Kevin Meyer Lieutenant Governor State Capitol Juneau, Alaska 99811 907.465.3520 WWW.LTGOV.ALASKA.GOV



530 West 7th Ave, Suite 1700 Anchorage, Alaska 99501 907.269.7460 LT.GOVERNOR@ALASKA.GOV

OFFICE OF THE LIEUTENANT GOVERNOR ALASKA

MEMORANDUM

TO:

Triptaa Surve, Department of Health and Social Services

FROM:

April Simpson, Office of the Lieutenant Governor

465.4081

DATE:

February 15, 2022

RE:

Filed Permanent Regulations: Department of Health and Social Services

Department of Health and Social Services regulations re: ambulatory surgical center (7

AAC 12)

Attorney General File:

2020200677

Regulation Filed:

2/15/2022

Effective Date:

3/17/2022

Print:

241, April 2022

cc with enclosures:

Joseph Felkl, Department of Law

Judy Herndon, LexisNexis

ORDER ADOPTING CHANGES TO REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES

The attached 7 pages of regulations, dealing with Ambulatory Surgical Center Requirements & Miscellany, specifically, 7 AAC 12. Facilities & Local Units, are adopted and certified to be a correct copy of the regulation changes that the Department of Health and Social Services adopts under the authority of AS 18.05.040, AS 47.32.010, and AS 47.32.030, and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

In considering public comments, the Department of Health & Social Services paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes adopted under this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

Adam Crum

Digitally signed by Adam Crum Date: 2022.02.04 08:56:20 -09'00'

Adam Crum, Commissioner Department of Health & Social Services

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on <u>Febr. 15</u> 2022, at 3:00 m., I filed the attached regulations according to the provisions of AS 44.62.040 -44.62.120.

Effective:

March 17,2022 241, April 2022

Register:

7 AAC 12.338(h)(4)(B) is amended to read:

(B) the prevention, transmission, and treatment of tuberculosis, in

accordance with 7 AAC 12.650(a)(1);

(Eff. 5/24/2007, Register 182; am 3 /17 /2022, Register 241)

Authority:

AS 18.05.040

AS 47.32.010

AS 47.32.030

7 AAC 12.340 is repealed and readopted to read:

7 AAC 12.340. Employee health. A hospice agency shall have an employee health program that meets the requirements of 7 AAC 12.650. The agency shall require contractors and volunteers performing patient care or services for the agency to meet the requirements of 7 AAC 12.650. (Eff. 5/24/2007, Register 182; am 3 / 17 / 2022, Register 241)

Authority:

AS 18.05.040

AS 47.32.010

AS 47.32.030

The article heading for 7 AAC 12, Article 8, is changed to read:

Article 8. Ambulatory Surgical Centers [FACILITIES].

7 AAC 12.350 is amended to read:

7 AAC 12.350. Scope. A facility that [WHICH] is not a part of a hospital, nor part of a physician's general medical practice, and that [WHICH] operates primarily for the purpose of providing surgical services to patients who do not require hospitalization is an ambulatory surgical center [FACILITY] and must comply with 7 AAC 12.350 - 7 AAC 12.370. (Eff. 11/19/83, Register 88; am 3 /13 /2072, Register 241)

Authority: AS 18.05.040 **AS 47.32.010 AS 47.32.030**

7 AAC 12 is amended by adding a new section to read:

7 AAC 12.352. Medical staff. The ambulatory surgical center medical staff shall

- (1) recommend to the governing body the appointment of and the medical and surgical privileges for each member of the medical staff annually, or if approved by the governing body, biennially;
- (2) ensure that each patient is under the care of a credentialed medical practitioner;
- (3) require that an order relating to patient care from a credentialed medical practitioner acting within the scope of the practitioner's license, including a telephonic or other oral order, be transcribed by date and time and be initialed or signed by the credentialed medical practitioner or by another credentialed medical practitioner responsible for the care of the patient, even if the order did not originate with the other practitioner;
 - (4) establish procedures for circumstances in which consultation is required;
- (5) establish standards of care by residents, interns, and medical students in accordance with a residency training program approved by the Council on Medical Education of the American Medical Association, the American Dental Association, or an applicable specialty board;
- (6) review at regular intervals, but not less than once every three months, clinical and scientific work, medical services, and maintenance of accurate medical records;
 - (7) establish guidelines for referral to a pathologist of anatomical parts, foreign

Register 241, April 2022 HEALTH AND SOCIAL SERVICES objects, and tissues removed by surgery;

- (8) establish procedures for supervision of advanced practice registered nurses and physician assistants; and
- (9) ensure that patient admission, assessment, and discharge meet the requirements of 42 C.F.R. 416.52, revised November 29, 2019 and adopted by reference. (Eff. 3 / 17/222, Register 241)

Authority: AS 18.05.040 AS 47.32.010 AS 47.32.030

7 AAC 12.355 is repealed and readopted to read:

7 AAC 12.355. Services required. An ambulatory surgical facility shall provide the following services:

- (1) surgical services that meet the following requirements:
- (A) a registered nurse with knowledge and experience in surgical techniques and procedures shall have supervisory responsibility for the surgical suite and, in cooperation with the surgical committee of the medical staff and the infection control committee, establish policies and procedures for the surgical service;
- (B) a list of which surgical privileges are held by individual members of the medical staff must be available in the surgical suite for reference by the supervisor;
- (C) before a surgical procedure begins, either the surgeon or the person responsible for administering anesthesia, and the surgical supervisor or the supervisor's designee shall
 - (i) confirm the patient's identity and the site and side of the body

to be operated upon; and

- (ii) except in the event of an emergency, ensure that the patient's medical record contains pre-surgical assessments that meet the requirements of 42 C.F.R. 416.52(a), adopted by reference in 7 AAC 12.352(9), and a signed statement of informed consent for the surgery;
 - (D) a daily register of operations must be maintained;
- (E) as determined by medical staff under 7 AAC 12.352(7), anatomical parts, foreign objects, and tissues that have been removed by surgery shall be referred to a pathologist designated by the ambulatory surgical center; a report of the pathologist's findings must be filed in the patient's medical record;
- (F) a registered nurse shall be present as a circulating nurse during each surgical procedure;
 - (2) anesthesia services that meet the following requirements:
- (A) a physician shall have overall responsibility for supervision of anesthesia services;
- (B) anesthesia care shall be provided by only a physician or dentist with anesthesia privileges or a certified registered nurse anesthetist;
- (C) an anesthesia staff member shall be available or on call at all times when a patient is present in the facility;
 - (D) a patient's medical record must include the following documentation:
 - (i) visits to a patient by an anesthesiologist or anesthetist before and after the anesthesia is administered; any individual described in (B) of this

paragraph and qualified to administer anesthesia may complete and document the post-anesthesia evaluation of a patient;

- (ii) the chosen anesthetic agent;
- (iii) the amount and duration of anesthetic agents, other drugs, intravenous fluids, and blood or blood products administered;
- (iv) a description of actions during the surgical procedure and presence or absence of complications; and
- (v) a record of events during induction, maintenance, and emergence from anesthesia;
- (E) rules for the safe use of flammable anesthetic agents must comply with 42 C.F.R. 416.44(c), revised July 5, 2016 and adopted by reference;
- (3) laboratory, radiological, medical record, and laundry services. (Eff. 11/19/83, Register 88; am 3 / 17 / 2022, Register 24)

Authority: AS 18.05.040 AS 47.32.010 AS 47.32.030

The section heading of 7 AAC 12.360 is changed to read:

7 AAC 12.360. Emergency equipment, [AND] treatment, and requirements.

7 AAC 12.360(b) is amended to read:

- (b) A registered nurse <u>must</u> [SHALL] be <u>on-site</u> [PRESENT] to provide emergency treatment <u>at all times when a</u> [FOR] patient <u>is present in the facility</u>.
- 7 AAC 12.360 is amended by adding a new subsection to read:

(c) An ambulatory surgical center shall provide written notice of the center's operation and population served to the nearest general acute care hospitals in the event that transfer of a patient who requires medical or emergency care beyond the scope of the ability or license of the center is needed. (Eff. 11/19/83, Register 88; am 3/11/2022, Register 24)

Authority: AS 18.05.040 **AS 47.32.010 AS 47.32.030**

7 AAC 12.365 is repealed and readopted to read:

7 AAC 12.365. Obstetrical care. An ambulatory surgical center that provides labor and delivery services shall provide a separate and individual suite for those services. (Eff. 11/19/83, Register 88; am 3 /17/2022, Register 241)

Authority: AS 18.05.040 **AS 47.32.010 AS 47.32.030**

7 AAC 12.566(b)(4) is amended to read:

(4) tuberculosis, in accordance with 7 AAC 12.650(a)(1). (Eff. 9/6/96, Register 139; am 3 / 17 / 2022, Register 24)

Authority: AS 18.05.040 **AS 47.32.010 AS 47.32.030**

7 AAC 12.571 is repealed and readopted to read:

7 AAC 12.571. Employee health program. A home health agency shall have an employee health program that meets the requirements of 7 AAC 12.650. (Eff. 9/6/96, Register 139; am 3/17/2022, Register 241)

Authority: AS 18.05.040 **AS 47.32.010 AS 47.32.030**

7 AAC 12.910(d) is amended to read:

(d) Specialized [AMBULATORY SURGICAL FACILITIES, SPECIALIZED] hospitals, rural primary care hospitals, critical access hospitals, nursing homes, and intermediate care facilities for individuals with an intellectual disability or related condition must have a signed agreement with a general acute care hospital for transfer of patients who require medical or emergency care beyond the scope of the ability or license of the facility. (Eff. 11/19/83, Register 88; am 5/4/97, Register 142; am 9/1/2000, Register 155; am 5/24/2007, Register 182; am 9/30/2007, Register 183; am 3/11/2022, Register 241)

Authority:

AS 47.32.010

AS 47.32.030

7 AAC 12.990(4) is amended to read:

AS 18.05.040

(4) <u>"ambulatory surgical center" or</u> "ambulatory surgical facility" means a facility described in <u>AS 47.32.900 and</u> 7 AAC 12.350;

(Eff. 11/19/83, Register 88; am 5/28/92, Register 122; am 5/4/97, Register 142; am 9/1/2000, Register 155; am 6/23/2006, Register 179; am 12/3/2006, Register 180; am 5/24/2007, Register 182; am 9/30/2007, Register 183; am 7/29/2011, Register 199; am 5/14/2021, Register 238; am 3/11/2022, Register 241)

Authority:

AS 18.05.040

AS 47.32.010

AS 47.32.030

MEMORANDUM

State of Alaska Department of Law

To: The Honorable Kevin Meyer

Lieutenant Governor

Date: February 7, 2022

File No.: 2020200677

Tel. No.: 907-465-3600

From: Rebecca C. Polizzotto

Chief Assistant Attorney General and Regulations Attorney
Legislation, Regulations, and
Legislative Research Section

Re: Department of Health and Social Services regulations re: ambulatory

surgical centers (7 AAC 12)

The Department of Law has reviewed the attached regulations of the Department of Health and Social Services against the statutory standards of the Administrative Procedure Act. Based upon our review, we find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations. The regulations were adopted by the Department of Health and Social Services after the close of the public comment period. The regulations update facilities licensure requirements for ambulatory surgical centers, including reduction of some administrative burdens on the centers and staffs, and make conforming changes.

The December 6, 2020 public notice and the February 4, 2022 adoption order both state that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

RCP:scw

Cc w/ enclosure: Triptaa Surve, Regulations Contact

Department of Health and Social Services

Paul Peterson, Assistant Attorney General

Department of Law

NOTICE OF PROPOSED CHANGES ON AMBULATORY SURGICAL CENTER REQUIREMENTS & MISCELLANY IN THE REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL SERVICES

BRIEF DESCRIPTION

The Department of Health & Social Services proposes to change regulations on Ambulatory Surgical Center Requirements and Miscellany to comply with federal regulations.

The Department of Health & Social Services proposes to adopt regulation changes in Title 7 of the Alaska Administrative Code, dealing with Ambulatory Surgical Services and Miscellany, including the following:

- 7 AAC 12. Facilities and Local Units, is proposed to be changed to comply with federal regulations as follows:
 - Remove transfer agreement requirement.
 - Replace 30-day history and physical requirement with language that defers to the operating physician's clinical judgment.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Ms. Susan Miller Dunkin at the Department of Health & Social Services, Division of Health Care Services, 4501 Business Park Blvd., Building L, Attention: Susan Miler Dunkin, Anchorage, AK 99503. Additionally, the Department of Health & Social Services will accept comments by electronic mail at susan.dunkin@alaska.gov. The comments must be received not later than 5 p.m. on January 15, 2021.

You may submit written questions relevant to the proposed action to Ms. Susan Miller Dunkin by e-mail at susan.dunkin@alaska.gov or at the Department of Health & Social Services, Division of Health Care Services, 4501 Business Park Blvd., Building L, Attention: Susan Miller Dunkin, Anchorage, AK 99503. The questions must be received at least 10 days before the end of the public comment period. The Department of Health & Social Services will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and agency website at http://www.dhss.alaska.gov/dhcs/Pages/default.aspx.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Ms. Susan Miller Dunkin at susan.dunkin@alaska.gov or at (907) 269-3638 not later than January 7, 2021, to ensure that any necessary accommodations can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Ms. Susan Miller Dunkin at susan.dunkin@alaska.gov or by telephone at (907) 269-3638. After the public comment period ends, the Department of Health & Social Services will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. You should comment during the time allowed if your interests could be affected.

Statutory authority: AS 18.05.040; AS 18.20.010; AS 18.20.060; AS 47.32.010; AS 47.32.020; AS 47.32.030.

Statutes being implemented, interpreted, or made specific: AS 18.05.040; AS 18.20.010; AS 18.20.060; AS 47.32.010; AS 47.32.020; AS 47.32.030.

Fiscal information: The proposed regulation changes are not expected to require an increased appropriation.

The Department of Health & Social Services, Division of Health Care Services, keeps a list of individuals and organizations interested in its regulations. Those on the list will automatically be sent a copy of all of the Department of Health & Social Services, Division of Health Care Services, notices of proposed regulation changes. To be added to or removed from the list, send a request to the Department of Health & Social Services, Division of Health Care Services at susan.dunkin@alaska.gov, giving your name, and either your e-mail address or mailing address, as you prefer for receiving notices.

DATE: December 3, 2020. /s/Adam Crum Commissioner, Department of Health & Social Services, State of Alaska.

ADDITIONAL REGULATION NOTICE INFORMATION (AS 44.62.190(d))

1.	Adopting agency: Department of Health & Social Services			
2.	General subject of regulation: <u>Ambulatory Surgical Center Requirements & Miscellany, specifically 7 AAC 12. Facilities & Local Units.</u>			
3.	Citation of regulation (may be grouped): 7 AAC 12.110, .120, .338, .340, .566, .571, .910.			
4.	Department of Law file number, if any: 2020200677			
5,	Reason for the proposed action: (X) Compliance with federal law or action (identify): 42 C.F.R. 416.41(b)(3); 42 C.F.R. 416.52(a) () Compliance with new or changed state statute () Compliance with federal or state court decision (identify):			
6.	Appropriation/Allocation: <u>Department of Health and Social Services/Health Care Services/ Health Facilities Licensing and Certification</u>			
7.	Estimated annual cost to comply with the proposed action to: A private person: \$0 Another state agency: \$0 A municipality: \$0			
8.	Cost of implementation to the	state agency an Initial Year FY		
	Operating Cost			
	Capital Cost	\$	\$ \$	
	1002 Federal receipts	\$	\$	
	1003 General fund match	\$	\$	
	1004 General fund	\$	\$	
	1005 General fund/			
	program	\$	\$	
	Other (identify)	\$	\$	
9.	The name of the contact pers Name: Ms. Susan Miller Dunl Title: Medicaid Program Spec Address: 4501 Business Park	<u>kin</u> cialist IV		

Telephone: (907) 269-3638 E-mail address: susan.dunkin@alaska.gov

10.	The origin of the proposed action: X Staff of state agency Federal government General public Petition for regulation change ⁷ Other (identify):		
11.	Susan Miller Susan Miller Susan Miller Value (Miller Dunkin) Date & Prepared by: Dunkin Date 2020,12.01 11:02:57 -09:00'		
	[signature]		
	Name (printed): Susan Miller Dunkin		
	Title (printed): Medicaid Program Specialist IV		
	Telephone: (907) 269-3638		

AFFIDAVIT OF NOTICE OF PROPOSED REGULATION AND FURNISHING OF ADDITIONAL INFORMATION

I, Susan Miller Dunkin, of the Department of Health & Social Services, under penalty of perjury, certify the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to Ambulatory Surgical Center Requirements & Miscellany, specifically, 7 AAC 12. Facilities and Local Units, has been given by being

- (1) published in a newspaper or trade publication;
- (2) furnished to every person who has filed a request for notice of proposed action with the state agency;
- (3) furnished to appropriate state officials;
- (4) furnished to interested persons;
- (5) furnished to the Department of Law, along with a copy of the proposed regulation;
- (6) furnished electronically to incumbent State of Alaska legislators;
- (7) posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1).

As required by AS 44.62.190, additional regulation notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (2), (4) and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

There is no notary public or other official empowered to administer oaths available to notarize this document as a result of social distancing requirements implemented statewide.

I certify under penalty of perjury that the foregoing is true.

Susan Miller Digitally signed by Susan Miller Dunkin
Dunkin
Dunkin
Digitally signed by Susan Miller Dunkin
Date: 2021.05.06
15:10:24-0800'

[original or password-protected electronic signature]
Susan Miller Dunkin, Medicaid Program Specialist IV

State of Alaska Anchorage, AK 99503

AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Susan Miller Dunkin, of the Department of Health & Social Services, under penalty of perjury, state the following:

In compliance with AS 44.62.215, the Department of Health & Social Services has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Department of Health & Social Services regulation on Ambulatory Surgical Center Requirements & Miscellany, specifically, 7 AAC 12. Facilities and Local Units.

There is no notary public or other official empowered to administer oaths available to notarize this document as a result of social distancing requirements implemented statewide.

I certify under penalty of perjury that the foregoing is true.

Susan Miller Digitally signed by Susan Miller Dunkin

Dunkin

Date: 2021.05.06
15:09:38 -08'00'

[original or password-protected electronic signature] Susan Miller Dunkin, Medicaid Program Specialist IV

State of Alaska Anchorage, AK 99503.

NCHORAGE DAILY NEWS AFFIDAVIT OF PUBLICATION

Account #: 270229 ST OF AK/DHSS/COMMISSIONERS 3601 C STREET STE 902, ANCHORAGE, AK 99503

Order #: W0019354

STATE OF ALASKA

NOTARY

PUBLIC

Cost: \$423.34

STATE OF ALASKA THIRD JUDICIAL DISTRICT

Lisi Misa being first duly sworn on oath deposes and says that she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

12/06/2020

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed

Subscribed and sworn to before me this 7th day of December 2020.

Notary Public in and for The State of Alaska. Third Division Anchorage, Alaska

MY COMMISSION EXPIRES

NOTICE OF PROPOSED CHANGES ON AMBULATORY SURGICAL CENTER REQUIREMENTS & MISCELLANY IN THE REGULATIONS OF THE DEPARTMENT OF HEALTH & SOCIAL

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DATE: December 3, 2020. /s/Adam Crum Commissioner, Department of Health & Social Services,

Published: December 6, 2020