



State of California—Health and Human Services Agency
Department of Health Care Services



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DATE: October 5, 2018

ALL PLAN LETTER 18-016
SUPERSEDES ALL PLAN LETTER 11-018

TO: ALL MEDI-CAL MANAGED CARE HEALTH PLANS

SUBJECT: READABILITY AND SUITABILITY OF WRITTEN HEALTH EDUCATION MATERIALS

PURPOSE:

The purpose of this All Plan Letter (APL) is to inform all Medi-Cal managed care health plans (MCPs) of updated requirements for reviewing and approving written health education materials. The documents that correspond to this APL have also been updated: Document A, Review and Approval Guidance for Written Health Education and Member Information Materials, and Document B, Readability and Suitability Checklist for Written Health Education Materials (Checklist). This letter and the corresponding documents supersede APL 11-018.

BACKGROUND:

APL 11-018 established requirements for the use of the Readability and Suitability Checklist for Written Health Education Materials, developed by the Department of Health Care Services (DHCS), to ensure reliability and consistency in the review of written health education materials. This letter covers the language and format requirements issued on May 6, 2016 by the federal Centers for Medicare & Medicaid Services (CMS) in rulemaking CMS-2390-F, known as the Final Rule.^{1,2}

Written health education materials are designed to assist members to modify personal health behaviors, achieve and maintain healthy lifestyles, and promote positive health outcomes by including information on health conditions, management of health conditions, and self-care. Topics may include messages about preventive care, health promotion, screenings, disease management, and healthy living.

Written member information materials provide members with essential information about access to and use of MCP services. Evidence of Coverage (EOC) booklets, enrollment and disenrollment forms, member rights and grievance information, new

¹ CMS-2390-F is available at: <https://www.gpo.gov/fdsys/pkg/FR-2016-05-06/pdf/2016-09581.pdf>

² Code of Federal Regulations (CFR), Title 42, Section 438.10 (c) and (d). The CFRs are searchable at: <https://www.ecfr.gov/cgi-bin/ECFR?SID=d15b0ce81c0ea804f39e129fd7f11a5f&mc=true&page=browse>

member welcome packets, provider directories, flyers promoting a health education class, and appointment reminders are all examples of written member information materials.

Document A provides definitions and examples of both written health education and written member information materials. Additionally, Document A clarifies when the MCP must use the Checklist and when to conduct field-testing to ensure that written health education materials are appropriate for the member target audience.

POLICY:

All written health education materials developed, adapted, purchased, or obtained free-of-charge for use by members must comply with requirements set forth in this APL. An MCP may continue to review, approve and use written health education materials without obtaining DHCS approval, as long as the MCP satisfies all provisions in this APL. MCPs must continue to submit all written member information materials for DHCS approval pursuant to Exhibit A, Attachment 13, of their managed care contract.

1. MCP Review and Approval Process

MCPs may approve any written health education materials for members, as long as the following conditions are met:

- a. The MCP has a qualified health educator/health education specialist on staff to assess and approve written health education materials. For the purpose of this APL, a qualified health educator³ is defined as a health educator with one of the following qualifications:
 - i. Master of Public Health (MPH) degree with a specialization in health education or health promotion, from a program of study accredited by the Council on Education for Public Health, sanctioned by the American Public Health Association.
 - ii. MCHES (Master Certified Health Education Specialist) awarded by the National Commission for Health Education Credentialing, Inc.

Individuals who do not meet the above-required qualifications may not approve written health education materials for the MCP, with the sole exception of staff who were hired prior to the release date of APL 11-018 (August 19, 2011) and who have already requested and received an exemption approval from DHCS.

- b. All written health education materials are assessed and approved using the

³ A qualified health educator/health education specialist has training and background that is equivalent to the DHCS requirements for Health Education Consultants II/III.

Checklist. Each provision on the Checklist is considered:

- i. **Met:** when 85-100% of the material being assessed meets the expected standards or specific criteria.
 - ii. **Somewhat met:** when 65-84% of the material being assessed meets the expected standards or specific criteria.
 - iii. **Not met:** when 0-64% of the material being assessed meets the expected standards or specific criteria.
- c. The MCP has its qualified health educator assess and approve all written health education materials. Qualified health educators are expected to use their professional judgement to determine when to approve written health education material based on the following guidelines:
- i. **Approved:** when the majority of the Checklist provisions are met.
 - ii. **Approved with justification:** when some of the Checklist provisions are somewhat met and/or not met, the qualified health educator must justify why the document is approved and the justification must be kept on file with the Checklist.
 - iii. **Not approved:** when a majority of the Checklist provisions are not met.
- d. The MCP keeps a signed/approved copy of the Checklist, including justification if needed, along with the approved written health education material (in either electronic or hard copy) for the life of the material and makes it available to DHCS upon request.
- e. If an MCP does not have a qualified health educator on staff, then the MCP must submit all written health education materials, along with a completed Checklist, to DHCS for review and approval. The MCP must complete all required sections of the Checklist, with the exception of section H (Qualified Health Educator Signature). A DHCS Health Education Consultant will complete section H and return the documents to the MCP.
- f. MCPs must ensure that all written health education materials meet DHCS' readability and suitability requirements, as established in this APL. An MCP may use the materials listed below without completing a Checklist, as long as the MCP has not made significant changes. If significant changes are made, DHCS suggests the use of the Checklist and field-testing. The MCP's qualified health

educator should use professional judgment to determine when to use the Checklist and/or field-test these types of materials.

- i. Materials produced by companies and entities listed on the DHCS 'Approved Companies for Written Health Education Materials' letter. MCPs may contact DHCS' Health Education Consultants for the most recent copy of the letter.
 - ii. Public domain materials produced by city, county, state, and federal government agencies.
 - iii. Materials produced by non-profit agencies or community-based organizations, such as the American Diabetes Association, the American Cancer Society, or the California Smokers' Helpline.
- g. To ensure that the health and medical information remain up-to-date, MCPs must review and approve previously approved written health education materials, including field-testing when required, **every five years**, or any time the material is updated or changed. With the release of this APL, all previously approved materials are now on the five-year review cycle and should be reviewed five years from the date of the last review and approval.

2. Readability and Suitability Checklist

The Centers for Medicare and Medicaid Services (CMS) recommends that written health education materials developed, adapted, or used for members should be systematically evaluated to assess their suitability for Medicaid populations. The Checklist was developed to assist MCPs in meeting these recommendations. The Checklist is designed for use with only English language materials, since the same criteria and provisions may not apply for all languages. MCPs must ensure that all written health education materials meet readability and suitability requirements, are provided in a manner and format that is easily understood,⁴ are culturally and linguistically appropriate for members,⁵ and are not discriminatory.⁶

3. Assessing Reading Level of Materials

MCPs should use the most appropriate readability formula to determine the reading level of written health education materials for their members. At a minimum, MCPs must provide members with written health education materials that are written at or below a

⁴ Title 42, United States Code, Section 1396u-2(a)(5)(A)

⁵ MCP Contract, Exhibit A, Attachment 10, Scope of Services

⁶ Section 1557 of the Affordable Care Act (see also APL 17-011)

sixth-grade reading level and use the required font size.⁷ Readability formulas are designed to be used with English language materials, as there are no identified standards for reading grade levels in other languages. Grade levels may differ by language and culture, so the sixth-grade reading level applies only to English language materials. After a written health education material is approved in English, it can then be translated into other languages. MCPs must work with qualified translators⁸ to ensure that the materials are accurately translated and are culturally and linguistically appropriate and easily understood in each language.

MCPs may exclude state-mandated legal language and MCP or vendor legal disclaimers in calculating the reading level of health education materials. In addition, medical terminology, technical words,⁹ and/or multi-syllable¹⁰ words that must be included in the health education material and that cannot be substituted for simpler, one- or two-syllable words may be counted only once when testing for reading level.

MCPs may also exclude proper nouns (for example, California Department of Health Care Services, ABC Health Plan), defined words, phone numbers, and website addresses in calculating the reading level of written health education materials.

MCPs are encouraged to use software programs or develop tools that will support the readability evaluation process. Possible tools include glossaries of word replacements, exclusion word lists that have been vetted through a review process, or guidelines on how to compose sentences that meet the sixth-grade reading level requirements.¹¹

4. Field-Testing of Materials

Field-testing ensures that written health education materials are understood by and accessible for the target member audience. Written health education materials developed by the MCP, or adapted or obtained from outside sources, must be field-tested, except as noted in Document A. The field-testing process will enhance the

⁷ 42 CFR Section 438.10(d)(6)

⁸ See the definition of *Qualified translator* in Title 45, CFR, Section 92.4.

⁹ For example, humidifier is a technical word that must be used in patient education materials on upper respiratory infections that recommend the use of a humidifier.

¹⁰ For example, diabetes is a multi-syllable word that must be used in patient education materials on diabetes.

¹¹ There are numerous resources available on the internet, such as the *Plain Language Thesaurus for Health Communications* put together by the Centers for Disease Control and Prevention's National Center for Health Marketing, that offer plain language equivalents to medical/technical terms, phrases and references that are often used in health care settings.

usability and increase the readability of newly-developed or adapted materials.¹²

The MCP's qualified health educator must provide oversight of the field-testing of all written health education materials and select the most appropriate methodology based on the complexity of the material. MCPs must document the field-testing process and results on the Checklist. Field-testing may include, but is not limited to, the following:

- a. Simple review of written health education materials during a Community Advisory Committee (CAC) meeting, Member Advisory Committee meeting, health education class, or other member event.
- b. Key informant interviews/surveys with members and/or community informants and/or internally qualified reviewers regarding written health education materials.
- c. Focus groups with targeted members to determine relevance and effectiveness of more complex written health educational materials.

MCPs may also accept results from field-testing conducted by a vendor or outside organization when using purchased materials or materials obtained from the public domain. However, the MCP's qualified health educator must determine that the field-testing was conducted appropriately and the participants represented a population similar to the MCP's targeted member pool. If a written health education material is not field-tested, an explanation must be included on the Checklist (e.g., material is similar to another that was previously field-tested, material was field-tested by another MCP, material was produced by the federal government, etc.).

5. Alternative Formats

Written health educational materials should take into account the specific needs of members such as Seniors and Persons with Disabilities (SPDs) and those who are visually impaired. Upon request by the member, family caregiver, or provider, MCPs are required to provide MCP-produced written health educational materials in alternative formats, including Braille, accessible PDFs, large-sized print, video- or audio-accessible materials online, a CD or DVD that is sent to the member, and/or other appropriate technologies and methods. If providing an alternative format causes undue hardship to the MCP, the MCP can provide the information in another reasonable format, such as by

¹² The *Toolkit for Making Written Material Clear and Effective*, written by CMS, can assist MCPs and their qualified health educators with the field-testing processes and can be found at: <https://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/index.html?redirect=/WrittenMaterialsToolkit>.

phone or in-person from a qualified health educator.¹³

Vendor-produced educational materials should also be provided to members in alternative formats whenever possible. If vendor-produced materials cannot be provided in an alternative format due to copyright laws or other administrative constraints, then the MCP must provide similar educational materials to members in an alternative format. The Checklist must be used to assess and approve written health education materials before they are converted to an alternative format.

6. Cultural Appropriateness

The MCP must ensure compliance with its Cultural and Linguistic Services Program described in Exhibit A, Attachment 9, of the MCP contract. A review of cultural appropriateness for written health education materials should include the use of images as well as content. MCPs should review materials to assure that they do not enforce cultural stereotypes and are inclusive in representation.

7. Font Size, Websites, and Newsletters

a. Font Size

All written health education materials must use at least a 12-point font.¹⁴ DHCS encourages MCPs to use a larger point font when doing so is considered a best practice, such as using at least an 18-point font for materials provided to members who are visually impaired.¹⁵

b. Websites and Other Digital Content

MCPs are not required to conduct a readability and suitability review of external websites or other digital content, also known as digital media. Forms of digital content include information that is digitally broadcast, streamed, or contained in computer files. Examples include, but are not limited to, interactive voice recordings (IVR), infographics, and webinars. DHCS recommends that MCPs regularly review the external websites that they provide links to on their member website, to ensure information is presented in a manner that is easily understood and culturally appropriate for members.

¹³ 42 CFR, Section 438.10 (c) and (d)

¹⁴ 42 CFR, Section 438.10(d)(6)

¹⁵ Ibid; see also the American Foundation for the Blind's Tips for Making Print More Readable, available at: <http://www.afb.org/info/reading-and-writing/making-print-more-readable/35>.

MCPs must use the Checklist to assess and approve health education documents, such as a PDF or PowerPoint presentation, posted on the MCP's member website. MCPs are not required to use the Checklist on the web page/text that is not part of a downloadable document. See Document A for more examples and Checklist requirements. DHCS recommends that MCPs use Web Content Accessibility Guidelines 2.0 as a guide for electronic content.¹⁶

MCPs are not required to use the Checklist for text messages, because of their brevity. However, text messages must be field-tested and meet sixth-grade reading level requirements, prior to distribution.

c. Newsletters

Newsletters that focus on health education messages, such as promoting healthy lifestyles and behaviors, do not require DHCS approval. In addition, MCPs are not required to complete a Checklist or field-test health education newsletters, but they are encouraged to use readability and suitability guidelines to develop newsletters that are easily understood by members.

If the newsletter focuses on member information, such as member rights and responsibilities, benefits, or access and use of services, then the MCP must submit the proposed language to their DHCS Contract Manager for approval. MCPs are not required to send the newsletter layout, just the proposed language. MCPs are strongly encouraged to consult with their qualified health educator regarding layout and formatting of their newsletters.

In addition, MCPs should develop criteria for translating newsletters, when appropriate or necessary.

DHCS Oversight

DHCS will monitor MCPs for compliance with the elements of this APL through field and desk monitoring reviews. DHCS may periodically request that MCPs submit a small sample of approved written health education materials for review. In addition, DHCS will investigate complaints about the readability and suitability of an MCP's written health education materials whenever necessary.

¹⁶ Web Content Accessibility Guidelines 2.0 is available at:
<http://www.w3.org/TR/WCAG20/>.

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MCPs may direct any questions regarding this APL, and/or requests for copies of the Readability and Suitability documents, to MMCDHealthEducationMailbox@dhcs.ca.gov.

Sincerely,

Original signed by Nathan Nau

Nathan Nau, Chief
Managed Care Quality and Monitoring Division