PROPOSED RULE MAKING



CR-102 (December 2017) (Implements RCW 34.05.320)

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DATE: April 19, 2022 TIME: 12:59 PM

WSR 22-09-069

Agency: Department or	f Health		
⊠Original Notice			
☐Supplemental Notice	e to WSR		
Continuance of WSR			
⊠Preproposal Statem	nent of Inqu	iry was filed as WSR 21-13-095;	or
Expedited Rule MakingProposed notice was filed as WSR ; or			
☐Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).			
□Proposal is exempt	under RCV	V .	
Title of rule and other identifying information: (describe subject) Chapter 246-455 WAC, Hospital Patient Discharge Information Reporting. The Department of Health (Department) is proposing amending existing rules and creating new rules on hospital patient discharge information reporting. The proposed rules prescribe new patient demographic information reported by hospitals; establish a waiver process; strengthen protections of patient health care information to align with federal law changes; clarify and add requirements for data collection and reporting; establish formalized procedures for requesting hospital patient discharge data; prescribe direct and indirect patient identifiers; update or add definitions; make technical updates and clarifications to existing rules; and establish fees for data files and analysis.			
Hearing location(s):			
	Time:	Location: (be specific)	Comment:
5/24/2022	11:00 am	In response to the coronavirus disease 2019 (COVID-19) public health emergency, the Department of Health will not provide a physical location for this hearing. This is to promote social distancing and the safety of the residents of Washington State. A virtual public hearing, without a physical meeting space, will be held instead. Register in advance for this hearing/webinar: https://us02web.zoom.us/webinar/register/WN_EeSuwngSQES5OSGK51Mbjw After registering, you will receive a confirmation email containing information about joining the webinar.	

Submit written comments to:

Name: Katitza Holthaus

Address: Department of Health

Center for Health Statistics

PO Box 47814

Ob was a in	- \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		
• •	a, WA 98504 ess.wa.gov/doh/policyreview		
Fax: 360-753-413	. ,		
Other:			
By (date) <u>05/24/20</u>	<u>022</u>		
Assistance for p	ersons with disabilities:		
Contact <u>Katitza H</u>			
Phone: 360-236-4			
Fax: 360-753-413	5		
TTY: 711			
	haus@doh.wa.gov		
Other:			
By (date) <u>05/10/20</u>			
prescribe new pat Second Substitute Department is pro proposed revision clarifying and add formalized proced updating and addi	tient demographic information re House Bill (E2SHB) 1272 (che posing revisions that support of sinclude strengthening protecting requirements for data colledures for requesting hospital paing definitions; making technical	effects, including any changes in existing rules reported by hospitals and establish a waiver procestapter 162, Laws of 2021). In addition to implement compliance with federal law and improve programations of patient health care information to align wite action and reporting; repeal an obsolete section of attent discharge data; prescribing direct and indirect all updates and clarifications to existing rules; and	ess to implement Engrossed nation of E2SHB 1272, the administration. The th federal law changes; rule; establishing ct patient identifiers;
files and analysis. Reasons suppor		72 requires hospitals to report race, ethnicity, gen	der identity, sevual
		nd zip code of primary residence in patient discha	
		72 amended various statutes, including RCW 43.	
		orized by RCW 43.70.052, the Center for Health of observation patient hospital stays through the C	
		rovides public health personnel, consumers, purc	
	access to information that can i		,, , , , , , , , , , , , , , , , , , , ,
compliance with fe then, there have b	ederal law and improve program been several advances and dev	ne Department is proposing revisions to chapter 2 m administration. The Department last revised the velopments that can only be addressed in rule.	e rules in 2015 and, since
Statutory author 43.70.052	ity for adoption: Engrossed S	second Substitute House Bill 1272 (Chapter 162, I	_aws of 2021) and RCW
Statute being im 43.70.052	plemented: Engrossed Secon	d Substitute House Bill 1272 (Chapter 162, Laws	of 2021) and RCW
ls rule necessary	hecause of a		
Federal Lav			☐ Yes ⊠ No
	urt Decision?		☐ Yes ☐ No
State Court			☐ Yes ☐ No
If yes, CITATION:			
Agency commen matters: None		ny, as to statutory language, implementation,	enforcement, and fiscal
Name of proper	ent: (person or organization)	Washington State Department of Health	Private
Name of propone	ent. (person or organization)	washington state Department of Fleath	☐Public ☑Governmental
Name of agency	personnel responsible for:		
	. Name	Office Location	Phone
Duaftin			
Drafting:	Katitza Holthaus	101 Israel Rd SE, Tumwater, WA 98501	360-236-4311
Implementation:	Katie Hutchinson	101 Israel Rd SE Tumwater WA 98501	360-236-4324

Enforcement:	Jean Remsbecker	101 Israel Rd SE, Tumwater, WA 98501	360-236-4307
s a school dist f yes, insert stat		t required under RCW 28A.305.135?	☐ Yes ⊠ No
•		ol district fiscal impact statement by contacting:	
Name: Addres			
Phone			
Fax:	•		
TTY:			
Email:			
Other:			
s a cost-benefi	t analysis required under l	RCW 34.05.328?	
	reliminary cost-benefit analy	rsis may be obtained by contacting:	
Name:	Katitza Holthaus		
Addres	ss: Department of Health		
	Center for Health Statist	ics	
	PO Box 47814 Olympia, WA 98504-781	1.4	
Phone	: 360-236-4311	14	
	60-753-4135		
TTY: 7			
	katitza.holthaus@doh.wa.go	OV	
Email:	ratitza.Hotti laus & uon.wa.yt		

Regulatory Fairness Act Cost	Considerations for a Small Busin	ness Economic Impact Statement:	
This rule proposal, or portions of the proposal, may be exempt from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):			
adopted solely to conform and/o	or comply with federal statute or reg	RCW 19.85.061 because this rule mak ulations. Please cite the specific federal describe the consequences to the state	statute or
U.S.C. Sec. 290dd-2, 42 C.F.R If the rule is not adopted, the Demental health data and could be ☐ This rule proposal, or portion	Part 2, and chapter 70.02 RCW are epartment will be out of compliance a subject to federal violations.	tions of patient health care information is exempt under RCW 19.85.061 and RC with limiting disclosure of substance uses the agency has completed the pilot in the control of the control	W 34.05.310(4)(e). e disorder and
	• • • • • • • • • • • • • • • • • • • •	the provisions of RCW 15.65.570(2) be	ecause it was
This rule proposal, or portion	ns of the proposal, is exempt under	RCW 19.85.025(3). Check all that appl	y:
RCW 34.05.310 (4	k)(b)	RCW 34.05.310 (4)(e)	
(Internal governme		(Dictated by statute)	
RCW 34.05.310 (4	•	RCW 34.05.310 (4)(f)	
(Incorporation by r	, , ,	(Set or adjust fees)	
RCW 34.05.310 (4	•	RCW 34.05.310 (4)(g)	
(Correct or clarify I		((i) Relating to agency hearings; or (ii) process	
(Contact of claim)	angaago)	requirements for applying to an age	, , ,
		or permit)	,
This rule proposal, or portion	ns of the proposal, is exempt under	RCW.	
Explanation of exemptions, if ne	ecessary: The following sections of	rule are exempt under RCW 19.85.025	(3):
WAC, Title Description of Change Exemption from RCW 19.85.025(3)			
Wile, Tide	Description of Change	Exemption from Re (17.000020(0))	1
246-455-001 Purpose.	Updates RCW citations	Correction of errors and addition of clarifying language that does not change the effect of the rule	
246-455-010 Definitions.	Adds definitions	Clarifies the meaning of terms used throughout the chapter.	
	Adds definitions	Incorporation of language explicitly and specifically dictated by statute	
246-455-040 Acceptable Language revisions and updated		Correction of errors and addition of clarifying language that does not change the effect of the rule.	
media for submission of data.	RCW citations	Incorporation of language explicitly and specifically dictated by RCW 43.70.052(1)(a)	
246-455-050 Time deadline	Language revisions and updated	Clarifying language that does not change the effect of the rule.	

Clarifying language that does not change the effect of the rule.

Language revisions and updated

RCW citations

246-455-060 Edits to data.

246-455-070 Revisions to submitted data.	Language revisions and updated RCW citations	Correction of errors and addition of clarifying language that does not change the effect of the rule Incorporation of language explicitly and specifically dictated by RCW 43.70.052(1)(a)
Repealed 246-455-080 Security of the data.	Removes outdated rule	Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
246-455-085 Data files— Release of data files and data use agreements.	Adds direct and indirect patient identifiers, clarifies data sharing, and incorporates federal requirements	Adoption of federal requirements without material change Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
New Section 246-455-105 Requests from government agencies for patient discharge data files containing direct patient identifiers.	Describes the process for a government agency to request identifying data	Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
New Section 246-455-200 Requests for patient discharge data files containing direct patient identifiers for research.	Describes the process for a researcher to request identifying data	Procedural rules not considered significant rule amendments
New Section 246-455-300 Requests from individuals or entities for patient discharge data files containing indirect identifiers.	Describes the process for an individual or organization to request de-identified data	Procedural rules not considered significant rule amendments
New Section 246-455-400 Patient discharge data use agreements.	Requirements for data use agreements	Incorporation of language explicitly and specifically dictated by statute
New Section 246-455-500 Data file production.	Preserves the Department's discretion to determine file formats	Rules relating only to internal governmental operations that are not subject to violation by a nongovernment party
New Section 246-455-990 Data file fees.	Sets a fee schedule as dictated by RCW 43.70.052	Incorporation of language explicitly and specifically dictated by statute Sets fees pursuant to legislative standards

COMPLETE THIS SECTION C	NLY IF NO EXEMPTION APPLIES		
If the proposed rule is not exempt , does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?			
 No Briefly summarize the agency's analysis showing how costs were calculated. The proposed rules do not impact small businesses. The proposed rules only impact hospitals; businesses with more than 50 employees. ☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here: 			
The public may obtain a copy of the small business eccontacting:	conomic impact statement or the detailed cost calculations by		
Name:			
Address:			
Phone:			
Fax:			
TTY:			
Email:			
Other:			
Date: 04/18/2022	Signature:		
Name: Kristin Peterson, JD for Umair A. Shah, MD, MPH	12.15/11		
Title: Deputy Secretary, Policy and Planning for Secretary of Health	Kistin fellisa		

AMENDATORY SECTION (Amending WSR 07-09-091, filed 4/18/07, effective 5/23/07)

WAC 246-455-001 Purpose. This chapter is adopted by the Washington state department of health pursuant to RCW 43.70.040(($_{7}$)) and 43.70.052(($_{7}$ and 70.170.010)) relating to the collection and maintenance of patient discharge data, including data necessary for identification of discharges by diagnosis-related groups.

AMENDATORY SECTION (Amending WSR 15-19-152, filed 9/22/15, effective 10/23/15)

- WAC 246-455-010 Definitions. The definitions in this section apply throughout this chapter, unless the context clearly requires otherwise:
- (1) "CHARS" means comprehensive hospital abstract reporting system.
- (2) "CHARS Companion Guide" means the written technical guidelines for creating and submitting hospital patient discharge data from the hospital to the department or the department's designee as required for CHARS.
- (3) "CHARS Procedure Manual" means the written instructions for reporting hospital discharge data to the department.
- ((3) "CHARS 837 Companion Guide" means the written technical guidelines for creating the ASC X12 837 Health Care Claim file for CHARS.))
- (4) "Custom data file" means a specialized patient discharge data file created and released by the department upon request of an individual. Custom data file does not mean standard data file.
- (5) "Data" means a data file containing multiple patient discharge records submitted to the department as required for CHARS.
- (6) "Data use agreement" means a signed agreement with the department for transmitting, receiving and using records containing individually identifiable or potentially identifiable health information. The agreement specifies, at a minimum, what information will be exchanged, the conditions or restrictions under which the information will be used and protected, restrictions on redisclosure of data and restrictions on attempts to locate information associated with a specific individual.
- $((\frac{5}{1}))$ "Department" means Washington state department of health.
- $((\frac{(6)}{(6)}))$ <u>(8) "Designee" means a private entity contracted by the department to perform data collection on behalf of the department as authorized by RCW 43.70.052(1).</u>
- (9) "Diagnosis-related groups (DRG)" is a classification system that groups hospital patients according to principal and secondary diagnosis, presence or absence of a surgical procedure, age, presence or absence of significant comorbidities or complications, and other relevant criteria.
- $((\frac{7}{}))$ <u>(10) "Direct patient identifier" means information that identifies a patient.</u>

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- (11) "Discharge data" means a collection of patient records in which each record represents a single patient discharged from the hospital following an inpatient or observation stay.
- (((8))) <u>(12) "Government agencies" include state boards, commissions, committees, departments, educational institutions, or other</u> state agencies which are created by or pursuant to statute, other than courts and the legislature; county or city agencies, federally recognized tribes and tribal organizations, and United States federal agencies.
- (13) "Hospital" means any health care institution ((which is required to qualify for a license)) licensed under chapter 70.41 RCW or ((as)) a psychiatric hospital <u>licensed</u> under chapter 71.12 RCW.
- (((9))) (14) "Human research review board" is the standing institutional review board operating under chapter 42.48 RCW.
- (15) "Indirect patient identifier" means information that may identify a patient when combined with other information.
- (16) "Office of Management and Budget" means a body within the Executive Office of the President of the United States which is tasked with coordinating United States Federal agencies and can be found at http://www.whitehouse.gov/omb.
- $((\frac{(10)}{(10)}))$ "Patient discharge" means the termination of an inpatient admission or observation stay, including an admission as a result of a birth, in a Washington hospital.
- (((11) Uniform Billing)) (18) "Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this rule, whether or not they are conducted or supported under a program that is considered research for other purposes.
- (19) "Standard data file" means the routine patient discharge data file created and released by the department, and does not mean custom data file.
- (20) "State" means Washington state unless otherwise specified.
 (21) "UB-04 data set" means the uniform billing data element specifications developed by the National Uniform Billing Committee which can be found at www.NUBC.org. ((Data elements are completely defined in the CHARS Procedure Manual which may be obtained on the defined in the complete the co partment's website or by contacting the department.))

AMENDATORY SECTION (Amending WSR 15-19-152, filed 9/22/15, effective 10/23/15)

- Reporting ((of UB-04)) data set information. WAC 246-455-020 (1) Hospitals shall collect and report the following data set elements to the department:
- (a) Patient control number: Patient's unique alpha-numeric number assigned by the hospital to facilitate retrieval of individual patient records;
 - (b) Patient medical record number;
 - (c) Type of bill;
- $((\frac{(c)}{(c)}))$ (d) National Provider Identifier (UB-04), or department assigned identifier, as applicable;
- (((d))) <u>(e)</u> Patient last name (((at least the first four let- ters)));

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((<del>(e)</del>)) <u>(f)</u> Patient first name ((<del>(at least the first three let-</del>
ters)));
      ((\frac{f}{f})) <u>(g)</u> Patient middle initial:
       ((\frac{g}{g})) <u>(h)</u> Patient Social Security number (at least the last
four digits);
      ((<del>(h)</del>)) <u>(i) Patient address;</u>
(j) Patient zip code (U.S.A.);
      ((\frac{1}{2})) (k) Patient country code (outside U.S.A.) International
Organization for Standardization (ISO) 3166-1;
      (((<del>(j)</del>)) (<u>l)</u> Patient's date of birth;
((<del>(k)</del>)) (<u>m</u>) Sex <u>assigned at birth;
((<del>(l)</del>)) (<u>n</u>) Admission date;</u>
       ((\frac{m}{m})) <u>(o)</u> Type of admission;
      ((<del>(n)</del>)) (p) Admitting diagnosis code;
(q) Patient's ICD code (1-3) reason for visit;
      (r) Point of origin for admission;
      ((<del>(o)</del>)) <u>(s)</u> Patient discharge status;
      ((\frac{p}{p})) (t) Statement covers period (from - through); (\frac{q}{p}) (u) Revenue code;
      ((\frac{r}{r})) <u>(v)</u> Units of service;
      ((\frac{(s)}{(s)})) Total charges; (\frac{(t)}{(s)}) Payer identification (up to three): Payer identifica-
tion number per the CHARS procedure manual identifying each payer
group from which the hospital may expect some payment of the bill;
      ((<del>(u)</del>)) <u>(y)</u> Principal diagnosis code;
      (((v))) (z) Other diagnosis codes;
       ((<del>(w)</del>)) <u>(aa)</u> External cause of injury (ECI) code;
       ((<del>(x)</del>)) <u>(bb)</u> Principal procedure code;
      ((<del>(y)</del>)) (cc) Other procedure code;
       ((<del>(z)</del>)) (dd) Referring provider's National Provider Identifier
(NPI), as applicable;
      (ee) Attending ((provider identifier)) provider's National Pro-
vider Identifier (NPI) according to Centers for Medicare and Medicaid
Services (CMS) schedule;
       ((<del>(aa)</del>)) <u>(ff)</u> Operating ((<del>physician identifier</del>)) <u>physician's</u> Na-
tional Provider Identifier (NPI) according to CMS schedule, as appli-
cable;
       ((<del>(bb)</del>)) (gg) Other ((<del>provider identifiers</del>)) provider's National
Provider Identifier (NPI) according to CMS schedule, as applicable;
       ((<del>(cc)</del>)) (hh) Admission hour;
       ((<del>dd)</del> Race - Per minimum Office of Management and Budget (OMB)
standards
      (ee) Ethnicity - Per minimum OMB standards
      (ff))) (ii) Race - Until hospitals are required to report race
consistent with WAC 246-455-025, race shall be reported per minimum
office of management and budget (OMB) standards;
      (jj) Ethnicity - Until hospitals are required to report ethnicity
consistent with WAC 246-455-025, ethnicity shall be reported per mini-
mum OMB standards;
      (kk) Discharge hour;
      ((<del>(gg)</del>)) (11) Procedure date;
      ((<del>(hh)</del>)) <u>(mm)</u> Present on admission status;
       ((<del>(ii)</del>)) <u>(nn)</u> Health care provider taxonomy code;
      ((\frac{(jj)}{(oo)})) Health care common procedure coding system (HCPCS); (\frac{(kk)}{(pp)}) Service date;
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(qq) Facility federal tax number;

(rr) Insured last name, first name, middle name, suffix;

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- (ss) Patient's relationship to insured code;
- (tt) Insured ID.
- (2) The hospital shall report all patient discharge data ((described in WAC 246-455-010 and 246-455-020)) required in this section according to UB-04 specifications unless noted otherwise.
- (3) If the department has a designee, the hospital shall report all patient discharge data required in this section to the designee. The designee will report the patient discharge data required in this section submitted by the hospital to the department in the format prescribed by the department.

NEW SECTION

WAC 246-455-025 Reporting of additional patient demographic information. (1) In addition to the data elements required by WAC 246-455-020, hospitals must collect additional information on patient's ethnicity, race, preferred language, disability, gender identity, and sexual orientation. When requesting demographic information under this section, hospitals must inform patients that providing the information is voluntary.

- (2) Patient's ethnicity shall be identified by the patient and reported using one of the following categories:
 - (a) Hispanic, Latino/a, Latinx;
 - (b) Non-Hispanic, Latino/a, Latinx;
 - (c) Patient declined to respond; or
 - (d) Unknown to patient.
- (3) Patient's race shall be identified by the patient and reported using one or more of the following categories. If the patient self-identifies as more than one race, each race shall be reported.
 - (a) Afghan;
 - (b) Afro-Caribbean;
 - (c) Alaska Native;
 - (d) American Indian;
 - (e) Arab;
 - (f) Asian;
 - (q) Asian Indian;
 - (h) Bamar/Burman/Burmese;
 - (i) Bangladeshi;
 - (i) Bhutanese;
 - (k) Black or African American;
 - (1) Central American;
 - (m) Cham;
 - (n) Chicano/a or Chicanx;
 - (o) Chinese;
 - (p) Congolese;
 - (q) Cuban;
 - (r) Dominican;
 - (s) Egyptian;
 - (t) Eritrean;
 - (u) Ethiopian;
 - (v) Fijian;
 - (w) Filipino;
 - (x) First Nations;
 - (y) Guamanian or Chamorro;

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(z) Hmong/Mong;
     (aa) Indigenous-Latino/a or Indigenous-Latinx;
     (bb) Indonesian;
     (cc) Iranian;
     (dd) Iraqi;
     (ee) Japanese;
     (ff) Jordanian;
     (gg) Karen;
     (hh) Kenvan;
     (ii) Khmer/Cambodian;
     (jj) Korean;
     (kk) Kuwaiti;
     (11) Lao;
     (mm) Lebanese;
     (nn) Malaysian;
     (oo) Marshallese;
     (pp) Mestizo;
     (qq) Mexican/Mexican American;
     (rr) Middle Eastern;
     (ss) Mien;
     (tt) Moroccan;
     (uu) Native Hawaiian;
     (vv) Nepalese;
     (ww) North African;
     (xx) Oromo;
     (yy) Pacific Islander;
     (zz) Pakistani;
     (aaa) Puerto Rican;
     (bbb) Romanian/Rumanian;
     (ccc) Russian;
     (ddd) Samoan;
     (eee) Saudi Arabian;
     (fff) Somali;
     (ggg) South African;
     (hhh) South American;
     (iii) Syrian;
(jjj) Taiwanese;
     (kkk) Thai;
     (111) Tongan;
     (mmm) Ugandan;
     (nnn) Ukrainian;
     (000) Vietnamese;
     (ppp) White;
     (qqq) Yemeni;
     (rrr) Other race;
     (sss) Patient declined to respond; and
     (ttt) Unknown to patient.
     (4) Patient's preferred language either written or spoken or both
shall be identified by the patient and reported to the department.
Preferred language shall be reported using the following categories:
     (a) Amharic;
     (b) Arabic;
     (c) Balochi/Baluchi;
     (d) Burmese:
     (e) Cantonese;
     (f) Chinese (unspecified);
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(q) Chamorro;

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- (h) Chuukese;
- (i) Dari;
- (j) English;
- (k) Farsi/Persian;
- (l) Fijian;
- (m) Filipino/Pilipino;
- (n) French;
- (o) German;
- (p) Hindi;
- (q) Hmong;
- (r) Japanese;
- (s) Karen;
- (t) Khmer/Cambodian;
- (u) Kinyarwanda;
- (v) Korean;
- (w) Kosraean;
- (x) Lao;
- (y) Mandarin;
- (z) Marshallese;
- (aa) Mixteco;
- (bb) Nepali;
- (cc) Oromo;
- (dd) Panjabi/Punjabi;
- (ee) Pashto;
- (ff) Portuguese;
- (gg) Romanian/Rumanian;
- (hh) Russian;
- (ii) Samoan;
- (jj) Sign languages;
- (kk) Somali;
- (11) Spanish/Castilian;
- (mm) Swahili/Kiswahili;
- (nn) Tagalog;
- (00) Tamil;
- (pp) Telugu;
- (qq) Thai;
- (rr) Tigrinya;
- (ss) Ukrainian;
- (tt) Urdu;
- (uu) Vietnamese;
- (vv) Other language;
- (ww) Patient declined to respond; or
- (xx) Unknown.
- (5) Patient's disability shall be identified by the patient and reported consistent with the categories in this subsection. If the patient self-identifies as more than one disability, each disability shall be reported.
- (a) The patient experiences any of the following in their daily living:
 - (i) Difficulty hearing;
 - (ii) Difficulty seeing, even when wearing glasses;
- (iii) Limitations in any activities because of a physical, mental, or emotional condition;
- (iv) Uses a cane, a wheelchair, a trained service animal, adaptive bed, adaptive telephone, or some other device;
- (v) Difficulty concentrating, remembering, or making decisions because of a physical, mental, or emotional condition;

- (vi) Difficulty walking or climbing stairs; (vii) Difficulty dressing or bathing; (viii) Difficulty doing errands alone such as visiting a doctor's office or shopping; (ix) Not listed above; (x) Not applicable (no limitations); (xi) Patient declined to respond; or (xii) Unknown. (b) The patient has any of the following disabilities or conditions: (i) Intellectual disability; (ii) Developmental disability; (iii) Physical disability; (iv) Brain injury; (v) Mental health disability; (vi) Neurocognitive disability; (vii) Deaf, d/Deaf, or hard of hearing; (viii) Blind, low vision, or visually impaired; (ix) Chronic medical condition; (x) Not listed above; (xi) Not applicable (no disability or condition); (xii) Patient declined to respond; or (xiii) Unknown. (6) Patient's gender identity shall be identified by the patient and reported using one or more of the following options. If the patient self-identifies as more than one gender, each gender shall be reported. (a) Male; (b) Female; (c) Man or Masculine/Masc; (d) Woman or Feminine/Femme; (e) Trans* or transgender; (f) Cis or cisgender; (g) Genderqueer; (h) Nonbinary; (i) Two spirit;(j) Gender fluid; (k) Bigender;

 - (1) Agender;
 - (m) Demigirl;
 - (n) Demiboy;
 - (o) Gender not listed above, please specify;
 - (p) Patient declined to respond; or
 - (q) Unknown.
- (7) Patient's sexual orientation shall be identified by the patient and reported using one or more of the following categories. If the patient self-identifies with more than one sexual orientation, each sexual orientation shall be reported.
 - (a) Straight;
 - (b) Gay;
 - (c) Lesbian;
 - (d) Queer;
 - (e) Bisexual;
 - (f) Pansexual/Bi+;
 - (q) Asexual;
 - (h) Sexual orientation not listed above, please specify;
 - (i) Patient declined to respond; or

(j) Unknown.

NEW SECTION

WAC 246-455-035 Waiver for reporting the additional patient demographic information. (1) Beginning October 1, 2022, a hospital that is certified by the Centers for Medicare and Medicaid Services as a critical access hospital, is certified by the Centers of Medicare and Medicaid Services as a sole community hospital, or qualifies as a medicare dependent hospital must comply with this section.

- (2)(a) A hospital subject to the additional patient demographic information reporting requirements in RCW 43.70.052 (6)(a) and WAC 246-455-025, and is experiencing an economic hardship, technological limitations that are not reasonably in the control of the hospital, or other exceptional circumstance demonstrated by the hospital, may submit an attestation to the department requesting a waiver of the additional patient demographic information reporting requirements in RCW 43.70.052 (6)(a) and WAC 246-455-025.
- (b) The waiver attestation with supporting documentation must be submitted on forms provided by the department. The waiver is deemed granted upon written or electronic approval from the department. The department may request additional information to complete the attestation. The department, in its discretion, may deny the waiver request if the hospital fails to comply with the requirements in RCW 43.70.052(6) and this section.
- (c) A hospital that has been granted a waiver shall be exempt from reporting the additional patient discharge information outlined by WAC 246-455-025 for one calendar year. The one calendar year starts at the beginning of the next calendar month after the waiver is approved. The waiver is effective when the department sends written or electronic approval to the hospital.
- (d) A hospital seeking an extension on its approved waiver must apply for an extension before the waiver expires. If the hospital does not apply for an extension before the waiver expires, the hospital must collect and report the additional patient discharge information in RCW 43.70.052 (6)(a) and WAC 246-455-025 and will not be eligible for an additional waiver.
- (e) For economic hardship or technological limitations that are not reasonably in the control of the hospital, a hospital may only submit up to a total of three waiver attestations to the department.
- (f) For other exceptional circumstances, there is no limit on the number of waiver attestations that a hospital may submit to the department.
- (g) The hospital must begin collecting the additional patient discharge information in RCW 43.70.052 (6)(a) and WAC 246-455-025 immediately following the waiver expiration.
- (h) Data collected under a waiver must be reported consistent with WAC 246-455-020, and data collected after the waiver expiration must be reported consistent with both WAC 246-455-020 and 246-455-025. Data must be submitted according to the deadline for submission required by WAC 246-455-050.
 - (3) For the purposes of this section:
 - (a) Economic hardship means:

- (i) A hospital with less than 30 days of operating days in cash as of December 31st based on audited financial statements;
- (ii) A hospital with a net loss or a negative change in net assets for two consecutive years based on audited financial statements;
- (iii) A bankruptcy in the previous year or a waiver submitted under this section due to bankruptcy in the previous year;
 - (iv) Opening a new hospital after January 1, 2022;
- (v) Operating a low-income hospital, that is defined as a hospital serving a minimum of 30 percent medicaid patients; or
- (vi) Intent to discontinue operating in Washington prior to January 1, 2023.
- (b) Technological limitation that is not reasonable in the control of the hospital means the integration of electronic health records system changes, switching electronic health record system vendors, or updating the hospital's current electronic health record system to comply with the requirements of this section and is in progress but has not yet been completed; and
- (c) Other exceptional circumstance means unforeseen circumstances that stress the hospital in such a way that compliance is not possible. Examples may include, but are not limited to, natural disasters, widespread health care emergencies, unforeseen barriers to integration, or unforeseen events that results in a statewide emergency.

AMENDATORY SECTION (Amending WSR 07-09-091, filed 4/18/07, effective 5/23/07)

- WAC 246-455-040 Acceptable media for submission of data. (1) A hospital((s)) shall submit data in the ((form)) format prescribed by the department. The data must comply with the requirements in the CHARS Procedure Manual and CHARS ((837)) Companion Guide. Additional information not listed in WAC 246-455-020 and 246-455-025 may be required by the department to successfully process data submission files. Copies of the CHARS Procedure Manual and CHARS ((837)) Companion Guide may be obtained on the department's website or by contacting the department.
- (2) A department designee shall submit data to the department in the format prescribed by the department.

AMENDATORY SECTION (Amending WSR 07-09-091, filed 4/18/07, effective 5/23/07)

- WAC 246-455-050 Time deadline for submission of data. (1) A hospital((s)) shall submit data to the department or ((s)) the department's designee within ((s)) 45 calendar days following the end of each calendar month.
- (2) The department designee shall submit the data to the department after receiving the data from the hospital in the time frame prescribed by the department.

[9] OTS-3630.2

AMENDATORY SECTION (Amending WSR 94-12-090, filed 6/1/94, effective 7/2/94)

- WAC 246-455-060 Edits to data. The department or the department's designee shall edit the data as follows:
- (1) Record layout compatibility edits on data submitted in accordance with WAC 246-455-020 and 246-455-025; and
- (2) Verification of the data set elements set forth in WAC 246-455-020 and 246-455-025.

AMENDATORY SECTION (Amending WSR 15-19-152, filed 9/22/15, effective 10/23/15)

- WAC 246-455-070 Revisions to submitted data. (1) All data revisions required as a result of the edits performed pursuant to WAC ((246-455-020)) 246-455-060 shall be corrected by the hospital and returned to the department or ((its)) the department's designee within ((fourteen)) 14 working days after the submission deadline in WAC 246-455-050.
- (2) The department's designee shall submit the data to the department after receiving the revised data from the hospital in the time frame prescribed by the department.

AMENDATORY SECTION (Amending WSR 15-19-152, filed 9/22/15, effective 10/23/15)

- WAC 246-455-085 Data files—Release of data files and data use agreements. (1) The department may create and release data files with patient discharge information as allowed under RCW 43.70.052 and this chapter. The type of information contained in the file, including direct and indirect patient identifiers, determines the category and permitted release of the data file.
- (((1) Confidential data files contain one or more direct patient identifiers.
- (a))) (2) The department may aggregate data from patient discharge information, and may release such aggregated data with either direct patient identifiers or indirect patient identifiers, or both, in accordance with RCW 43.70.052 and this chapter.
- (3) In order to maintain the confidentiality of patient discharge data, for individual requests for data the department in its discretion may designate any of the patient discharge data collected under RCW 43.70.052 and this chapter as either a direct patient identifier or an indirect patient identifier in addition to the elements already designated by the department in subsection (6) of this section.
- (4) The department may distribute a ((confidential)) data file with direct patient identifiers only to:
- $((\frac{1}{2}))$ <u>(a)</u> Government agencies after entering into a data use agreement; or

- $((\frac{(ii)}{)})$ Researchers with approval from the Washington state $((\frac{1RB}{)})$ institutional review board and a signed confidentiality agreement with the department.
- (5) The department may distribute a data file that contains indirect patient identifiers only to agencies, researchers, and other persons upon receipt of a signed data use agreement with the department.
- (((b))) <u>(6)</u> Direct <u>and indirect</u> patient identifiers ((means information that identifies a patient. Direct identifiers include:
 - (i) Patient first name;
 - (ii) Patient middle name(s);
 - (iii) Patient last name;
 - (iv) Social Security number;
 - (v) Patient control number or medical record number;
 - (vi) Patient zip code + four digits;
 - (vii) Dates that include day, month, and year; and
 - (viii) Admission and discharge dates in combination.
- (c) Government agencies include: Washington state boards, commissions, committees, departments, educational institutions, or other Washington state agencies which are created by or pursuant to statute, other than courts and the legislature; Washington county or city agencies, U.S. federal agencies.
- (d) In order to comply with RCW 70.02.240 protecting mental health information for youth, for patients under age eighteen, the confidential data file will not include mental health related diagnosis or procedure codes or any diagnosis related groups or major diagnosis category.

(e))) are as follows:

	Direct or Indirect Patient
Patient Discharge Data Element	Identifier Identifier
Patient control number	Direct
Patient medical record number	Direct
Patient first name	<u>Direct</u>
Patient middle initial	<u>Direct</u>
Patient last name	<u>Direct</u>
Patient Social Security number	<u>Direct</u>
Patient address	<u>Direct</u>
Patient city	<u>Indirect</u>
Patient county	<u>Indirect</u>
Patient zip code and four digits	<u>Direct</u>
Patient zip code (five digits only)	<u>Indirect</u>
Patient state	<u>Indirect</u>
Patient country code	<u>Indirect</u>
Patient's date of birth (month, day, year)	<u>Direct</u>
Age in years	<u>Indirect</u>
Sex assigned at birth	<u>Indirect</u>
Race	<u>Indirect</u>
Ethnicity	Indirect
Gender identity	<u>Indirect</u>
Sexual orientation	<u>Indirect</u>
Preferred language	Indirect

	Direct or Indirect Patient
Patient Discharge Data Element	<u>Identifier</u>
<u>Disability</u>	<u>Indirect</u>
Admission date (month, day, year)	<u>Direct</u>
Admission hour	<u>Indirect</u>
Type of admission	<u>Indirect</u>
Point of origin for admission	<u>Indirect</u>
Patient discharge status	<u>Indirect</u>
Discharge hour	<u>Indirect</u>
Statement covers period (from through)	<u>Direct</u>
Type of bill	<u>Indirect</u>
Revenue code	<u>Indirect</u>
Units of service	Indirect
Total charges	<u>Indirect</u>
Payer identification	<u>Indirect</u>
Principal diagnosis code	<u>Indirect</u>
Other diagnosis code	<u>Indirect</u>
External cause of injury code	<u>Indirect</u>
Principal procedure code	<u>Indirect</u>
Other procedure code	<u>Indirect</u>
Admitting diagnosis code	<u>Indirect</u>
Patient's reason for visit ICD code (1-3)	Indirect
Procedure date (month, day, year)	<u>Direct</u>
Present on admission status	Indirect
Service date (month, day, year)	<u>Direct</u>
Insured last name, first name, middle name, suffix	<u>Direct</u>
Patient's relationship to insured (code)	<u>Indirect</u>
Insured ID	<u>Direct</u>
Facility federal tax number	<u>Indirect</u>
National Provider Identifier for provider(s)	Indirect
First and last name of provider(s)	<u>Indirect</u>
Health care provider taxonomy code	<u>Indirect</u>
Health care common procedure coding system	Indirect

⁽⁷⁾ In order to comply with 42 U.S.C. Sec. 290dd-2 and 42 C.F.R. Part 2, for any hospitalization that includes substance abuse disorder related diagnosis or procedure codes or any diagnosis related groups or major diagnosis category to the extent collected by the department, the department will remove substance abuse disorder related diagnosis or procedure codes or any diagnosis related groups or major diagnosis category from the direct patient identifier data file.

 $[\]underline{\mbox{(8)}}$ Information and records related to mental health services will be disclosed consistent with both RCW 43.70.052 and chapter 70.02 RCW.

⁽⁹⁾ In order to comply with WAC 246-490-110 protecting the identity of facilities that provide abortions, for any hospitalization

that includes a diagnosis or procedure code indicating an induced termination of pregnancy, the ((confidential)) data file with direct patient identifiers will not include patient name, facility ID, provider identifiers, or geographic identifiers less than state.

- $((\frac{f}{f}))$ The department may provide the fewest data elements necessary for the stated purpose of the project.
- ((2) Potentially identifiable data files contain indirect patient identifiers.
- (a) The department may distribute a potentially identifiable data file to anyone after entering into a data use agreement with the requestor or requesting organization.
- (b) Indirect patient identifier means information that may identify a patient when combined with other information. Identification of a specific patient is more likely when a file contains a group of ten or fewer similar hospitalizations.
- (c) Indirect patient identifiers include the following data elements, in combination or individually, when they create a group of ten or fewer similar hospitalizations in a file:
 - (i) Hospital or provider identifiers;
 - (ii) Five digit zip code;
 - (iii) County, state, and country of residence;
 - (iv) Dates that include month and year;
 - (v) Admission and discharge hour;
- (vi) Secondary diagnosis, procedure, present on admission, external cause of injury, and payer codes;
 - (vii) Age in years;
 - (viii) Race and ethnicity.
- (d) The potentially identifiable data file does not contain any direct identifiers listed in subsection (1)(b)(i) through (viii) of this section.
 - (3) Public data file with no patient identifiers:
- (a) The department may release an unrestricted public data file that does not contain information that alone or in combination with other information identifies a patient.
- (b)) (11) The department may release an unrestricted public data file that does not contain direct or indirect patient identifiers to anyone. The department may create a public file by:
- $((\frac{(i)}{(i)}))$ (a) Removing all data elements $((\frac{identified}{identified}))$ designated as indirect in subsection $((\frac{(2)}{(c)})(i)$ through $(\frac{(identified)}{(viii)}))$ (6) of this section; or
- $((\frac{(ii) By}{)})$ (b) Aggregating or anonymizing data $(\frac{(identified)}{designated})$ designated as indirect in subsection $((\frac{(2)(c)(i)}{through})$, $(\frac{(vii)}{through})$, $(\frac{(vii)}{through})$) (6) of this section so that each combination of indirect patient identifiers remaining in the public file must appear at least $(\frac{(ten)}{through})$ 10 times $(\frac{(-1)}{through})$; and
- (c) ((The public data file does not contain any)) Removing all data elements designated as direct (($identifiers\ listed$)) in subsection (($identifiers\ listed$)) in subsection (($identifiers\ listed$)) in subsection.

NEW SECTION

WAC 246-455-105 Requests from government agencies for patient discharge data files containing direct patient identifiers. (1) A government agency requesting data files that contain direct patient

identifiers for nonresearch purposes must comply with the requirement of RCW 43.70.052 and this section. The department will not release data to a government agency requesting data from the department pursuant to this section until all requirements of this section have been completed to the satisfaction of the department.

- (2) A government agency submitting a data request under this section for nonresearch purposes must submit all of the following to the department in the form or format required by the department:
- (a) A completed application on the form provided by the department;
- (b) A signed data use agreement with the department that conforms with WAC 246-455-400;
- (c) All information required in subsection (3) of this section; and
 - (d) All fees required by WAC 246-455-990.
- (3) A government agency submitting a data request under this section for nonresearch purposes must submit to the department all of the following information:
- (a) Name, title, organizational affiliation, and contact information (mailing address, telephone number, and email address) of the requestor, the organization official authorized to execute agreements, the organization information technology security officer, and organization privacy officer;
- (b) Purpose or intended use of the data being requested, including any proposed redisclosure of the data;
 - (c) Length of time and frequency of the data being requested;
- (d) Physical and electronic security measures to be taken to assure confidentiality and security of identifying information, including stored information;
- (e) Provision for return or destruction of the information at the conclusion of use;
 - (f) Population of interest;
- (g) Names and titles of all persons who will have access to the data;
- (h) The plan for use of the data and certification to abide by the department's small numbers guidelines;
- (i) Patient discharge data elements needed to achieve the purpose; and
 - (j) Years of the requested data.
- (4) The department may request additional information regarding the request for patient discharge data containing direct identifiers. If additional information is requested, the government agency must submit the information within 30 days of the department's request or the request for data may be denied.
- (5) If the department determines the request for data submitted pursuant to this section is in fact for research purposes, the department will require the government agency to comply with the provisions of WAC 246-455-200.
- (6) If the department suspects or is unsure if the request for data submitted pursuant to this section is for research purposes, the department may require the government agency to comply with the provisions of WAC 246-455-200.
- (7) The department may deny a request for data if the government agency submitting a data request under this section fails to meet any of the requirements of this chapter or RCW 43.70.052.

- WAC 246-455-200 Requests for patient discharge data files containing direct patient identifiers for research. (1) A researcher requesting data files that contains direct patient identifiers for research must comply with the requirements of RCW 43.70.052 and this section. The department will not release data to a researcher requesting data from the department until all the requirements of this section have been completed to the satisfaction of the department.
- (2) A researcher submitting a data request under this section must submit all of the following to the department:
- (a) A completed records request form associated with the human research review board application that contains all the information required in subsection (3) of this section;
- (b) Approval from the human research review board of the research proposal for which the data is being requested;
 - (c) A signed confidentiality agreement with the department; and (d) All fees required by WAC 246-455-990.
- (3) A researcher submitting a data request under this section must submit all of the following information on the records request forms provided by the human research review board to the department for review and approval:
 - (a) Project title;
- (b) Principal investigator name, title, and contact information (telephone number and email address);
 - (c) Study abstract that includes:
 - (i) Description of the proposed research study and objectives;
 - (ii) Research study design and analysis plan;
 - (iii) Duration of research study;
- (iv) The plan for dissemination of the results and a certification that the researcher will abide by the department's small numbers quidelines in the dissemination of results; and
- (v) A plan for the return or destruction of the information at the conclusion of the research study.
- (d) Patient discharge data elements needed to complete the research study;
 - (e) Years of the requested data; and
 - (f) Geographic area of interest of the research study.
- (4) The department may request additional information regarding the research proposal. If additional information is requested, the researcher must submit the information within 30 days of the department's request or the request for data may be denied.
- (5) If the researcher submitting a data request under this section receives an exempt determination letter from the human research review board, the researcher may:
- (a) If the researcher is a governmental agency, comply with the provisions of WAC 246-455-105; or
 - (b) Submit a request to receive data pursuant to WAC 246-455-300.
- (6) The department may deny a request for data for research purposes if the researcher submitting a data request under this section fails to meet any of the requirements of this chapter or RCW 43.70.052.

WAC 246-455-300 Requests from individuals or entities for patient discharge data files containing indirect patient identifiers.

- (1) All requests for data under this section must comply with the requirements of RCW 43.70.052 and this section. The department will not release data to an individual or entity requesting data from the department pursuant to this section until all the requirements of this section have been completed to the satisfaction of the department.
- (2) The data released pursuant to this section will only be in the data file format prescribed by the department.
- (3) An individual or entity submitting a data request under this section must submit all of the following on the form or in the format required by the department:
- (a) A completed application on the form provided by the department;
- (b) A signed data use agreement with the department that conforms with WAC 246-455-400;
- (c) All information required in subsection (4) of this section; and
 - (d) All fees required by WAC 246-455-990.
- (4) An individual or entity submitting a data request under this section must submit all of the following information to the department:
- (a) Name, title, organizational affiliation, and contact information (mailing address, telephone number, and email address) of the requestor, the organization official authorized to execute agreements, the organization information technology security officer, and the organization privacy officer;
- (b) Purpose or intended use of the data being requested, including any proposed redisclosure of the data;
 - (c) Length of time data is needed or length of the project;
- (d) Physical and electronic security measures to be taken to assure confidentiality and security of identifying information including storage of data, and provision for return or destruction of the information at the conclusion of use;
- (e) Names and titles of all persons who will have access to the data;
- (f) The plan for dissemination of the results and certification to abide by the department's small numbers guidelines; and
 - (q) Years of data requested.
- (5) The department may request additional information regarding the request for data under this section. If additional information is requested, the individual or entity must submit the information within 30 days of the department's request or the request for data may be denied.
- (6) The individual or entity must download the data from the secured file transfer site within two weeks. If after the two weeks, the requestor has not retrieved the data, the individual or entity must submit a new request and payment.
- (7) The department may deny a request for data if the individual or entity submitting a data request under this section fails to meet any of the requirements of this chapter or RCW 43.70.052.

NEW SECTION

- WAC 246-455-400 Patient discharge data use agreements. (1) All written data use agreements with the department for the release of patient discharge data must comply with the requirements of RCW 43.70.052 and this section.
- (2) A data use agreement with the department is required for the following:
- (a) Government agencies requesting data that contains direct patient identifiers for nonresearch purposes; and
- (b) Individuals or entities requesting data that contains only indirect patient identifiers.
- (3) The department may use standard form data use agreements for all data requests, consistent with the provisions of this section and RCW 43.70.052. If the department chooses to use a standard form data use agreement for data requests, the requestor shall sign the standard form data use agreement prepared by the department pursuant to this subsection. If the department chooses to negotiate the terms of the standard form data use agreement for data requests, the ultimate decision to modify the standard form data use agreement to accommodate a data request lies solely with the department.
- (4) An individual or entity requesting data under this section must comply with all the terms and conditions of the data use agreement. If the individual or entity violates the data use agreement, it will result in the immediate termination of the data use agreement and result in denial of patient discharge data in the future.

NEW SECTION

- WAC 246-455-500 Data file production. (1) The department retains the discretion to determine what form or format is most appropriate to provide to a particular requestor. Where the department provides data files on a routine schedule, the department may automate file production. The department may manually produce data files when deemed appropriate. Nothing in this chapter should be deemed to entitle any requestor to receive data in a particular form or format, and nothing in this chapter should be deemed to require the department to produce the data in a particular form or format.
- (2) Where the department provides data files on a routine schedule, the department may allow a requestor to update their original data request with the department. If the department permits a requestor to update their data request, the requestor must pay the fee required by WAC 246-455-990(4).

NEW SECTION

- WAC 246-455-990 Data file fees. (1) The department may not charge a fee for state officials and agencies receiving data funded through the state general appropriation.
 - (2) The department shall collect nonrefundable fees as follows:

- (a) One hundred ten dollars per standard data file;
- (b) Fifty dollars per standard data file for students with proof of valid student status; and
 - (c) One hundred ten dollars per custom data file.
- (3) For data requests where data files are provided on a routine schedule to an entity, the department may enter into an agreement with that entity and charge a fee equivalent to the actual costs incurred by the department for reimbursement of the data request.
- (4) Updates to data requests allowed by WAC 246-455-500(2) will be assessed a fee by the department equivalent to the actual costs incurred by the department to update the data request.
 - (5) The department may waive fees for the following:
 - (a) Local health jurisdictions receiving standard data files;
- (b) Tribes, tribal organization within the state, and Indian health service designated tribal epidemiology centers serving tribes within the state receiving standard data files; and
 - (c) Patient discharge data sharing initiated by the department.

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 246-455-080 Security of the data.