



Office of the National Coordinator
for Health Information Technology

HTI-1 Final Rule: Information Blocking Enhancements

Michael Lipinski, JD
Regulatory and Policy Affairs Division Director
Office of Policy

Rachel Nelson, JD
Compliance and Administration Branch Chief, Regulatory and Policy Affairs Division
Office of Policy

Cassie Weaver, JD
Policy Analyst, Compliance and Administration Branch, Regulatory and Policy Affairs Division
Office of Policy

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Disclaimers

- The materials contained in this presentation about the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing" (HTI-1) Final Rule are based on the rule as published in the Federal Register, which amends provisions contained in 45 CFR parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official provisions are contained in the final rule and 45 CFR parts 170 and 171. Please note that other Federal, state and local laws may also apply.
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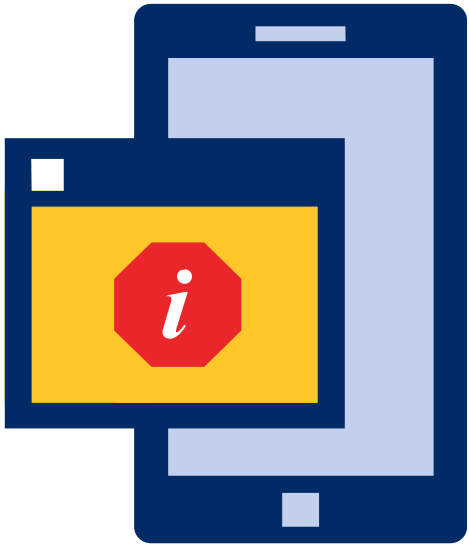


Information Blocking Overview

Overview of Information Blocking Elements

What Makes an Individual or Entity an Information Blocker?

- Actor regulated by the information blocking provision
- Involves electronic health information (EHI)
- Practice is likely to interfere with access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not required by law
- Not covered by an exception



Information Blocking – Knowledge Standard

Health Care Providers

“...**knows** that such practice is **unreasonable** and is likely to interfere with the access, exchange or use of electronic health information....”

Health IT Developers of Certified Health IT and HINs/HIEs

“...**knows, or should know**, that such practice is likely to interfere with the access, exchange or use of electronic health information....”

Information Blocking – Definition of Electronic Health Information (EHI)

- EHI means **electronic protected health information (ePHI)** to the extent that the ePHI would be included in a **designated record set** as these terms are defined for HIPAA.
 - *Except for* psychotherapy notes (45 CFR 164.501) and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
- This is applicable whether or not the information is held by or for a HIPAA covered entity.



Information Blocking Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI



1. Preventing Harm Exception



2. Privacy Exception



3. Security Exception



4. Infeasibility Exception



5. Health IT Performance Exception

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI



6. **Content and Manner Exception**



7. Fees Exception



8. Licensing Exception

New - Exceptions that involve practices related to actors' participation in TEFCA



9. **New** TEFCA Manner Exception



Information Blocking Enforcement

Information Blocking Claims: By the Numbers

Information Blocking Claims: By the Numbers

Rachel Nelson and Cassie Weaver | FEBRUARY 28, 2022



The 21st Century Cures Act (Cures Act), signed into law by President Obama in 2016, directed ONC to implement a standardized process for the public to report claims of possible information blocking. The information blocking claims reporting process welcomes claims of possible information blocking from **anyone** who believes they may have experienced or observed information blocking. Any information received by ONC in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information (claimant) is protected from disclosure under the Cures Act. The Cures Act authorizes the HHS Office of Inspector General (OIG) to investigate any claim of information blocking.

Today, we posted a **Quick Stat** visualization of data on the information blocking claims we have received through the **Report Information Blocking Portal** since April 5, 2021—the applicability date of the **information blocking regulations**. Moving forward, we generally plan to update these resources on a monthly basis and provide our data in two formats—a **web page** showing cumulative numbers to date and a **downloadable file [XLSX – 92 KB]** that shows what the cumulative counts were each month dating

<https://www.healthit.gov/buzz-blog/21st-century-cures-act/information-blocking-claims-by-the-numbers>

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HealthIT.gov TOPICS ▾ BLOG NEWS ▾ DATA ABOUT ONC ▾

HealthIT.gov > Data > Quick Stats > **Information Blocking Claims: By the Numbers**

Information Blocking Claims: By the Numbers

Total number of portal submissions received, number of submissions that represent claims of possible information blocking, and number of claims by type of potential actor and type of claimant

Source
Submissions received through the Report Information Blocking Portal.

Citation
Office of the National Coordinator for Health Information Technology. 'Information Blocking Claims: By the Numbers,' Health IT Quick-Stat #59 <https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>. December 2023.

Overview Notes

The 21st Century Cures Act (Cures Act), signed into law by President Obama in December 2016, directed ONC to implement a standardized process for the public to report claims of possible information blocking. This Quick Stats page displays data on claims or suggestions of possible information blocking¹ ONC has received through the Report Information Blocking Portal since April 5, 2021 – the applicability date of the information blocking regulations.

Information on submissions received through the Report Information Blocking Portal²

Total number of information blocking portal submissions received	936
Total number of possible claims of information blocking	869
Total number of submissions received that did not appear to be claims of potential information blocking ³	67

<https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers>

Information Blocking Claims



What happens when a claim is submitted to the Information Blocking Portal?

The Office of the National Coordinator for Health Information Technology

This guide is for informational purposes only. The official requirements are contained in the relevant statutes and regulations.

✉ **Points at which ONC communicates with submitter**

ONC Scope



ONC acknowledges receipt of the claim and shares it with OIG. ✉

Is it a claim against a Healthcare Provider?

Yes →

No ↓

Is it a claim against a Health Information Network/Health Information Exchange?

Yes →

No ↓

Is it a claim against an Offeror of Certified Health IT?

Yes →

No ↓

Is it a claim against a Health IT Developer of Certified Health IT?

Yes →

Yes →

ONC may investigate and may take action under the ONC Health IT Certification Program* ✉

***For example, ONC may issue a Notice of Non-conformity to the developer because the developer's actions did not conform to the Certification Program requirement in 45 CFR § 170.401. A developer may be required to submit a Corrective Action Plan and could also face suspension or termination of the certification.*

Not an information blocking claim. ✉
No information blocking authority for ONC or OIG. ONC informs the submitter.

OIG Scope



OIG Authority: OIG may investigate, and the HCP may be subject to appropriate disincentives.*

OIG Authority: OIG may investigate and may issue civil monetary penalties.

OIG Authority: OIG may investigate and may issue civil monetary penalties.

OIG Authority: OIG may investigate and may issue civil monetary penalties.

**Appropriate disincentives will be established by HHS in a future rulemaking.*



What Are the Consequences for Information Blocking?

Actor	Consequence
Health care providers	<ul style="list-style-type: none">• Appropriate disincentives
Health information networks and Health information exchanges	<ul style="list-style-type: none">• Civil monetary penalties (CMPs) up to \$1 million per violation
Health IT developers of certified health IT	<ul style="list-style-type: none">• Civil monetary penalties (CMPs) up to \$1 million per violation• Certification action which could include a termination or ban

HHS/OIG “Information Blocking” Final Rule



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Information Blocking

Last Updated: 09-14-2023


[View the Final Rule](#)

On June 27, 2023, HHS-OIG posted its [final rule implementing information blocking penalties](#). The final rule establishes the statutory penalties created by the 21st Century Cures Act. If OIG determines that an individual or entity has committed information blocking, they may be subject up to a \$1 million penalty per violation.

The final rule does not impose new information blocking requirements. OIG incorporated regulations published by the Office of the National Coordinator for Health Information Technology (ONC) as the basis for enforcing information blocking penalties. For more information on ONC's information blocking regulations see: [Information Blocking](#).

To report complaints about information blocking, please visit the [ONC Information Blocking Portal](#) or the [OIG Hotline](#).


OIG Information Blocking Fast Facts



Enforcement

Enforcement of the information blocking penalties will begin September 1, 2023.

OIG will not impose a penalty on information blocking conduct occurring before September 1, 2023.




Enforcement Priorities

- patient harm
- significantly impacted a provider's ability to care for patients
- of long duration
- cause financial loss to Federal health care programs, other government/private entities or
- was performed with actual knowledge.

<https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/>

HHS/ONC Health Care Provider Disincentives Rulemaking

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HHS/ONC

RIN: 0955-AA05

Publication ID: Fall 2023

Title: Establishment of Disincentives for Health Care Providers Who Have Committed Information Blocking

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act (Cures Act) to establish appropriate disincentives for health care providers determined by the HHS Inspector General to have committed information blocking. Consistent with the Cures Act, the rulemaking establishes a first set of disincentives using HHS authorities under applicable Federal law, including authorities delegated to the Centers for Medicare & Medicaid Services.

Agency: Department of Health and Human Services(HHS)

Priority: Substantive, Nonsignificant

RIN Status: Previously published in the Unified Agenda

Agenda Stage of Rulemaking: Proposed Rule Stage

Major: No

Unfunded Mandates: No

CFR Citation: [45 CFR 171](#) [42 CFR 414](#) [42 CFR 425](#) [42 CFR 495](#)

Legal Authority: [42 U.S.C. 300jj-52](#) [42 U.S.C. 1302](#) [42 U.S.C. 1306](#) [42 U.S.C. 1395hh](#) [42 U.S.C. 1395jj](#) [42 U.S.C. 1395rr\(1\)](#) [5 U.S.C. 552.2](#)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/01/2023	88 FR 74947
NPRM Comment Period End	01/02/2024	

Request for Advisory Opinion Authority


HHS Office of the National Coordinator for Health IT

FY 2024 President's Budget: Justification of Estimates to the Appropriations Committee

Proposed Law

1. Advisory Opinions for Information Blocking

Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department's view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.



HTI-1 Final Rule - Enhancements to Information Blocking Regulations

Overview of Information Blocking Enhancements



Definitions

- Offer Health IT
- Health IT Developer of Certified Health IT
- Business Associate
- Information Blocking



Exceptions

- Infeasibility Exception – 1 revised and 2 new conditions
- Manner Exception – renamed, removed obsolete “content” condition
- TEFCA Manner Exception – new



New and Updated Definitions

Information Blocking Definition - Updated

45 CFR 171.103:

(a) Information blocking means **a practice** that **except as required by law** or covered by an exception set forth in subparts B, C, or D of this part, is likely to **interfere with** access, exchange, or use of **electronic health information** (EHI); and

(b) If conducted by:

(1) A **health IT developer of certified health IT, health information network or health information exchange**, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of EHI; or

(2) A **health care provider**, such provider knows that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.



Health IT Developer of Certified Health IT Definition - Updated

Health IT developer of certified health IT means an individual or entity, other than a health care provider that self-develops health IT **that is not offered to others**, that develops or offers health information technology (as that term is defined in [42 U.S.C. 300jj\(5\)](#)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to [42 U.S.C. 300jj](#)–11(c)(5) (ONC Health IT Certification Program).

[45 CFR 171.102](#)



New Definition: “Offer Health IT”

- Establishes what it means to “offer health IT.” In general, it includes: providing or supplying, or offering to provide or supply, certified health IT for deployment by or for other individuals or entities under any arrangement or terms not consistent with an exclusion codified as part of the definition.
- Explicitly codifies that we do not interpret certain activities as offers of health IT: funding donation and subsidy arrangements; implementation and use activities; health IT selection and implementation consulting; legal services and certain operations management services arrangements. These are described in the exclusions (paragraphs of the definition).

Some Examples of Benefits

- Encourages beneficial arrangements under which health care providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT by giving funding sources certainty that making **funding** available for this purpose does not make them an offeror of health IT.
- Gives health care providers (and others) who deploy certified health IT certainty that implementing certain health IT features and enabling certain uses of the health IT they deploy will *not* be considered offering certified health IT (regardless of who developed that health IT).
- Establishes certainty for outside counsel that neither representing a client in negotiations or other matters with health IT vendors nor facilitating use of a client’s health IT for legal discovery purposes is considered an offering of health IT.



Information Blocking Exceptions

“Reasonable and Necessary Activities”



Manner Exception Updates



Manner Exception – Renumbered Existing Manner Requested and Alternative Manner Conditions

§ 171.301

Manner exception—When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows the conditions of this section.

(a) *Manner requested....*

(b) *Alternative manner...*



Infeasibility Exception Updates



Infeasibility Exception – Conditions

(a)(1) *Uncontrollable events...* (revision)

(a)(2) *Segmentation* (no change)

(a)(3) *Third party seeking modification use* (new)

(a)(4) *Manner Exception exhausted* (new)

(a)(5) *Infeasible under the circumstances* (no substantive change, redesignated from (a)(3))

- To meet *infeasible under the circumstances*, actor must demonstrate six separate factors that led to its determination that complying with the request would be infeasible under the circumstances.
 - type of EHI and purpose; cost to the actor; financial and technical resources available to the actor; non-discriminatory practice; control over predominant technology; why the actor was unable to provide the EHI in an alternative manner.

(b) *Responding to requests* (must be met in complement to at least 1 condition from paragraph (a) – no change)

Infeasibility Exception – Uncontrollable Events Condition

Revised the language of the condition:

Uncontrollable events. The actor cannot fulfill the request for access, exchange, or use of electronic health information **because of** a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority **that in fact negatively impacts the actor's ability to fulfill the request.**

Benefits

The revisions make clear that the fact that an uncontrollable event specified in § 171.204(a)(1) occurred is not a sufficient basis alone for an actor to meet the *uncontrollable events* condition of the Infeasibility Exception. The actor must demonstrate that the uncontrollable event had a negative impact on the actor's ability to fulfill the request.

Infeasibility Exception – Third Party Seeking Modification Use Condition

Third party seeking modification use. The request is to enable use of EHI in order to modify EHI provided that the request for such use is not from a health care provider requesting such use from an actor that is its business associate.

Not available when the request is from a health care provider requesting (directly, or through another business associate of the health care provider) such modification use from an actor that is its business associate.

- An actor may choose to verify that the modification use request came from the health care provider themselves or accept the third party's representation of a request as coming from a health care provider.

Benefits

Reduces actor burden and uncertainty.

- Less documentation requirements compared to the *infeasible under the circumstances* condition.
- No need to determine if another exception applies to the request, such as the Security Exception.

Note: Other exceptions, or other conditions of the Infeasibility Exception, may apply where *third party seeking modification use* condition is not met.

Infeasibility Exception – Manner Exception Exhausted Condition

1. The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;
2. The actor offered **at least two alternative manners** in accordance with § 171.301(b), one of which must either be certified health IT or via published content and transport standards; and
3. The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.

• *Currently provides*

• *Same*


• *Substantial number*

• ***Similarly Situated****

*Shall not discriminate based on whether the requestor is an individual or competitor (or facilitates competition) or based on the health care provider type and size

Benefits

- Provides certainty (do not have to meet the *infeasibility under the circumstances* condition)
- Reduces inappropriate or unnecessary diversion of actor resources
- Ensures actors reasonably allocate resources toward interoperable, standards-based manners



**New Subpart D - Exceptions
That Involve Practices
Related to Actors'
Participation in TEFCA**



***NEW* Subpart D: Exceptions That Involve Practices Related to Actors' Participation in TEFCA**

ONC added a new subpart to the information blocking regulations.

§ 171.400: Purpose and Effect of Exceptions

§ 171.401: Reserved (potential definitions)

§ 171.402: Reserved

§ 171.403: TEFCA Manner Exception:

When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information to only via TEFCA not be considered information blocking?

NEW TEFCA Manner Exception

An actor may limit the manner in which it fulfills a request for access, exchange, or use of electronic health information to only via TEFCA **IF**:

1. The actor and requestor are both part of TEFCA.
2. The requestor is capable of such access, exchange, or use of the requested electronic health information from the actor via TEFCA.
3. The request for access, exchange, or use of EHI is not via the standards adopted in 45 CFR 170.215 (**FHIR**), including version(s) of those standards approved pursuant to 45 CFR 170.405(b)(8) (**SVAP**).
4. The actor complies with the Fees and Licensing Exceptions.

Benefits

- Aligns with the Cures Act's goals for interoperability and the establishment of TEFCA by acknowledging the value of TEFCA in promoting access, exchange, and use of EHI in a secure and interoperable way.
- Provides a clear, efficient process for actors participating in TEFCA to prioritize the use of TEFCA means for fulfilling requests for access, exchange, and use of EHI from other TEFCA entities.



Exceptions in Practice



“Stacking” Exceptions:

- Available to all actors
- Not something new or limited to a specific combination of exceptions
- Not limited to one exception per practice

Example: Actor has agreed to patient request to have certain EHI withheld from some or all sharing (Privacy Exception). Health care provider cannot segment this EHI from other EHI they could under applicable law make available (Infeasibility Exception)



Opportunities to Learn More

Resources Available on HealthIT.gov!

Visit <https://healthIT.gov/HTI-1> for additional information.

Fact Sheets

- General Overview
- Final Rule At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- HTI-1 Information Blocking
- HTI-1 Key Dates

Measurement Spec Sheets

- For each of the Insights Condition measures

HTI-1 AT-A-GLANCE FACT SHEET
Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule
December 2023

Standards and Certification Criteria

- Adopts United States Core Data for Interoperability Version 3 (USCDI v3) as the new data set baseline across applicable certification criteria.
- Adopts the proposed versions of "minimum standards" code sets that serve as the baseline for Program certification.
- Revises the "electronic case reporting" certification criterion to be based on consensus-based, industry developed electronic standards and implementation guides by HL7.
- Adopts a "decision support interventions" (DSI) certification criterion as a revised version of the "clinical decision support" (CDS) certification criterion. The DSI certification criterion includes, among other changes, new transparency requirements.
- Adds new requirements for the "standardized API for patient and population services" certification criterion, including requirements for issuing refresh tokens and revoking access privileges.
- Adds new data elements and renames the demographics certification criterion.
- Revises the "internet-based method" certification criterion to support an internet-based method restriction.

HTI-1 OVERVIEW FACT SHEET
Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule
December 2023

Overview

In this final rule, ONC implements provisions of the 21st Century Cures Act, makes updates to the ONC Health IT Certification Program (Certification Program) including new and updated standards, certification criteria, and implementation specifications in 45 CFR Part 170, establishes a new baseline version of the United States Core Data for Interoperability (USCDI), and provides enhancements to support information sharing through updates to the information blocking regulations.

Rule Highlights

- Implements the Cures Act's "EHR Reporting Program" to require transparent reporting on different types of certified health IT metrics through the new "Insights" Condition and Maintenance of Certification.
- Provides updates to the information blocking regulations in response to feedback from affected parties.
- Adopts United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the baseline USCDI standard as of January 1, 2026.
- Updates the Certification Program's standards, criteria, and requirements, including:
 - Standardized application programming interfaces (APIs), including adoption of the SMART App Launch Implementation Guide v2;
 - Electronic case reporting using HL7 Consolidated Document Architecture (CDA) and HL7 Fast Healthcare Interoperability Resources (FHIR) based specifications;
 - A revised decision support intervention (DSI) certification criterion based on the prior clinical decision support certification criterion that includes new capabilities and transparency requirements for Health IT Modules; and
 - New functionality that enables an "internet-based method" for a patient to request a restriction on the use and disclosure of their EHI.

Discontinuing Year-Themed Editions for Health IT Certification Criteria

To simplify the Certification Program and support more modular and extensible future updates, the HTI-1 Final rule discontinues year-themed editions of certification criteria. This change also supports broader use of certification criteria and standards adopted by ONC for other federal agencies and programs.

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Upcoming Webinars



Overview of HTI-1 Final Rule with Q&A

February 1, 1:00 PM ET



Insights Condition

February 8, 3:00 PM ET

ONC HTI-2 Proposed Rule

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HHS/ONC **RIN: 0955-AA06** **Publication ID: Fall 2022**

Title: •Patient Engagement, Information Sharing, and Public Health Interoperability

Abstract:

The rulemaking builds on policies adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification final rule (85 FR 25642) and included in the Health Information Technology: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing proposed rule (0955-AA03). The rulemaking advances electronic health information sharing through proposals for: standards adoption; the certification of health IT to support expanded uses of application programming interfaces (APIs), such as electronic prior authorization, patient engagement, and interoperable public health exchange; and supporting patient engagement and other information sharing principles under the information blocking regulations.

Agency: Department of Health and Human Services(HHS) **Priority:** Other Significant
RIN Status: First time published in the Unified Agenda **Agenda Stage of Rulemaking:** Proposed Rule Stage
Major: Undetermined **Unfunded Mandates:** No

CFR Citation: [45 CFR 170](#) [45 CFR 171](#)
Legal Authority: [42 U.S.C. 300jj-11](#) [42 U.S.C. 300jj-14](#) [42 U.S.C. 300jj-19a](#) [42 U.S.C. 300jj-52](#) [5 U.S.C. 552](#) [Pub. L. 114-255](#)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2023	



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