category, and treatment episode, the decision shall identify the material clinical, evidentiary, legal, or procedural distinction that supports the different outcome.

XII. Conclusion: The Right to Be Heard Must Match the Reality of Care

What happened to Victory Wound Care should not happen to any provider operating in good faith.

A series of treatments for one patient, one wound, and one care plan became a multi-year, multi-front legal contest. The provider faced three different denial theories across four levels of review. It built careful rebuttals to each theory it received, then watched new theories appear in the decisions that followed, with no mechanism to respond at the same level where they arose. It submitted thousands of pages of documentation and still received a decision that mischaracterized the wound's basic clinical nature. It prevailed when adjudicators reached the clinical merits. It lost procedurally on related dates that were never evaluated on the record.

The most troubling dimension of this case is where the process took the dispute. At some point, Victory stopped arguing about whether it had provided appropriate care to a patient who needed it. The system asked it to argue about Q-code nomenclature, MPIM policy chapters, FDA pathway classifications, and the meaning of inter-agency coding guidance. The government's own billing and regulatory infrastructure became the instrument of the denial. A bedside provider should not bear the burden of resolving ambiguity created by the government's own coding, coverage, and payment systems.

The no-rebuttal ratchet and the documentation-only trap together convert what should be a coherent clinical defense into a multi-front procedural endurance contest. The theory shifts. The claims fragment. The record grows. The money flows out. And the provider who can outlast the process survives, while the one who cannot may close, leaving patients without access to care that two independent ALJs found was medically reasonable and necessary.

The reforms described in this paper are practical and proportionate. Episode-of-care docketing aligns the appeal process with the clinical unit of wound care. Material Issues Notices give providers fair warning before new theories become final. Rationale ledgers make theory drift visible. Pre-denial conferences close the information gap that produces errors like the pressure ulcer mischaracterization. QIC finality tables prevent consolidation ambiguity from eliminating appeal rights. Contractor accountability metrics address the upstream source of downstream burden. Recoupment stays protect providers from practice-ending financial pressure during the gap between a rationale shift and a meaningful hearing.

Medicare can protect the Trust Funds and provide due process. These goals reinforce each other. Accurate initial determinations conserve public money. Clear rationale reduces appeals. Coherent episode-level adjudication improves legitimacy. Provider dialogue improves the record that reaches every subsequent level. Contractor accountability strengthens program integrity over time rather than shifting error costs downstream indefinitely.

A system that forces providers to prove the same episode before multiple judges while the theory shifts at each level is not efficiently protecting public funds. It is converting program integrity into procedural attrition. The changes described here would make the process coherent enough for legitimate providers to defend themselves.

That is not too much to ask.