DATE: AUG 19 2011

MMCD 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 is to provide information to Medi-Cal managed care plans (Plans) regarding requirements for the readability and suitability of health education materials.

The contract requires the Plans to submit all written Member information materials to MMCD for approval (Exhibit A, Attachment 13). With the release of this all plan letter, Plans will be able to approve and use written Member health education materials without obtaining MMCD approval, so long as provisions in this all plan letter are met.

This all plan letter only applies to written health education materials for Medi-Cal managed care beneficiaries (Members). 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 all plan letter. This all plan letter does not apply to informing materials. (Federal regulation 42 USC 1396u-2(a)(5)(A), Code of Federal Regulations, Title 42, Chapter IV, 438.10 (c)(d) and California Code of Regulations, Title 22, Sections, 53876(a), 53851(b)(2)(e), 53853(d); 53910.5(a)(2)).

BACKGROUND

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

Informing materials are vital documents that provide Members with essential information about access to and usage of Plan services. Evidence of Coverage (EOC) booklets, enrollment, and disenrollment forms/information, member rights and grievance information, new member welcome packets, provider directories, and facility...
directories are examples of informing materials. The enclosed Health Education Table of Terms and Examples (Attachment B) provides definitions and examples of health education materials and informing materials. Additionally, the table includes examples of Plan generated documents/materials that do not require Medi-Cal Managed Care Division (MMCD) approval.

POLICY

1. Health Plan Approval

Plans can approve written member health education materials as long as the following conditions are met:

a. Materials are assessed and approved using the enclosed Readability and Suitability Checklist (Attachment A), and all required elements or items have been met.

b. The signed/approved Readability and Suitability Checklist, along with the approved health education material, must be kept (electronic file or hard copy) by the Plan and made available to the Department of Health Care Services (DHCS) for auditing/monitoring purposes upon request.

c. The assessment and approval process must be conducted by a qualified health educator/health education specialist with the equivalent training and background required by DHCS for their Health Education Consultants. For the purposes of this all plan letter, a qualified health educator is defined as a health educator with one of the following qualifications:

   - Master of Public Health (MPH) degree with a health education or health promotion emphasis.
   - Master’s degree in community health with a specialization in health education or health promotion.
   - MCHES (Master Certified Health Education Specialist) awarded by the National Commission for Health Education Credentialing, Inc.

Plan staff assigned health education duties who do not meet the definition of a “qualified health educator” as listed above, may not approve health education materials for the Plan. The Plan may request a one-time exemption from MMCD for health educators without the required qualifications/credentials who were hired prior to release of this all plan letter. This exemption will “grandfather” currently employed health educators and allow them to approve health education materials.
Exemptions will not be approved for health educators without the required qualifications hired after release of this all plan letter.

If a Plan does not have a qualified health educator (as defined above) on staff to assess and approve health education materials, the Plan will be required to continue to submit health education materials to MMCD for review and prior approval. A completed Readability and Suitability Checklist must accompany all materials submitted to MMCD for review and approval. All required sections of the checklist must be completed except for section H (Health Education Certification and Signature). This section will be completed by an MMCD health education consultant.

2. Readability Formulas

Plans are required to provide health education materials to Members at or below a sixth grade reading level. MMCD suggests using a readability formula that is most appropriate and reliable for the type of material and target audience. Different reading formulas use a variety of criteria to calculate grade level, such as the number of words per sentence, the number of words with three or more syllables, the number of familiar words, percentage of difficult words, the number of “difficult or hard” words, etc. Plans may manually calculate the reading level of materials or may use software, such as Readability Calculations (includes SMOG, Fry Graph, FOG, Flesch Reading Ease, Dale-Chall), or equivalent software to test the readability that is appropriate for the sample size. Requirements for reading level and readability formulas are applicable only for written materials produced in English.

Plans may exclude State-mandated legal language in calculating the reading level of health education material. In addition, medical terminology, technical words, and/or multi-syllable words that must be included in the health education material and cannot be substituted for simpler one or two syllable words may be counted only once when testing for reading level. For example, diabetes is a multi-syllable word that must be used in a diabetes patient education handbook, and the word “diabetes” cannot be substituted for another word. Therefore, the word “diabetes” can be counted only one time when calculating the reading level of the handbook. An example of a technical word that cannot be substituted for a one or two syllable word is “humidifier”. Patient education materials regarding upper respiratory infections often recommend the use of a humidifier.
3. **Readability and Suitability Checklist**

The Centers for Medicare and Medicaid Services (CMS) recommends that health education materials developed, adapted, or used for Members should be systematically evaluated to assess their suitability for Medicaid populations. Plans must ensure that all health education materials are provided in a manner and format that is easily understood and culturally and linguistically appropriate for Members. As much as possible, health education materials should include plain and simple language to increase Member understanding of the important health/medical information included in the material. There are numerous resources available on the internet, such as the Centers for Disease Control and Prevention’s (CDC’s) National Center for Health Marketing, “Plain Language Thesaurus for Health Communications” that offer plain language equivalents to medical/technical terms, phrases and references that are often used in health care settings. Using plain and simple language will increase the readability of materials, thereby making materials accessible for a wider range of Members with varying health literacy skills. Health literacy is defined by Healthy People 2010 as, “The degree to which individuals have the capacity to obtain, process and understand basic (health) information and services needed to make appropriate health decisions.”

The enclosed Readability and Suitability Checklist (Attachment A) addresses the following criteria:

- Publication Description (title, target audience, development date, etc.)
- Content and Key Messages
- Layout
- Visuals
- Cultural Appropriateness
- Language Translations
- Field Testing
- Medical Content
- Approval Signature(s)

4. **Field-Testing of Materials**

Health education materials which are developed, adapted, or obtained from outside sources must be field tested, with the exception of the materials outlined below. Field testing ensures that the materials are appropriate for Member target audiences. The field-testing process will enhance the effectiveness and increase the readability of newly developed or adapted materials. While most health
education materials require field testing, there are a few types of brief health communications/health education materials that do not require this testing. Examples of health education materials that do not require field-testing include, but are not limited to the following:

- Brief updates on preventing colds and the availability of seasonal flu vaccinations.
- Newsletters (Plan are not required to complete a Readability and Suitability Checklist to assess and approve health education related newsletter articles, but are encouraged to use readability/suitability guidelines to develop these articles whenever possible.)
- Flyers, handouts or posters about a new program or service available to members, or instructions on how to access and use services, such as a prenatal class, new asthma management class, etc.
- Health education materials developed by local county/city health departments, California state governmental organizations, or the U.S. federal government.

The Plan’s qualified health educator must provide oversight for the field-testing of all health education materials, and select the most appropriate methodology based on the complexity of the material, or determine that a health education material does not require field testing. The field-testing process and results must be documented on the Readability and Suitability Checklist. Field-testing may include, but is not limited to the following:

- Simple review of health education materials during a Community Advisory Committee (CAC) or other Member event
- Key informant interviews with Members and/or community informants
- Focus groups with targeted Members to determine relevance and effectiveness of more complex education materials
- Written Member surveys

Plans may accept field testing results conducted by a vendor or outside organization when using purchased materials or materials obtained from the public domain, as long as the Plan’s qualified health educator determines that the field testing was conducted appropriately, and participants represent a population similar to the Plan’s targeted Members. If a health education material is not field tested, an explanation must be included on the Checklist explaining the reason, e.g. material is similar to another that was previous field tested, material was field tested by another plan, material was produced by the federal government, etc.
5. Alternative Formats

Educational materials should take into account the specific needs of new and established Members, especially newly enrolled Seniors and Persons with Disabilities (SPDs). Upon request by the Member, family care-giver, or provider, Plans are required to provide Plan-produced educational materials in alternative formats including Braille, large size print, video or audio, accessible materials online or on CD, and/or use other appropriate technologies and methods. Vendor-produced educational materials should also be provided to Members in alternative formats whenever possible. If vendor produced materials cannot be provided in alternative formats due to copyright laws or other administrative constraints, then the Plan must provide similar educational materials to Members in alternative formats. The Readability and Suitability Checklist must be used to assess and approve written health education materials before they are converted to an alternative format.

6. Policies and Procedures (P&Ps)

Plans must develop and submit to MMCD within 60 days of release of this letter Policies and Procedures (P&P) for reviewing and approving health education materials to demonstrate and document their ability to implement these new requirements. This P&P must be incorporated into the deliverable that describes the health education system and must include the following elements:

- Specific qualifications of the health educator(s) authorized to approve the Plan’s health education materials (not required for Plans without a health educator qualified to complete section H of the Checklist (Health Education Certification and Signature)
- Process for reviewing education materials using the Readability and Suitability Checklist
- Readability formula(s) to be used
- Field-testing process
- Process for handling requests for alternative formats
- Process for translating health education materials
- Clinical review/approval process for ensuring medical content accuracy
- Staff training
- Specific qualifications of the health educator(s) authorized to approve the Plan’s health education materials (not required for Plans without a health educator qualified to complete section H of the Checklist (Health Education Certification and Signature)
The health educator must ensure that appropriate Plan staff receive training on the Plan's P&P for ensuring readability and suitability of health education materials, including how to use the Readability Calculations (includes SMOG, Fry Graph, FOG, Flesch Reading Ease, Dale-Chall), or other software the Plan has adopted to test for reading level. Oversight of health education materials review and final approval must be provided by a qualified health educator.

7. Plan's Review and Approval Process

Within twelve months of release of this all plan letter, Plans must review and approve all health education materials not previously approved by MMCD. The Readability and Suitability Checklist must be used to approve all health education materials. The Plan’s qualified health educator must approve (with signature) all Readability and Suitability Checklists to ensure that health education materials meet minimum requirements set forth in this all plan letter. The qualified health educator will also determine whether educational materials require the additional review of medical content expert(s) to verify medical/content accuracy.

Plans must implement a process to review and approve previously approved materials every three years to ensure that health and medical information, as well as visual images, remains current and up-to-date. Plans must implement a review process that ensures reliability, consistency, and timely review of health education materials using the Readability and Suitability Checklist. Plans must keep on file at all times, either electronically or hard copy, all approved Readability and Suitability Checklists with attached health education materials. This requirement only applies to materials in current use. These documents must be made available to auditors and DHCS/MMCD staff upon request at any time.

MMCD OVERSIGHT

MMCD will monitor Plans for compliance with the elements of this all plan letter through field and desk monitoring reviews and by review and approval of the Plans' policies and procedures, including the Readability and Suitability Checklist. Plans are to provide MMCD with any requested corrective action over findings identified and MMCD will conduct corrective action follow-up, as necessary. MMCD may periodically request that Plans submit a small sample of approved Readability and Suitability Checklists with approved health education materials. In addition, MMCD will investigate complaints about the readability and suitability of a Plan’s health education material whenever necessary. Please contact your MMCD Contract Manager for questions about this all plan letter.
Sincerely,

Tanya Homman, Chief
Medi-Cal Managed Care Division

Enclosures:  Attachment A: Readability and Suitability Checklist
            Attachment B: Health Education Table of Terms and Examples
**Attachment A: Readability and Suitability Checklist**

**This Checklist Applies to Health Education Materials Only (See Attachment B for definition)**

<table>
<thead>
<tr>
<th>Title of Material:</th>
<th>Main Topic:</th>
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<table>
<thead>
<tr>
<th>Key Message(s):</th>
<th>Date Last Reviewed:</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Target Audience:</th>
<th>Developed By:</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Material Format:</th>
<th>Date Developed:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flyer</td>
<td>Brochure</td>
</tr>
</tbody>
</table>

**READING LEVEL (6th GRADE READING LEVEL OR LOWER)**

<table>
<thead>
<tr>
<th>Date Assessed:</th>
<th>Reading Level:</th>
<th>Method Used:</th>
</tr>
</thead>
</table>

List medical/technical term(s) that were scored only once:

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**A. CONTENT**

**Required:** (All required items must be met in order to approve the material.)

1. Content is accurate and up-to-date
2. Number of concepts/messages is limited to 2-3 per page
3. Sentences are simple
4. Technical terms are defined
5. Material is written in an active voice

**Recommended:** (Items follow best practice guidelines, but are not required for approval.)

6. Material has a positive tone
7. Material explains how and where to get help or more information

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**B. LAYOUT**

**Required:** (All required items must be met in order to approve the material.)

1. Font size is at least 12-point; senior-specific materials are at least 14-point
2. Serif font styles are used for blocks of text
3. All capital letters are used only for headings and when grammatically correct
4. There is an adequate amount of white space (aim for 30%)
5. The layout guides the reader appropriately
6. Headings and subheadings are used to organize and separate ideas
7. Main points are emphasized using bold, italics, boxes or increased font size
8. Bullets or numbers are used for lists
9. There is adequate contrast between the print color and the background color

**Recommended:** (Items follow best practice guidelines, but are not required for approval.)

10. Left margin is justified (text is aligned on the left)
11. Right margin is unjustified (text is not aligned on the right)
C. VISUALS

Required: (All items in this section must be met in order to approve the material.)

1. Visuals are relevant to accompanying text
2. Visuals are simple and uncluttered
3. People and activities are representative of the intended audience
4. Phone numbers are bolded if they appear in the text document

Recommended: (Items follow best practice guidelines, but are not required for approval.)

5. Visuals have captions, if needed
6. Graphs and charts only used when absolutely necessary
7. Material is printed on non-glossy paper

D. CULTURAL APPROPRIATENESS

Required: (All required items be met in order to approve the material.)

1. Visuals are culturally appropriate for the intended audience (material is not offensive, does not reinforce stereotypes, and is inclusive in representation)
2. Content is culturally appropriate for the intended audience (provides culturally meaningful information such as “how to” advice and examples)
3. Topic-specific cultural relevance is reflected where applicable (such as food and exercise habits of the intended audience)
4. Plan-produced materials are available in alternative formats upon request

E. TRANSLATED/NON-ENGLISH MATERIALS ONLY (Complete this section, if applicable.)

This material is available in the following languages, in addition to English:
- Arabic
- Armenian
- Cantonese
- Farsi
- Hmong
- Khmer
- Korean
- Mandarin
- Russian
- Spanish
- Tagalog
- Vietnamese
- Other (specify)

Required: (All items in this section must be met in order to approve the material.)

1. Translation accurately conveys all the information found in the English version
2. Translation is based on meaning (not a literal translation)
3. Word and phrase usage is consistent
4. Material is sensitive to local language (phrases, words, expressions)
5. Translation was reviewed by at least one person in addition to the translator

F. FIELD TESTING (The Plan’s health educator will determine field testing methodology and/or whether field testing is needed for this material.)

Was this material field tested? □ Yes □ No □ N/A If no, please explain:

Type of field testing conducted: □ Focus Groups: # of Focus Groups: □ Individual Member Interviews
□ Community Advisory Committee (CAC) Review □ Other: ______

Page 2 of 3
Brief Summary of Field Testing Results:

G. MEDICAL CONTENT REVIEW (The Plan's health educator will determine whether the material requires clinical review to verify medical accuracy. Check "N/A" if not applicable to material.)

[ ] APPROVED
[ ] N/A

Required: (All items in this section must be met, unless "N/A" is checked above.)

1. Content is medically accurate
   [ ] Met
2. Content is up-to-date
   [ ] Met

Primary Medical Content Reviewer:
Reviewed by: [ ] Physician [ ] NP, PA, RN [ ] Pharmacist [ ] Other (describe):
Print Name: ________________________________
Signature: ________________________________
Title: ________________________________
Date: ________________________________

Secondary Medical Content Reviewer (optional)
Reviewed by: [ ] Physician [ ] NP, PA, RN [ ] Pharmacist [ ] Other (describe):
Print Name: ________________________________
Signature: ________________________________
Title: ________________________________
Date: ________________________________

H. HEALTH EDUCATOR CERTIFICATION & SIGNATURE (Leave blank if submitting to MMCD for approval)

My signature below certifies that this material has been reviewed as stated and, if approved, meets the criteria outlined in MMCD All Plan Letter 11-018. Materials must be reviewed and re-certified every 3 years.

Initial Material Review & Certification
[ ] APPROVED
[ ] NOT APPROVED

If not approved, describe reason(s):

Print Name: ________________________________
Signature: ________________________________
Title: ________________________________
Date: ________________________________

Subsequent (3-year) Material Review & Certification
[ ] APPROVED
[ ] NO LONGER APPROVED

If not approved, describe reason(s):

Print Name: ________________________________
Signature: ________________________________
Title: ________________________________
Date: ________________________________

Subsequent (6-year) Material Review & Certification
[ ] APPROVED
[ ] NO LONGER APPROVED

If not approved, describe reason(s):

Print Name: ________________________________
Signature: ________________________________
Title: ________________________________
Date: ________________________________
<table>
<thead>
<tr>
<th>List of Terms:</th>
<th>Defined Term:</th>
<th>Examples:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Written Member Health Education Materials</td>
<td>Materials designed to assist members to modify personal health behaviors, achieve, and maintain healthy lifestyles, promote positive health outcomes including updates on current health conditions, self-care, and management of health conditions. Topics may include messages about preventive care, health promotion, screenings, disease management, healthy living, and health communications.</td>
<td>• Handout with instructions on controlling asthma symptoms&lt;br&gt;• Pamphlet on risk factors for heart disease&lt;br&gt;• Packets of self-care information on diabetes&lt;br&gt;• Brochure with tips on weight management&lt;br&gt;• Brochure about pediatric immunizations&lt;br&gt;• Preventive health mailings on the importance of getting timely prenatal care&lt;br&gt;• Guidelines for preparing for surgery</td>
</tr>
<tr>
<td>Written Member Informing Materials</td>
<td>Informing materials/documents provide essential information to members regarding access to and usage of Plan services.</td>
<td>• Evidence of Coverage (EOC)&lt;br&gt;• Newsletters&lt;br&gt;• Member Services Guide&lt;br&gt;• Enrollment and disenrollment information&lt;br&gt;• Welcome packets&lt;br&gt;• Marketing information documents&lt;br&gt;• Provider directory or listings&lt;br&gt;• Form letters, notices of action or other documents regarding access and use of plan services, such as:&lt;br&gt;  - Member rights and grievance, acknowledgement and/or resolution&lt;br&gt;  - Obtaining afterhours access, urgent care, translation services,&lt;br&gt;  - How to obtain translated written materials (health education or informing) or materials in alternative formats&lt;br&gt;  - Instructions on how to access and use health education services Plan generated preventive service reminders (appointment and immunization reminders, initial health examination notices, prenatal care and follow-up, etc.) The text and format needs to be approved only once.</td>
</tr>
<tr>
<td>Other Materials Used by Health Plans for Day-to-Day Business Operations</td>
<td>Materials/forms used by the health plan to operate the day-to-day business transactions of the health plan that do not required DHCS approval.</td>
<td>• Materials for providers to place orders for health education materials, plan forms, or other plan provided materials&lt;br&gt;• Letters and other communication to providers, provider groups, Community Advisory Committees (CACs), community groups or external organizations or partners</td>
</tr>
</tbody>
</table>