

REGULATORY REVIEW AND EVALUATION ACT:

EVALUATION REPORTS DUE JULY 1, 2017 FOR:

**Subtitle 05 FREESTANDING AMBULATORY
SURGICAL FACILITIES**

Subtitle 07 HOSPITALS

Subtitle 08 HEALTH FACILITIES GRANTS

SUBMITTED BY:

**Maryland Department of Health
Office of Regulation and Policy Coordination
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EVALUATION REPORTS

Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES

10.05.05 Freestanding Ambulatory Surgical Facilities

Subtitle 07 HOSPITALS

- 10.07.01 Acute General Hospitals and Special Hospitals
- 10.07.02 Comprehensive Care Facilities and Extended Care Facilities
- 10.07.06 Hospital Patient Safety Program
- 10.07.07 Nursing Referral Service Agencies
- 10.07.08 Freestanding Medical Facilities
- 10.07.09 Residents' Bill of Rights: Comprehensive Care Facilities and Extended Care Facilities
- 10.07.10 Home Health Agencies
- 10.07.11 Health Maintenance Organizations
- 10.07.12 Health Care Facilities Within Correctional Institutions
- 10.07.17 Limited Service Hospital
- 10.07.18 Comprehensive Rehabilitation Facilities
- 10.07.21 Hospice Care Programs

Subtitle 08 HEALTH FACILITIES GRANTS

- 10.08.01 Construction Funds For Public and Nonprofit Nursing Homes
- 10.08.02 Construction Funds For Public & Nonprofit Community Mental Health, Addiction, & DD Fac.
- 10.08.03 Construction Funds for Public and Nonprofit Adult Day Care Centers
- 10.08.04 Construction Funds for Public and Nonprofit Assisted Living Facilities
- 10.08.05 Construction Funds for Federally Qualified Health Centers
- 10.08.06 Construction Funds for Conversion of Nursing Facilities

EXEMPTIONS REQUESTED

In accordance with State Government Article, §10-132-1, Annotated Code of Maryland, the Secretary has certified to the Governor and the AELR Committee that a review of the following chapters would not be effective or cost-effective and therefore are exempt from the review process based on the fact that they were either initially adopted (IA), comprehensively amended (CA) during the preceding 8 years, or Federally mandated (FM):

Subtitle 05 FREESTANDING AMBULATORY CARE FACILITIES

- | | |
|--|----------------------|
| 10.05.01 General Requirements | CA 2/27/17 & 3-13-17 |
| 10.05.02 Freestanding Birthing Centers | CA 2/15/16 |
| 10.05.03 Freestanding Major Medical Equipment Facilities | CA 2/27/17 |
| 10.05.04 Freestanding Kidney Dialysis Centers | CA 2/18/13 |

Subtitle 07 HOSPITALS

- | | |
|--|------------|
| 10.07.03 Health Care Staff Agencies | CA 9/15/14 |
| 10.07.04 Res. Treatment Centers for Emotionally Disturbed Children & Adolescents | CA 5/22/17 |

10.07.05 Residential Service Agencies	CA 5/1/12
10.07.13 Forensic Residential Centers (FRCs)	IA 1/26/09
10.07.14 Assisted Living Programs	CA 12/29/08
10.07.15 License Fee Schedule for Hospitals and Related Institutions	CA 8/29/16
10.07.16 Limited Private Inpatient Facilities	IA 12/10/15
10.07.20 Intermediate Care Facilities for Individuals with Intellectual Disabilities...(ICF/IID)	CA 1/20/14
10.07.22 Hospice Care Programs: Hospice House Requirements	IA 6/10/13

CHAPTERS THAT ARE VACANT / TRANSFERRED

Subtitle 07 HOSPITALS

10.07.19 VACANT Transferred to Title 31 Maryland Insurance Administration – COMAR 31.10.21

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

See attached table.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None.

- (6) Provide a summary of any relevant scientific data gathered.

None.

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and Assistant Attorney general reviewed the regulations and determined there were no conflicts between COMAR 10.05.02 and the federal regulations.

- (8) Provide a summary of any other relevant information gathered.

The program manager met with surveyors and the providers of freestanding ambulatory surgical centers and there was no relevant information gathered on COMAR 10.05.05.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

The Office of Health Care Quality has reviewed COMAR 10.05.05 with internal staff and external stakeholders. There were 7 comments submitted in regards to COMAR 10.05.05 through the online comment platform. OHCQ reviewed all comments, however no suggested revisions were accepted. OHCQ determined the regulations are sufficient as written.

Person performing review:

Amanda Thomas

Health Policy Analyst for
Regulatory Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and

(e) any public hearing held.

On August 12, 2016 the OHCQ posted information on its website to notify all stakeholders of the opening of a 30 day comment period. Additionally OHCQ sent e-mail notifications to critical stakeholders and groups as identified by OHCQ program managers.

(4) Provide summaries of:

- (a) all comments received from stakeholders, affected units, or the public; and
- (b) the adopting authority's responses to those comments.

No comments regarding 10.07.01 were received from stakeholders. OHCQ will review Inpatient Prospective Payment Systems regulations published by the Centers for Medicare and Medicaid Services (CMS) as well as changes to the Maryland Health Care Decisions Act mandated by bills passed during the 2017 Maryland Legislative Session and amend this chapter as appropriate.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

(6) Provide a summary of any relevant scientific data gathered.

None

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General have reviewed 10.07.01 to assess the chapter for any conflicts with federal law and none were found.

(8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ hospital surveyors.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No
Provide explanations of the above responses, as needed:

N/A

D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

- X no action
- amendment
- repeal
- repeal and adopt new regulations
- reorganization

Summary:

The OHCQ reviewed COMAR 10.07.01 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore no changes to the chapter will be made.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

10.07.02

Chapter Name:

Comprehensive Care Facilities and Extended Care Facilities

Authority:

Health-General Article, §§19-308, 19-308.1, 19-323, and 19-1401 et seq.; Public Safety Article, §14-110.1; Annotated Code of Maryland

Date Originally Adopted or Last Amended:

Regulations .03 and 05, amended effective August 2017

Purpose:

The purpose and intent of this chapter is to prescribe minimum standards to be met by facilities to which are admitted two or more nonrelated persons who do not need the intensive care provided by a hospital but who are unable to be cared for appropriately in the home environment.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

The Office of Health Care Quality (OHCQ) has reached out to all Maryland facilities meeting the definitions of Comprehensive Care and Extended care facilities. Additionally, OHCQ conducted outreach to Lifespan, HFAM, Leading Age, Voices for Quality Care, Mental Health Association of Maryland, and other organizations representing both trade associations and advocacy organizations. Also, OHCQ conducted public forums to which members of the public were invited.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Department of Aging, State Ombudsman Program, Disability Rights Maryland, Maryland Health Care Commission.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and

(e) any public hearing held.

Three public forums were held between October and November 2014 and minutes from the meetings were posted on the OHCQ website. Additionally two online comment opportunities were provided between March 2015 and April 2016. Information about comment opportunities was sent to a subscriber list of over 140 individuals and organizations.

(4) Provide summaries of:

- (a) all comments received from stakeholders, affected units, or the public; and
- (b) the adopting authority's responses to those comments.

As a result of the outreach described above, over 900 total comments were received, reviewed, and addressed by OHCQ staff. Every comment was categorized according to regulation and subject. These were reviewed by an OHCQ committee and adjudicated and the chapter updates as a draft. The draft was distributed to the same stakeholders for further comment and the results were processed in the same manner.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

(6) Provide a summary of any relevant scientific data gathered.

None

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General have reviewed 10.07.02 to assess the chapter for any conflicts with federal law and none were found.

(8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ Long Term Care surveyors.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- no action
- amendment
- repeal
- repeal and adopt new regulations

Summary:

The OHCQ reviewed COMAR 10.07.02 with internal staff and solicited input from external stakeholders through an iterative process. The regulations in this chapter were posted for public comment, and many comments were received. OHCQ staff received, categorized, discussed, and adjudicated all received comments. Several drafts of proposed regulations were posted for informal comment and a final draft was produced in 2016. We are presently waiting for approval from the Governor's Office to proceed with the proposal. Once approval is received, we will proceed with promulgation in accordance with the regulatory process outlined in the Administrative Procedures Act, State Government Article, Title 10, Subtitle 1, Annotated Code of Maryland.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
Government Affairs

Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
- (a) all comments received from stakeholders, affected units, or the public; and
 - (b) the adopting authority's responses to those comments.

No comments regarding 10.07.06 were received from stakeholders. OHCQ Patient Safety Program staff proposed reducing the time allowed for hospitals to provide Plans of Correction, require OHCQ to provide timely feedback to hospitals on root cause analyses, and require OHCQ to produce an annual Hospital Patient Safety Report.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General reviewed 10.07.06 to assess the chapter for any conflicts with federal law and none were found.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ hospital surveyors as well as Patient Safety Program staff.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

OHCQ posted COMAR 10.07.06 for comment by internal staff and external stakeholders. Only one set of comments were received from OHCQ staff as described in B(4) above. These were reviewed internally and will be incorporated into proposed regulations.

Person performing review: Matthew E. Weiss

Title: Health Policy Analyst for
Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

On June 5, 2016 the OHCQ the regulations were posted on the OHCQ website for a thirty-day comment period. Additionally OHCQ sent e-mail notifications to critical stakeholders and groups as identified by OHCQ program managers.

- (4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

After reaching out to stakeholders and agencies, no comments regarding 10.07.07 were received from stakeholders.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.
None

- (6) Provide a summary of any relevant scientific data gathered.
None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.
The program manager and the Assistant Attorney General have reviewed 10.07.07 to assess the chapter for any conflicts with federal law and none were found.

- (8) Provide a summary of any other relevant information gathered.
The program manager solicited comments from OHCQ nursing referral agency surveyors

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? [] Yes [X] No

Has the agency promulgated all regulations required by recent legislation? [X] Yes [] No

Provide explanations of the above responses, as needed:

N/A

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

- X no action
amendment
repeal
repeal and adopt new regulations
reorganization

Summary:

The OHCQ reviewed COMAR 10.07.07 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes are necessary.

Person performing review: Matthew E. Weiss

Title: Health Policy Analyst for Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
 (a) all comments received from stakeholders, affected units, or the public; and
 (b) the adopting authority's responses to those comments.

No comments regarding 10.07.08 were received from stakeholders.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General reviewed 10.07.01 to assess the chapter for any conflicts with federal law and none were found.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ hospital surveyors.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
 (check all that apply)

- X no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

The OHCQ reviewed COMAR 10.07.08 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes to 10.07.08 will be made.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
 Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

OHCQ anticipated that COMAR 10.07.02 would have been proposed at the beginning of 2017; however, that proposal has not been released by the Governor's Office for promulgation as of yet. Because COMAR 10.07.09 depends heavily on COMAR 10.07.02 for its substance, OHCQ will reach out to the Maryland State Ombudsman Program, Department of Aging, Lifespan, HFAM, Leading Age, Mental Health Association of Maryland, Legal Aid, Disability Rights Maryland, Voices for Quality Care, The Society for Post-Acute and Long-Term Care Medicine and the public once the proposal for COMAR 10.07.02 has been adopted.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Please see section D: Summary for details.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

Please see section D: Summary for details.

(4) Provide summaries of:

- (a) all comments received from stakeholders, affected units, or the public; and
- (b) the adopting authority's responses to those comments.

Please see section D: Summary for details.

(5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

Please see section D: Summary for details.

(6) Provide a summary of any relevant scientific data gathered.

Please see section D: Summary for details.

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

Please see section D: Summary for details.

(8) Provide a summary of any other relevant information gathered.

Please see section D: Summary for details.

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No
Provide explanations of the above responses, as needed:

N/A

D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- no action
- amendment (anticipated)
- repeal
- repeal and adopt new regulations
- reorganization

Summary:

OHCQ anticipated that COMAR 10.07.02 would have been proposed at the beginning of 2017; however, that proposal has not been released by the Governor's Office for promulgation as of yet. Because COMAR 10.07.09 depends heavily on COMAR 10.07.02 for its substance, OHCQ is unable to open this chapter for comments until 10.07.02 has been released. Once this occurs, OHCQ will post the chapter for an informal comment period through its website as well as direct outreach to a variety of stakeholders and individuals. Comments will be received, categorized and addressed by an internal committee, and a proposed draft will be circulated to the same stakeholders for a second review. A final draft will be produced after additional comments are processed as described above. Once a final draft is agreed upon, we will proceed with promulgation in accordance with the regulatory process outlined in the Administrative Procedures Act, State Government Article, Title 10, Subtitle 1, Annotated Code of Maryland.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

The purpose of these regulations is:
A. To promote the interests and general well-being of all patients of home health agencies providing service within the State;
B. To protect those interests by a public declaration of support for a patient's bill of rights; and
C. To assure that the treatment of patients is, at all times, fully consistent with the provisions of this law.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
 (a) all comments received from stakeholders, affected units, or the public; and
 (b) the adopting authority's responses to those comments.

After reaching out to stakeholders, providers, and agencies, no comments regarding 10.07.10 were received through the website.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General have reviewed 10.07.10 to assess the chapter for any conflicts with federal law and none were found.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ home health agency surveyors.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
 (check all that apply)

- no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

The OHCQ reviewed COMAR 10.07.10 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes were necessary.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
 Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

10.07.11

Chapter Name:

Health Maintenance Organizations

Authority:

Health-General Article, §19-701 et seq.; Insurance Article, §2-109(a)—(c); Annotated Code of Maryland

Date Originally Adopted or Last Amended:

Regulation .09A and .10 amended effective March 2017

Purpose:

The purpose of these regulations is to regulate various phases of the operations of health maintenance organizations in accordance with the mandates of Health-General Article, §§19-701—19-734, Annotated Code of Maryland.

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

Health Maintenance Organizations, Office of Health Care Quality (OHCQ) Hospital unit.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Maryland Insurance Administration

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

On April 18, 2016 the regulations were posted for comment on the OHCQ website. Additionally e-mail notification was sent to HMOs in Maryland.

- (4) Provide summaries of:
 (a) all comments received from stakeholders, affected units, or the public; and
 (b) the adopting authority's responses to those comments.

No comments were received. OHCQ wishes to review recently published Network Adequacy regulations developed by the Maryland Insurance Administration which may necessitate changes to this chapter.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General reviewed 10.07.11 to assess the chapter for any conflicts with federal law and identified none.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ hospital unit surveyors and program staff.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

- X no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

The OHCQ reviewed COMAR 10.07.11 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes to 10.07.11 will be made.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
 Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

No comments were received either through the website or in response to the e-mail campaign.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General reviewed 10.07.12 to assess the chapter for any conflicts with federal law and none were noted.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ hospital surveyors and program staff.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- X no action
amendment
repeal
repeal and adopt new regulations
reorganization

Summary:

The OHCQ reviewed COMAR 10.07.12 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes to 10.07.12 will be made.

Person performing review: Matthew E. Weiss

Title: Health Policy Analyst for
Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

No comments were received.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General reviewed 10.07.17 to assess the chapter for any conflicts with federal law and none exist.

- (8) Provide a summary of any other relevant information gathered.

None

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

The OHCQ reviewed COMAR 10.07.17 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes to 10.07.17 will be made.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;
(c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
(d) any mailing by the adopting authority; and
(e) any public hearing held.

- (4) Provide summaries of:
 (a) all comments received from stakeholders, affected units, or the public; and
 (b) the adopting authority's responses to those comments.

After reaching out to providers, stakeholders, and agencies, no comments regarding 10.07.18 were received from stakeholders.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General have reviewed 10.07.18 to assess the chapter for any conflicts with federal law and none were found.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ comprehensive rehabilitation facility surveyors.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

- no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

The OHCQ reviewed COMAR 10.07.18 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes were necessary.

Person performing review: Matthew E. Weiss

Title: Health Policy Analyst for Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

- (4) Provide summaries of:
(a) all comments received from stakeholders, affected units, or the public; and
(b) the adopting authority's responses to those comments.

After reaching out to licensed providers, stakeholders, and agencies, we received no comments and a consensus was reached on the adequacy of the existing regulations.

- (5) Describe any interunit conflict reviewed and the resolution or proposed resolution of that conflict.

None

- (6) Provide a summary of any relevant scientific data gathered.

None

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

The program manager and the Assistant Attorney General have reviewed 10.07.21 to assess the chapter for any conflicts with federal law and none were found.

- (8) Provide a summary of any other relevant information gathered.

The program manager solicited comments from OHCQ hospice care program surveyors.

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- X no action
amendment
repeal
repeal and adopt new regulations
reorganization

Summary:

The OHCQ reviewed COMAR 10.07.21 with internal staff and solicited input from external stakeholders. The regulations in this chapter were posted for public comment, however no comments were received. Therefore, no changes are necessary.

Person performing review:

Matthew E. Weiss

Title:

Health Policy Analyst for
Government Affairs

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit’s website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and

(e) any public hearing held.

There were various methods utilized in order to solicit public comment for these regulations. A notice was published in the Maryland Register notifying the public that these regulations were being reviewed and the Maryland Department of Health and Mental Hygiene is inviting public comments for these regulations. In addition, a notice was posted on the website for the Office of Capital Planning, Budgeting, and Engineering Services (OCPBES) notifying the public that these regulations were currently being reviewed and public comments were being solicited. The website also contained links to these regulations and an email address where the public and stakeholders could send their comments. Also, all known stakeholders were emailed and notified that these regulations were currently being reviewed. The email provided a link to the OCPBES website where stakeholders could review the regulations and provide comments. A public hearing was also planned, however due to the lack of any comments from the public or from stakeholders, a public hearing was not held.

- (4) Provide summaries of:
- (a) all comments received from stakeholders, affected units, or the public; and
 - (b) the adopting authority's responses to those comments.

There were no comments received from stakeholders, affected units, or the public.

- (5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

There was no inter-unit conflict regarding these regulations.

- (6) Provide a summary of any relevant scientific data gathered.

There are 228 Nursing Homes in Maryland, of which 214 have dual Medicare and Medicaid certification, 10 have Medicare only certification, and 4 have Medicaid only certification. The percentage of certified beds occupied has remained constant at 86%.¹ The 2016 annual Maryland Nursing Home Care cost for a semi-private room is \$113,333 (State Median) with a 5% five year annual growth based on 365 days of care.²

1 CMS Nursing Home Data Compendium, 2015. Retrieved from: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/nursinghomedatacompendium_508-2015.pdf

2 The Genworth Cost Survey. Retrieved from: <https://www.genworth.com/about-us/industry-expertise/cost-of-care.html>

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

Nationwide 15,643 nursing homes participate in the Medicare and Medicaid programs. Consolidated Medicare and Medicaid requirements for participation in long term care (LTC) facilities (42 Code of Federal Regulations (CFR) part 483, subpart B) were first published in the Federal Register (FR) on February 2, 1989 (54 FR 5316).¹ These regulations have been revised and added to since that time, principally as a result of legislation or a need to address a specific issue. However, despite substantial changes in service delivery in this setting there has not been a

comprehensive review and update since 1991 (56 FR 48826, September 26, 1991). The Centers for Medicare & Medicaid Services (CMS), the U.S. Department of Health and Human Services (HHS) published the final rule on October 4, 2016 the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs were revised. These changes were necessary to reflect the substantial advances made in the theory and practice of service delivery and safety for nursing homes. These revisions are also an integral part of the efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs and in patient safety, while at the same time reducing procedural burdens on providers.² Statutory authority citations (Authority) were added to include, as an example, the compliance and ethics program, quality assurance and performance improvement (QAPI), and reporting of suspicion of a crime requirements. The definitions for “abuse”, “adverse event”, “exploitation”, “misappropriation of resident property”, “mistreatment”, “neglect”, “person-centered care”, “resident representative”, and “sexual abuse” were added. The requirement for facilities to investigate and report all allegations of abusive conduct was also added. The Authority added that facilities cannot employ individuals who have had a disciplinary action taken against their professional license by a state licensure body as a result of a finding of abuse, neglect, mistreatment of residents or misappropriation of their property.²

1 Nursing Home Data Compendium 2015 Edition. Retrieved from: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/nursinghomedatacompendium_508-2015.pdf

2 Centers for Medicare & Medicaid Services on 10/04/2016. Retrieved from: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-10-04.html>

(8) Provide a summary of any other relevant information gathered.

Generally the number of nursing homes has gradually declined over the past 10 years. In the latest available data, nationally the number of nursing homes participating in Medicare and Medicaid has decreased steadily from 2005 to 2014. Non-profit nursing homes have declined in number by 6.3% between 2010 and 2014, while for-profit nursing homes, which now constitute 69.8% of all nursing homes (and 72.2% of nursing home beds), increased by 1.6% over the same period. Government-owned nursing homes remain the smallest sector (6.2% of homes; 6.5% of beds) but have increased substantially in number since 2010 (an increase of 8.5%). From 2010 to 2014, dually participating nursing homes continued to become more prevalent, as the numbers of both Medicare-only and Medicaid-only nursing homes declined. In 2014, 92.2% of US nursing homes were dually certified. The number of Medicare-only nursing homes decreased by 1.4% to 764, while the number of Medicaid-only nursing homes saw the greatest decrease, dropping by 23.6% to 463, representing 3.0% of all homes and 2.1% of beds.¹ Fourteen states have had an increase in the number of nursing homes, and there has been no net change in an additional eight states. Arizona (9.0%) and South Carolina (8.0%) had the largest increase; Montana (8.8%), Vermont (5.0%) and Connecticut (4.9%) had the biggest declines.¹

1 Nursing Home Data Compendium 2015 Edition. Retrieved from: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Downloads/nursinghomedatacompendium_508-2015.pdf

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

D. Actions Needed. (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

- no action
- amendment
- repeal
- repeal and adopt new regulations
- reorganization

Summary:

Department, Office and other entry names will be updated and corrected.

Person performing review:

James Soucy

Title:

Director, Office of Capital Planning, Budgeting and Engineering Services

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

Authority:

Date Originally Adopted or Last Amended:

Purpose:

A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

(1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

All known stakeholders were invited to review the regulations and provide comments. These were providers that previously applied for funding or had previously expressed an interest in receiving grant funding under these regulations. These stakeholders were emailed and notified that the regulations were currently being reviewed. The email provided a link to the Office of Capital Planning, Budgeting, and Engineering Services website where stakeholders could review the regulations and provide comments and feedback to an email address that was provided.

(2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Not applicable.

(3) Describe the process used to solicit public comment, including:
(a) any notice published in the Maryland Register;
(b) any notice published in newspapers of general circulation;

- (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
- (d) any mailing by the adopting authority; and
- (e) any public hearing held.

There were various methods utilized in order to solicit public comment for these regulations. A notice was published in the Maryland Register notifying the public that these regulations were being reviewed and the Maryland Department of Health and Mental Hygiene is inviting public comments for these regulations. In addition, a notice was posted on the website for the Office of Capital Planning, Budgeting, and Engineering Services (OCPBES) notifying the public that these regulations were currently being reviewed and public comments were being solicited. The website also contained links to these regulations and an email address where the public and stakeholders could send their comments. Also, all known stakeholders were emailed and notified that these regulations were currently being reviewed. The email provided a link to the OCPBES website where stakeholders could review the regulations and provide comments. A public hearing was also planned, however due to the lack of any comments from the public or from stakeholders, a public hearing was not held.

- (4) Provide summaries of:
 - (a) all comments received from stakeholders, affected units, or the public; and
 - (b) the adopting authority's responses to those comments.

There were no comments received from stakeholders, affected units, or the public.

- (5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

There was no inter-unit conflict regarding these regulations.

- (6) Provide a summary of any relevant scientific data gathered.

In 2014, about 1 in 5 adults aged 18 or older (18.1 percent, or 43.6 million adults) had any mental illness (AMI) in the past year, and 4.1 percent (9.8 million adults) had serious mental illness (SMI). The percentage of adults with AMI remained stable from 2008 to 2014, and the percentage of adults with SMI in 2014 was similar to the percentages in 2010 to 2013. Approximately 21.5 million people aged 12 or older in 2014 had a substance use disorder (SUD) in the past year, including 17.0 million people with an alcohol use disorder, 7.1 million with an illicit drug use disorder, and 2.6 million who had both an alcohol use and an illicit drug use disorder. Estimates of binge drinking among people aged 12 or older did not change over the period from 2002 to 2014 (23.0 percent in 2014). Regardless of SMI status, alcohol dependence or abuse was more common than illicit drug dependence or abuse.¹ In Maryland, services for persons with developmental disabilities are administered by the Developmental Disabilities Administration (DDA) in collaboration with the Maryland State Department of Education and the Department of Health and Mental Hygiene (DHMH) Office for Genetics and People with Special Health care needs. DDA partners with individuals with developmental disabilities and their families to provide leadership and resources to enable these individuals to live fulfilling lives. DDA is guided by the principle that individuals with developmental disabilities have the right to direct their lives and services. In 2015, the total unduplicated number of persons with disabilities receiving state-funded services in nursing facilities, assisted living facilities, or community alternatives was 29,039.²

¹ Office of Communications, SAMHSA, HHS

² Maryland Department of Disabilities. Retrieved from <http://dda.dhmh.maryland.gov/Pages/home.aspx>

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

Under the Affordable Care Act, mental health and substance use disorder services are among the 10 essential health benefits that most health insurance plans must cover. This includes behavioral health treatment, counseling, and psychotherapy. For providers, the Affordable Care Act means a shift to new models of integrated care, such as health homes that coordinate care for people with chronic conditions, and value-based payment initiatives such as accountable care organizations (ACOs) that tie reimbursement to health outcomes.¹ The disability rights movement has brought about significant progress and increased opportunities for people with intellectual and developmental disabilities. Landmark legislation has created meaningful change for people with disabilities and opened doors to employment, education, housing and other access to community life. More recently, however, one major law (the Budget Control Act of 2011) is posing a threat to the funding for all federal programs that the disability community has worked so hard to achieve.²

1 Center for Behavioral Health Statistics and Quality. (2015) Results from the 2014 National Survey on Drug Use and Health (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from <http://www.samhsa.gov/data/>

2 U.S. Department of Health and Human Services. Retrieved from https://acl.gov/Programs/AIDD/DDA_BOR_ACT_2000/Index.aspx

(8) Provide a summary of any other relevant information gathered.

In 2014, about 3.3 percent of all adults had both any mental illness (AMI) and substance use disorder (SUD) in the past year, and 1.0 percent had both serious mental illness (SMI) and SUD. An estimated 340,000 adolescents aged 12 to 17 in 2014 (1.4 percent of all adolescents) had a SUD and a major depressive episode (MDE) in the past year. The estimate in 2014 for the co-occurrence of a MDE and a SUD in the past year among adolescents was similar to those in most years between 2006 and 2013.¹ Medicaid, the Affordable Care Act (ACA), Supplemental Security Income (SSI), Social Security, Medicare and civil rights laws like the Americans with Disabilities Act (ADA) are critical for people with Intellectual/Developmental Disability (I/DD) and their families, providing benefits, supports, and civil rights protections that help make community living possible.²

1 Center for Behavioral Health Statistics and Quality. (2015). Behavioral health trends in the United States: Results from the 2014 National Survey on Drug Use and Health (HHS Publication No. SMA 15-4927, NSDUH Series H-50). Retrieved from <http://www.samhsa.gov/data/>

2 U.S. Department of Health and Human Services. Retrieved from https://acl.gov/Programs/AIDD/DDA_BOR_ACT_2000/Index.aspx

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

no action

- X amendment
- repeal
- repeal and adopt new regulations
- reorganization

Summary:

Department, Office and other entry names will be updated and corrected.

Person performing review:

James Soucy

Title:

Director, Office of Capital
Planning, Budgeting and
Engineering Services

**Regulatory Review and Evaluation Act
Evaluation Report Form
2012 – 2020**

Chapter Codification:

Chapter Name:

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A. Review Criteria. (State Government Article, §10-132(1)(i), Annotated Code of Maryland; COMAR 01.01.3002.20E)

- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

All known stakeholders were invited to review the regulations and provide comments. These were providers that previously applied for funding or had previously expressed an interest in receiving grant funding under these regulations. These stakeholders were emailed and notified that the regulations were currently being reviewed. The email provided a link to the Office of Capital Planning, Budgeting, and Engineering Services website where stakeholders could review the regulations and provide comments and feedback to an email address that was provided.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Not applicable.

- (3) Describe the process used to solicit public comment, including:
 - (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
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There were various methods utilized in order to solicit public comment for these regulations. A notice was published in the Maryland Register notifying the public that these regulations were being reviewed and the Maryland Department of Health and Mental Hygiene is inviting public comments for these regulations. In addition, a notice was posted on the website for the Office of Capital Planning, Budgeting, and Engineering Services (OCPBES) notifying the public that these regulations were currently being reviewed and public comments were being solicited. The website also contained links to these regulations and an email address where the public and stakeholders could send their comments. Also, all known stakeholders were emailed and notified that these regulations were currently being reviewed. The email provided a link to the OCPBES website where stakeholders could review the regulations and provide comments. A public hearing was also planned, however due to the lack of any comments from the public or from stakeholders, a public hearing was not held.

- (4) Provide summaries of:
- (a) all comments received from stakeholders, affected units, or the public; and
 - (b) the adopting authority's responses to those comments.

There were no comments received from stakeholders, affected units, or the public.

- (5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

There was no inter-unit conflict regarding these regulations.

- (6) Provide a summary of any relevant scientific data gathered.

Maryland licenses two types of adult day care services: Adult Day Care and Adult Medical Day Care. They are licensed through the Office of Health Care Quality (OHCQ) within the Department of Health and Mental Hygiene. A search of Adult Day Care Services in Maryland, which would include both types of facilities, provided a listing of more than 100 facilities. The average monthly cost for Maryland, according to the 2015 Genworth Financial Cost of Care Survey, was \$1,712 per month. The monthly base rate for Maryland adult day care is higher when compared to neighboring states (Pennsylvania \$1,300, Virginia \$1,408). Maryland, is also more expensive compared to the national average of \$1,473.¹

¹ 2015 Genworth Financial Cost of Care Survey. Retrieved from <https://www.genworth.com/about-us/industry-expertise/cost-of-care.html>

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

Long-term care services include a broad range of health, personal care, and supportive services that meet the needs of frail older people and other adults whose capacity for self-care is limited because of a chronic illness; injury; physical, cognitive, or mental disability; or other health-related conditions.¹ Long-term care services include assistance with activities of daily living [(ADLs) e.g., dressing, bathing, and toileting], instrumental activities of daily living [(IADLs) e.g., medication management and housework]; and health maintenance tasks. Long-term care services assist people to improve or maintain an optimal level of physical functioning and quality of life, and can include help from other people and special equipment or assistive devices.² In February 2016, the National Center for Health Statistics (NCHS) released a report entitled *Long-Term Care Providers and Services Users in the United States: Data from the National Study of Long-Term Care Providers, 2013 – 2014*. That report includes national descriptive information on the supply, organizational characteristics, staffing, and services offered by paid, regulated providers of long-term care services; and the demographic, health, and functional characteristics of users of these services.³ On

September 28, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a final rule to make major changes to improve the care and safety of the nearly 1.5 million residents in the more than 15,000 long-term care facilities that participate in the Medicare and Medicaid programs. The policies in this final rule are targeted at reducing unnecessary hospital readmissions and infections, improving the quality of care, and strengthening safety measures for residents in these facilities.

Changes finalized in this rule include:

- Strengthening the rights of long-term care facility residents, including prohibiting the use of pre-dispute binding arbitration agreements.
- Ensuring that long-term care facility staff members are properly trained on caring for residents with dementia and in preventing elder abuse.
- Ensuring that long-term care facilities take into consideration the health of residents when making decisions on the kinds and levels of staffing a facility needs to properly take care of its residents.
- Ensuring that staff members have the right skill sets and competencies to provide person-centered care to residents. The care plans developed for residents will take into consideration their goals of care and preferences.
- Improving care planning, including discharge planning for all residents with involvement of the facility's interdisciplinary team and consideration of the caregiver's capacity, giving residents information they need for follow-up after discharge, and ensuring that instructions are transmitted to any receiving facilities or services.
- Allowing dietitians and therapy providers the authority to write orders in their areas of expertise when a physician delegates the responsibility and state licensing laws allow.
- Updating the long-term care facility's infection prevention and control program, including requiring an infection prevention and control officer and an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.⁴

1 U.S. Department of Health and Human Services (HHS). Retrieved from: <https://www.hhs.gov/>

2 CDC Vital and Health Statistics, Series 3, Number 38, February 2016. Retrieved from: https://www.cdc.gov/nchs/data/series/sr_03/sr03_038.pdf

3 National Center for Health Statistics (NCHS). Retrieved from: <https://www.cdc.gov/nchs/>

4 Centers for Medicare & Medicaid Services. Retrieved from: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-09-28.html>

(8) Provide a summary of any other relevant information gathered.

In 2014, about 67,000 paid, regulated long-term care services providers served about nine million people in the United States. Long-term care services were provided by 4,800 adult day services centers, 12,400 home health agencies 4,000 hospices, 15,600 nursing homes, and 30,200 assisted living and similar residential care communities. In 2014, more than 1.5 million nursing employee full-time equivalents (FTEs)—including registered nurses (RNs), licensed practical nurses (LPNs) or licensed vocational nurses (LVNs), and aides— and about 35,200 social work employee FTEs worked in these sectors.¹

1 CDC Vital and Health Statistics, Series 3, Number 38, February 2016. Retrieved from: https://www.cdc.gov/nchs/data/series/sr_03/sr03_038.pdf

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

X no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

Department, Office and other entry names will be updated and corrected.

Person performing review:

James Soucy

Title:

Director, Office of Capital
Planning, Budgeting and
Engineering Services

**Regulatory Review and Evaluation Act
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Chapter Codification:

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Purpose:

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- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
- (4) Are the regulations effective in accomplishing their intended purpose? Yes No

B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

All known stakeholders were invited to review the regulations and provide comments. These stakeholders were emailed and notified that the regulations were currently being reviewed. The email provided a link to the Office of Capital Planning, Budgeting, and Engineering Services website where stakeholders could review the regulations and provide comments and feedback to an email address that was provided.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Not applicable.

- (3) Describe the process used to solicit public comment, including:
- (a) any notice published in the Maryland Register;
 - (b) any notice published in newspapers of general circulation;
 - (c) any notice posted on the unit's website or on a Statewide website created for units to post notices of regulation review;
 - (d) any mailing by the adopting authority; and
 - (e) any public hearing held.

There were various methods utilized in order to solicit public comment for these regulations. A notice was published in the Maryland Register notifying the public that these regulations were being reviewed and the Maryland Department of Health and Mental Hygiene is inviting public comments for these regulations. In addition, a notice was posted on the website for the Office of Capital Planning, Budgeting, and Engineering Services (OCPBES) notifying the public that these regulations were currently being reviewed and public comments were being solicited. The website also contained links to these regulations and an email address where the public and stakeholders could send their comments. Also, all known stakeholders were emailed and notified that these regulations were currently being reviewed. The email provided a link to the OCPBES website where stakeholders could review the regulations and provide comments. A public hearing was also planned, however due to the lack of any comments from the public or from stakeholders, a public hearing was not held.

- (4) Provide summaries of:
- (a) all comments received from stakeholders, affected units, or the public; and
 - (b) the adopting authority's responses to those comments.

There were no comments received from stakeholders, affected units, or the public.

- (5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

There was no inter-unit conflict regarding these regulations.

- (6) Provide a summary of any relevant scientific data gathered.

The United States has an estimated 22,200 residential assisted living facilities with 713,300 residents based on a 2012 study conducted by the National Center for Health Statistics. Nearly half of the facilities with 50 or more units had dementia care services and 52 percent were certified to receive Medicaid payments. Although states generally have provisions covering areas such as staff training, their requirements vary considerably. Forty states require direct care worker training, but the number of required training hours ranges from 1 to 80. In 2014, the Centers for Medicare and Medicaid Services established requirements for community-based service providers, including residential care settings that receive Medicaid payments for services provided to eligible residents. The requirements address characteristics and standards that must be present for a setting to be considered non-institutional. Some states may need to revise their residential care regulations to comply with the requirements regarding, for example, person-centered planning, privacy, choice of roommate, access to food, and other issues related to autonomy and choice. In Maryland, assisted living programs are overseen by the Assisted Living Unit within the Department of Health and Mental Hygiene (DHMH). There are 350 assisted living residences in Maryland with 10 or more beds, and the State requires each of the assisted living facilities to complete a Uniform Disclosure form describing the policies and services provided.¹ The cost of providing assisted living residences is usually paid for out of private funds; however there is a Maryland program called the Senior Assisted Group Home Subsidy Program which provides State funds for eligible residents who are unable to afford the cost of assisted living and might otherwise be in nursing homes. The subsidy supports the cost of services provided in assisted living residences. In order to use this program a client must have low or moderate income and meet other eligibility requirements.²

¹ Urban Institute analysis for the U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Planning and Evaluation (ASPE). Retrieved from: <https://aspe.hhs.gov/report/performance-improvement-2001/office-assistant-secretary-planning-and-evaluation-aspe>

² U.S. Department of Health & Human Services, Compendium of Residential Care and Assisted Living Regulations and Policy. Retrieved from: <https://aspe.hhs.gov/basic-report/compendium-residential-care-and-assisted-living-regulations-and-policy-2015-edition>

(7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

There are no federal rules or regulations for Assisted Living service providers. Residential care settings are licensed and regulated at the state level. In Maryland the Office of Health Care Quality (OHCQ) is the agency within the Department of Health and Mental Hygiene (DHMH) charged with monitoring the quality of care in Maryland's health care facilities and community-based programs.¹ In Pennsylvania, the Bureau of Human Services Licensing (BHSL) is responsible for the oversight of the Assisted Living Residences (55 Pa.Code Chapter 2800). In Virginia, the Virginia Board of Long-Term Care Administrators is responsible for the oversight of the Assisted Living Residences.

¹ National Center on Assisted Living, *Assisted Living State Regulatory Review 2007* (March 2007). Retrieved from: http://www.ncal.org/about/2007_reg_review.pdf .

(8) Provide a summary of any other relevant information gathered.

In the U.S. the majority of assisted living residents are White and non-Hispanic (87 percent), female (72 percent), and over the age 85 (51 percent). These residents have chronic health conditions that may require monitoring, medical treatment, and/or result in physical or cognitive impairments. The ten most frequent conditions (based on the National Survey of Residential Care Facilities) were high blood pressure (57 percent), Alzheimer's disease or other dementias (42 percent), heart disease (34 percent), depression (28 percent), arthritis (27 percent), osteoporosis (21 percent), diabetes (17 percent), chronic obstructive pulmonary disease and allied conditions (15 percent), cancer (11 percent), and stroke (11 percent). About a quarter of residents (26 percent) had 4-10 chronic health conditions.¹

¹ USDHHS Compendium of Residential Care and Assisted Living Regulations and Policy 2015 Edition. Retrieved from: <https://aspe.hhs.gov/system/files/pdf/110391/15alcom.pdf>

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

no action
 amendment
 repeal
 repeal and adopt new regulations

reorganization

Summary:

Department, Office and other entry names will be updated and corrected.

Person performing review:

James Soucy

Title:

Director, Office of Capital
Planning, Budgeting and
Engineering Services

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- (1) Do the regulations continue to be necessary for the public interest? Yes No
- (2) Do the regulations continue to be supported by statutory authority and judicial opinion? Yes No
- (3) Are the regulations obsolete or otherwise appropriate for amendment or repeal? Yes No
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B. Outreach and Research. (State Government Article, §10-135(a)(2)(i)–(viii), Annotated Code of Maryland)

- (1) List any stakeholders invited to review the regulations and provide a summary of their participation in and input into the review process.

All known stakeholders were invited to review the regulations and provide comments. These were providers that previously applied for funding or had previously expressed an interest in receiving grant funding under these regulations. These stakeholders were emailed and notified that the regulations were currently being reviewed. The email provided a link to the Office of Capital Planning, Budgeting, and Engineering Services website where stakeholders could review the regulations and provide comments and feedback to an email address that was provided.

- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Not applicable.

- (3) Describe the process used to solicit public comment, including:
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There were various methods utilized in order to solicit public comment for these regulations. A notice was published in the Maryland Register notifying the public that these regulations were being reviewed and the Maryland Department of Health and Mental Hygiene is inviting public comments for these regulations. In addition, a notice was posted on the website for the Office of Capital Planning, Budgeting, and Engineering Services (OCPBES) notifying the public that these regulations were currently being reviewed and public comments were being solicited. The website also contained links to these regulations and an email address where the public and stakeholders could send their comments. Also, all known stakeholders were emailed and notified that these regulations were currently being reviewed. The email provided a link to the OCPBES website where stakeholders could review the regulations and provide comments. A public hearing was also planned, however due to the lack of any comments from the public or from stakeholders, a public hearing was not held.

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There were no comments received from stakeholders, affected units, or the public.

- (5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

There was no inter-unit conflict regarding these regulations.

- (6) Provide a summary of any relevant scientific data gathered.

In Maryland, there are 17 FQHC providers including one urban Native American Clinic (Baltimore City) and a Washington D.C. based FQHC that has established sites in Maryland (Montgomery and Prince George's counties). There are a total of 149 service delivery sites across Maryland and 17 administrative sites (total 166 FQHC sites). According to data published by Health Resources & Services Administration (HRSA) there were 303,352 patients served by FQHCs in Maryland in 2015.¹

¹ Uniform Data System Report 2015. Retrieved from: <https://bphc.hrsa.gov/uds/datacenter.aspx?q=d&year=2013&state=MD#glist>

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

FQHC benefits under Medicare were added effective October 1, 1991, when Section 1861(aa) of the Social Security Act was amended by Section 4161 of the Omnibus Budget Reconciliation Act of 1990. FQHCs are safety net providers that primarily provide services typically furnished in an outpatient clinic. FQHCs include community health centers, migrant health centers, health care for the homeless health centers, public housing primary care centers, and health center program "look a likes." They also include outpatient health programs or facilities operated by a tribe.¹ There are a total of 1,375 Federally Qualified Health Centers in the United States. In 2015, the number of patients served by the FQHC's in the U.S was 24,2958,946. The largest number of total FQHC encounters or visits are in New York (9,109,689) and the lowest in Northern Mariana Islands (3,472).² In Maryland there were 1,313,872 total FQHC encounters or visits in 2015.³

¹ DHHS Center for Medicare & Medicaid Services. Retrieved from: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/fqhcfactsheet.pdf>

² HRSA Health Center Data: Health Center Program Grantee Data, 2015. Retrieved from: <https://bphc.hrsa.gov/uds/datacenter.aspx>

³ HRSA Program Grantee Data Comparison. Retrieved from: <https://bphc.hrsa.gov/uds/datacomparisons.aspx>

(8) Provide a summary of any other relevant information gathered.

Maryland Medicaid Policy Changes FY 2016 and FY 2017

Eligibility, Application and Renewal Policies¹

- Participating in Connecting Criminal Justice with Health Care learning collaborative to identify best practices for Maryland. Does not suspend or terminate coverage, but restricts payments to inpatient hospital stays longer than 24 hours.

Delivery System and Payment Reforms¹

- Health Choice Section 1115 waiver renewal filed in June 2016 proposing new initiatives, including residential treatment for substance use disorder in facilities regardless of size; local pilots to provide limited housing related services for certain individuals who are homeless or at risk of homelessness; and local pilots to provide home visiting for high risk pregnant women. (While the waiver renewal has a proposed effective date of January 1, 2017; many changes are proposed to be effective July 1, 2017).

Provider Rates and Provider Fees¹

- In 2016, there were across the board rate increases, except for nursing facilities.
- Rate increases for nursing facilities, hospitals and managed care organizations (MCOs) were set at 5.9% in CY 2016 and 1% in CY 2017.

Benefits and Pharmacy¹

- Benefits for Behavioral Analysis services were added for qualified children with Autism Spectrum Disorder. (FY 2016)
- Section 1115 waiver renewal was revised in FY 2017 to extend dental benefits to young adults aging out of the foster care system.
- In 2016, Physician Assistants were added as a new provider type.
- The state intends to expand use of prior authorization requirements for use of Fentanyl and Methadone in fee for service (FFS) arrangements in FY 2017 and all Fentanyl products in MCOs in FY 2017. The state is implementing enhanced education efforts in both FFS and MCO arrangements in FY 2017, sending letters to patients and providers when patients are receiving high dose or other high risk combinations of drugs.

¹ The Henry J. Kaiser Family Foundation. Retrieved from: <http://kff.org/search/?s=Maryland>

C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland) (check all that apply)

- X no action
- amendment
- repeal
- repeal and adopt new regulations
- reorganization

Summary:

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James Soucy

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- (2) List any other affected agencies that were invited to review the regulations and provide a summary of their participation in and input into the review process.

Not applicable.

- (3) Describe the process used to solicit public comment, including:
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- (5) Describe any inter-unit conflict reviewed and the resolution or proposed resolution of that conflict.

There was no inter-unit conflict regarding these regulations.

- (6) Provide a summary of any relevant scientific data gathered.

There is a considerable increase in the construction of assisted living facilities and some health care facilities are converting whole floors, wings or parts of wings from nursing home or hospital occupancy to assisted living units. The Department of Housing and Urban Development (HUD) has an Assisted Living Conversion Program (ALCP) to provide private, nonprofit owners of eligible developments with grants to convert some or all of the dwellings units in the project into an Assisted Living Facility (ALF) or Service-Enriched Housing (SEH) for elderly residents aging in place.¹

¹ U.S. Department of Housing and Urban Development. Retrieved from:
https://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/mfh/progdesc/alcp

- (7) Provide a summary of any relevant information gathered related to the regulations of other states or the federal government.

HUD's Assisted Living Conversion Program is designed to test new approaches to assist low-income seniors in remaining in their current residences. HUD has an Assisted Living Conversion Program (ALCP) to provide private, nonprofit owners of eligible developments with grants to convert some or all of the dwellings units in the project into Assisted Living Facility (ALF) or Service-Enriched Housing (SEH) for elderly residents aging in place.¹

¹ U.S. Department of Housing and Urban Development. Retrieved from:
https://portal.hud.gov/hudportal/HUD?src=/press/press_releases_media_advisories/2017/HUDNo_17-007

- (8) Provide a summary of any other relevant information gathered.

On January 13, 2017 HUD awarded \$15 million three year grant to select owners of HUD-assisted senior housing developments. These three-year grants will produce evidence about the effectiveness of this enhanced supportive services model for elderly households and to evaluate the value of enhanced service coordination paired with affordable housing for seniors. Two facilities in

Maryland were among the grantees, Arlington II Non-Profit Housing in Baltimore and the Harry and Jeannett Weinberg Village in Owings Mills.¹

¹ U.S. Department of Housing and Urban Development. Retrieved from:
https://portal.hud.gov/hudportal/HUD?src=/press/press_releases_media_advisories/2017/HUDNo_17-007

- C. Under COMAR 01.01.2003.20E(3), does the agency have any existing policy statements, guidelines, or standards being applied or enforced which should be promulgated as regulations, in accordance with the Administrative Procedure Act? Yes No

Has the agency promulgated all regulations required by recent legislation? Yes No

Provide explanations of the above responses, as needed:

N/A

- D. **Actions Needed.** (State Government Article, §10-135(a)(2)(ix) – (xi), Annotated Code of Maryland)
(check all that apply)

no action
 amendment
 repeal
 repeal and adopt new regulations
 reorganization

Summary:

Department, Office and other entry names will be updated and corrected.

Person performing review: James Soucy

Title: Director, Office of Capital Planning, Budgeting and Engineering Services