DATA ACCESS

Information blocking and the designated record set: what the federal EHI rule actually requires of a practice

ABSTRACT

The 21st Century Cures Act information blocking rule (45 C.F.R. Part 171) inverted the default posture of American health-record law. Where HIPAA permits sharing and allows up to 30 days to answer a patient's right-of-access request, the information blocking rule treats unreasonable interference with the access, exchange or use of electronic health information (EHI) as a violation unless required by law or covered by a documented regulatory exception. Since October 2022 EHI has encompassed the entire HIPAA designated record set, not merely USCDI summaries. For five years enforcement lagged the rule; by late 2026 federal disincentives for providers, up to $1 million civil monetary penalties for developers and exchanges, and active ASTP/ONC nonconformity investigations are all in place, with 2,450 possible claims logged through July 2026. Empirical studies of immediate test-result release show overwhelming patient preference (95.7% in a four-center survey of 8,139 users, including 95.3% of those with abnormal results) alongside a measurable rise in pre-clinician viewing (from 10.4% to 40.3% at one center, and 68.6% nationally in 2024 survey data) and doubled six-hour message volumes. This review sets out the rule's scope, exceptions, enforcement machinery and operational record requirements as of November 2026.

Type Regulatory and operational review **References** 26 **Reading time** 15 min

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1 From permitted disclosure to prohibited interference

For twenty years after the HIPAA Privacy Rule took effect, compliance in an independent medical practice meant controlling what did not leave the office. HIPAA creates a patient right of access under 45 C.F.R. § 164.524, with a thirty-calendar-day response clock and one thirty-day extension, and it *permits* disclosures for treatment, payment and health care operations without requiring them.[1,2] A clinic that routed portal lab results through a seven-day clinician hold, or printed paper charts on request three weeks later, stayed comfortably inside HIPAA's perimeter.

Section 4004 of the 21st Century Cures Act (42 U.S.C. § 300jj-52) and its implementing regulation at 45 C.F.R. Part 171 reversed that baseline.[3,4] Under § 171.103, a regulated actor commits information blocking when it engages in a practice that, except as required by law or covered by a regulatory exception, is likely to interfere with, prevent or materially discourage the access, exchange or use of electronic health information (EHI).[4] The prohibition took

effect on April 5, 2021, expanded to the full designated record set on October 6, 2022, acquired civil monetary penalties for developers and networks in September 2023 and Medicare disincentives for providers in July 2024, and entered active federal investigation in 2025 and 2026.[4,5,6,7]

2,450	95.7%	68.6%	$1M
possible information blocking claims logged through July 2026	of 8,139 surveyed portal users preferring immediate result release	of US adults with portal access viewing results before clinician contact	statutory ceiling per violation for certified IT developers and HINs

Practices routinely misunderstand three parts of the rule. First, it applies to every health care provider under 42 U.S.C. § 300jj(3), whether or not the practice uses certified EHR technology.[3,8] Second, the data in scope is no longer the compact USCDI clinical summary; it is the entire electronic designated record set.[9] Third, an informal office habit — holding imaging reports until a follow-up visit, charging a flat portal fee, or declining to share records electronically because a fax is easier — can trigger a complaint unless it satisfies every element of a specific exception.[4,10]

2 Actors, knowledge standards and what EHI actually includes

Part 171 regulates three categories of actors: health care providers, health IT developers of certified health IT, and health information networks or exchanges (HINs/HIEs).[4] The statutory knowledge standard splits them into two tiers. Developers and HINs/HIEs violate the rule if they know, *or should know*, that a practice is likely to interfere with access, exchange or use of EHI. Health care providers are held to a narrower actual-knowledge standard: the provider must know that the practice is unreasonable and is likely to interfere with, prevent or materially discourage EHI access, exchange or use.[3,4] That distinction protects accidental misconfiguration more than institutional policy; once a practice writes a blanket delay rule or refuses an electronic request repeatedly, actual knowledge is difficult to contest.

The designated record set, not USCDI

During the rule's first eighteen months, EHI was temporarily limited to the data classes in the United States Core Data for Interoperability (USCDI) version 1, a subset whose gaps for clinical retrieval are reviewed in a companion paper in this library. On October 6, 2022, that transitional cap expired.[4,9] Under 45 C.F.R. § 171.102, EHI now means electronic protected health information (ePHI) to the extent that it would be included in a designated record set as defined by HIPAA at 45 C.F.R. § 164.501, regardless of whether the group of records is maintained by a HIPAA covered entity.[1,4]

The designated record set sweeps far beyond problem lists and structured labs. For a medical practice it comprises medical records and billing records about individuals, plus any other electronic records used in whole or in part to make decisions about individuals — progress notes, consultation letters, diagnostic images and reports, scanned outside faxes filed into the chart, signed procedure logs, prior-authorization packets, itemized billing statements and portal message threads.[1,9] Two narrow exclusions carry over verbatim from HIPAA: psychotherapy notes (maintained separately from the medical record under § 164.501) and information compiled in reasonable anticipation of, or for use in, a civil, criminal or administrative action or proceeding.[1,4] Everything else sitting in the practice's electronic chart is EHI.

That scope has an immediate consequence for AI-assisted records. As set out in the library's write-path specification, an unreviewed draft note that has not been attested is distinct from a signed clinical document, yet practices and EHR vendors still have to define cleanly in their designated record set policy which encounter artifacts are used to make decisions about a patient and which are transient system intermediates.[1]

3 The regulatory exceptions: safe harbors with documentation burdens

Part 171 does not make every withholding or delay unlawful. Instead, Subparts B, C and D define regulatory exceptions — safe harbors that prevent a practice from being treated as information blocking if, and only if, the actor satisfies every condition of the exception at the time of the decision.[4] Failing to meet an exception does not automatically prove information blocking (an investigator still evaluates whether the conduct meets the definition and knowledge standard), but relying on an exception without meeting its prerequisites forfeits the safe harbor.[8]

TABLE 1

Core information blocking exceptions in 45 C.F.R. Part 171 (Subparts B, C and D), grouped by operational function, incorporating amendments through HTI-1 and HTI-3 as of November 2026.[4,11,12]

Exception (45 C.F.R.)	When a practice may rely on it	Condition most often missed
Preventing Harm (§ 171.201)	Individualized determination by a licensed clinician (or data-corruption finding) that withholding will substantially reduce risk of harm to life or physical safety (or substantial harm for a representative)	Cannot be used as a blanket delay for all labs or pathology; requires an individualized clinical judgment tied to the specific patient and record
Privacy (§ 171.202)	Federal or state privacy precondition is unmet, HIPAA denial ground applies, or the patient requested not to share	Must apply the precondition consistently and document the specific legal barrier or patient request
Security (§ 171.203)	Practice is directly related to safeguarding confidentiality, integrity and availability of EHI	Must be tailored to the specific security risk and implemented consistently under a written organizational policy, not ad hoc exclusion of a third-party app
Infeasibility (§ 171.204)	Uncontrollable events, inability to segment non-shareable EHI, third-party modification requests, Manner Exception Exhausted, or infeasible under the circumstances	Requires a written response explaining why the request is infeasible within 10 business days of receiving it
Health IT Performance (§ 171.205)	Planned or unplanned downtime necessary to maintain or improve health IT performance	Downtime must be for no longer than necessary and applied in a consistent, non-discriminatory way
Protecting Care Access (§ 171.206)	Added by HTI-3 (Dec. 2024): good-faith belief that sharing EHI creates substantial risk of legal action over lawful reproductive health care	Requires good-faith individualized or policy-based determination tied specifically to reproductive health care legal exposure
Manner (§ 171.301) & TEFCA Manner (§ 171.403)	Fulfills the request in the manner requested, or works through specified alternative content/manner tiers (or TEFCA exchange when both parties participate)	Cannot drop straight to paper or fax when the practice is technically able to fulfill in the requested electronic manner
Fees (§ 171.302) & Licensing (§ 171.303)	Reasonably cost-based fees or reasonable, non-discriminatory IP licensing terms for exchange	Electronic patient access via a portal or API cannot be charged a fee; fees cannot be based on opportunistic or exclusionary pricing

Two operational details trip clinics up more than any others. First, the Preventing Harm exception (§ 171.201) is narrower than many clinicians assume: for a patient's own record, the harm threshold is physical safety or life, mirroring HIPAA's § 164.524(a)(3) reviewable denial ground, not ordinary emotional distress upon reading an abnormal biopsy or MRI report.[2,4] Second, the Infeasibility exception (§ 171.204) carries a hard ten-business-day written notice clock; silent non-response forfeits the exception even when fulfilling the request truly was impossible.[4,11]

State law can still require a delay because Part 171 explicitly carves out practices "required by law."[4] Several states, including California and Texas, have enacted statutes creating short mandatory holds on sensitive pathology, genetic or radiology results before electronic portal release so clinicians have a window to call the patient.[13] Tennessee had

not enacted an equivalent mandatory portal-delay statute for general adult test results as of late 2026; a practice in Cleveland, Tennessee therefore works directly under the federal default unless an individualized exception or specific confidentiality rule (such as 42 C.F.R. Part 2 substance-use confidentiality or minor-consent rules) applies.

4 Immediate test-result release: what the empirical literature shows

No operational consequence of Part 171 generated sharper debate among clinicians than the end of automatic release holds on laboratory, imaging and pathology results. Five years of post-Cures empirical studies now replace speculation with measurements across millions of results.

Workflow impact and patient-before-clinician viewing

Steitz and colleagues analyzed 3,221,394 test results delivered to 294,799 patients at Vanderbilt University Medical Center between January 2020 and April 2021, spanning that institution's January 20, 2021 switch to Cures Act immediate release.[14] Among tests previously subject to any release delay, the share viewed by patients before a clinician jumped nearly fourfold, from 10.4% to 40.3%. Daily patient-initiated portal messages sent within six hours of viewing a previously delayed test nearly doubled, rising from a median of 77.5 (IQR 13.75–105.25) to 146 (IQR 12.0–169.0) messages per day.[14]

A later Vanderbilt cross-sectional study of 290,349 adult patients reviewing 968,774 outpatient results between 2022 and 2023 found that patients repeatedly refreshed the portal in anticipation of 25.9% of all results.[15] Refreshing was more frequent for highly sensitive tests, yet refresh behavior while awaiting *nonsensitive* results predicted a higher probability of sending a message within 24 hours — suggesting that anticipatory worry and patient communication habits, not merely abnormal pathology, drive inbox workload.[15] How clinics handle the resulting message stream is examined in the library's review of AI-drafted patient message replies.

Patient preference, comprehension and disparities

Against that inbox burden stands an unusually lopsided preference finding. In a multisite survey of 8,139 portal users across four US academic medical centers after April 2021 (response rate 18.8%), Steitz and colleagues found that 95.7% (7,520 of 7,859) wanted test results released through the portal as soon as available, even if their clinician had not yet reviewed them.[16] Crucially, that preference held among patients who had actually received abnormal results: 95.3% (2,337 of 2,453) of respondents with non-normal results still wanted immediate portal release, though a subset reported increased worry and 39.9% (2,123 of 5,318) turned to an internet search after viewing their result.[16] In a smaller interview study of 230 solid-tumor patients reviewing pathology reports via portal, 85.2% (196 of 230) preferred immediate release even for bad news, while 14.7% would opt out over fear of distress or misunderstanding medical terminology.[17]

National survey evidence published in August 2026 clarifies both reach and comprehension. Analyzing 4,982 respondents from the 2024 Health Information National Trends Survey (weighted to 174.7 million US adults offered portal access with a recent medical test), Bather and colleagues found that 68.6% (95% CI, 66.4%–70.9%) viewed immediately released test results before hearing from their clinician.[18] Only 6.6% (95% CI, 5.1%–8.1%) rated their

understanding of the results and care implications as poor, while 26.8% understood fairly well, 31.7% well and 34.9% very well. Yet poor comprehension clustered unequally: it was significantly associated with lower digital literacy, living in the Midwest or South, and reporting medical care discrimination.[18]

TABLE 2

Selected post-Cures empirical studies of immediate test-result release through patient portals.

Study	Design and sample	Primary finding
Steitz et al., 2021[14]	Pre–post cohort, 294,799 patients, 3.22M results (1 center)	Patient-before-clinician review of previously delayed tests rose from 10.4% to 40.3%; 6-hour messages rose from median 77.5 to 146/day
Steitz et al., 2023[16]	4-center survey, 8,139 respondents (18.8% response)	95.7% preferred immediate portal release (95.3% among abnormal results); 39.9% searched the internet after viewing
Steitz et al., 2025[15]	Cross-sectional, 290,349 patients, 968,774 results (1 center)	Patients refreshed portal before release for 25.9% of tests; refreshing for nonsensitive results predicted 24-hour messaging
Bather et al., 2026[18]	HINTS 2024 national survey, 4,982 US adults (weighted 174.7M)	68.6% viewed results before clinician contact; 6.6% rated comprehension poor, concentrated in lower digital literacy and Midwest/South

LIMITATIONS OF THE IMMEDIATE-RELEASE LITERATURE

The multisite preference survey had an 18.8% response rate among active portal users at academic medical centers, which selects for higher health and digital literacy than a rural or safety-net clinic.[16] The single-center Vanderbilt cohorts reflect one MyChart configuration and notification workflow.[14,15] And self-rated comprehension in HINTS is not an objective test of whether a patient correctly interpreted a reference range or pathology staging.[18] The evidence supports immediate release as a patient-preferred default paired with plain-language context and proactive pre-test counseling, not as a substitute for clinician follow-up.

5 EHI export (§ 170.315(b)(10)) versus FHIR APIs

Practices and even EHR sales teams frequently conflate two separate federal data-access mechanisms: standardized FHIR APIs and complete EHI export. Both stem from the 2020 Cures Act Final Rule, yet they serve different jobs and expose different slices of the chart.[4,19]

The standardized API criterion, 45 C.F.R. § 170.315(g)(10), delivers structured FHIR R4 resources conforming to US Core and the mandated USCDI version.[19] It excels for patient-authorized apps, automated read-only integrations and population queries over standardized fields. What it cannot deliver is everything outside USCDI —

billing ledgers, custom specialty questionnaires, scanned referral packets, consent forms, procedural fluoroscopy images or clinic-specific structured tables.

That gap is what 45 C.F.R. § 170.315(b)(10), *Electronic Health Information export*, was written to close.[4,19] Applicable to certified health IT developers since December 31, 2023, the criterion requires two capabilities: (1) single-patient EHI export runnable by an authorized practice user without developer assistance, and (2) patient-population EHI export for switching EHR systems or bulk migration.[19] Unlike (g)(10), (b)(10) mandates no single wire format; instead, the export must be electronic and computable, accompanied by a publicly accessible hyperlink to documentation describing the export format so a receiving system can parse it.[19]

For an independent practice, the distinction matters twice: first when a patient requests their *complete* electronic record rather than a portal summary (where a FHIR USCDI bundle alone leaves out billing records and scanned attachments), and second when the practice leaves an incumbent EHR vendor (where legacy "data extraction fees" or proprietary database lock-in can constitute information blocking by the developer under § 171.302).[4,19]

6 Enforcement arrives: OIG penalties, CMS disincentives and 2026 actions

For more than four years after April 2021, information blocking operated largely on compliance letters and voluntary self-correction because neither enforcement rule was complete. That period ended in stages between 2023 and 2026.[5,6,7]

First, on July 3, 2023, the HHS Office of Inspector General (OIG) published its Civil Monetary Penalties final rule (88 FR 42820, codified at 42 C.F.R. Part 1003, Subpart N), effective September 1, 2023.[5] Developers of certified health IT and HINs/HIEs found by OIG to have committed information blocking face civil monetary penalties of up to $1 million per violation (subject to statutory inflation adjustment), with enforcement prioritized toward conduct causing patient harm, impairing care delivery, lasting a long duration or causing financial loss to federal programs.[5]

Second, on July 1, 2024, HHS and CMS published the Provider Disincentives final rule (89 FR 54662), effective July 31, 2024.[6] Because the Cures Act did not authorize OIG to fine health care providers directly, OIG investigates and refers substantiated findings to CMS, which imposes three programmatic Medicare penalties:[6]

- **Eligible hospitals and critical access hospitals:** loss of meaningful EHR user status under the Medicare Promoting Interoperability Program, cutting 75% of the annual market basket update (or reducing CAH payment from 101% to 100% of reasonable costs).
- **MIPS-eligible clinicians:** a score of zero in the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category (normally 25% of the final MIPS score), driving a negative Medicare Part B payment adjustment.
- **Accountable Care Organizations:** ineligibility to participate in the Medicare Shared Savings Program (MSSP) for at least one year for the provider or ACO involved.

Third, active federal enforcement began in late 2025 and 2026. In September 2025, HHS, ASTP/ONC and OIG announced a coordinated enforcement push.[7,20] Public portal telemetry from ASTP/ONC recorded 2,563 submissions and 2,450 possible claims of information blocking between April 2021 and July 31, 2026, with patients submitting the largest share and health care providers most frequently named.[20,21] In February 2026, ASTP/ONC officials announced that the agency had begun issuing notices of potential nonconformity to certified EHR developers; by June and October 2026, trade reporting documented both provider-organization corrective action plans and seven letters of potential nonconformity issued across the program.[22,23] The HTI-5 final rule released on October 26, 2026 trimmed several certification criteria for developers while leaving Part 171 provider obligations intact, with HTI-5 information blocking proposals still under agency review.[24]

WHO THE 2024 DISINCENTIVES MISS — AND WHO THEY STILL REACH

A small independent practice that is exempt from MIPS (for instance, below the low-volume Medicare threshold) and does not participate in an MSSP ACO currently falls outside the three 2024 CMS disincentives.[6] That gap is narrower than it looks: HHS explicitly signaled future rulemaking for additional provider disincentives, HIPAA's Office for Civil Rights (OCR) independently enforces the Right of Access Initiative with direct financial settlements against small practices under 45 C.F.R. § 164.524,[2,25] and OIG publishes substantiated information blocking determinations publicly.[6]

7 Operationalizing compliance in an independent clinic

Information blocking compliance is rarely solved by buying a new software badge; it fails at the front desk, in release-of-information queues and in unexamined EHR defaults.[10,24] Five operational controls close almost all realistic exposure for an ambulatory practice:

1. **Inventory the designated record set in writing.** List every electronic repository holding clinical or billing records used to make decisions about patients — EHR notes, portal threads, external faxes, imaging reports, procedure logs and billing statements — and confirm that a single-patient electronic export actually pulls them all.[1,19]
2. **Eliminate blanket release holds not mandated by state law.** Configure labs, imaging and notes to release to the patient portal promptly on availability, replacing blanket multi-day holds with pre-test counseling for sensitive biopsies and individualized, documented clinical holds only when § 171.201 or a specific state statute is genuinely met.[4,16]

3. **Audit electronic fulfillment and the ten-day infeasibility clock.** Track every third-party and patient record request with receipt date, requested electronic manner, fulfillment date and exception invoked. If an electronic request cannot be fulfilled as requested, issue the written infeasibility explanation inside ten business days.[4,11]
4. **Separate patient-authorized app access from arbitrary security blocks.** Under § 171.203 and ONC guidance, a practice or vendor cannot block a patient-chosen health app merely because the app is outside the HIPAA covered-entity umbrella; once a patient directs EHI to an app of their choice, the practice's security review is bounded to objective technical integrity, not vetting the app's privacy policy.[4,8]
5. **Check EHR and clearinghouse contracts for lock-in fees.** Review vendor schedules for export fees, interface surcharges or exclusivity clauses that could impede migration or care-coordination exchange, and document requests to the vendor in writing so responsibility stays clearly apportioned.[4,26]

None of these steps guarantees immunity from a complaint, and patients can still submit allegations to ASTP/ONC over ordinary clinical disagreements.[21] What they provide is contemporaneous, auditable evidence that the practice's default is electronic access and that any exception was individualized, timely and tied to the text of 45 C.F.R. Part 171. For how these obligations intersect with HIPAA business associate agreements and health IT certification, see the library's companion papers on HIPAA and language models and regulating AI in certified EHRs.

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