DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Office of Clinical Standards and Quality/ Survey & Certification Group

Ref: S&C: 12-08-NH

DATE: December 2, 2011

TO: State Survey Agency Directors

FROM: Director

Survey and Certification Group

SUBJECT: Federal Requirements for the Independent Informal Dispute Resolution

(Independent IDR) Process for Nursing Homes - Interim Advance Guidance

Superseding S&C: 12-02-NH

Memorandum Summary

- Implementation Date: The Federal requirement for Independent IDR process will only apply to all standard and/or complaint surveys begun on or after January 1, 2012 that initiate an enforcement action for which a civil money penalty is imposed and is subject to being placed in escrow. Any revisit survey conducted on or after January 1, 2012 that is associated with standard or complaint surveys completed before January 1, 2012 will not be subject to the Independent IDR process.
- Clarification of Cost Allocation: S&C: 12-02-NH provided some information on standard cost allocation methods States should use for costs associated with the Independent IDR process. We are providing additional clarification in this memorandum, superseding S&C: 12-02-NH.
- State Operations Manual (SOM): This memorandum provides interim advanced guidance regarding Federal requirements for the Independent IDR process.

A. Background

New regulations have been added at 42 CFR, Sections 488.331 and 488.431 as required under section 6111 of the Patient Protection and Affordable Care Act of 2010 enacted on March 23, 2010. This memorandum provides interim advanced guidance regarding the Federal requirements for the Independent IDR process for nursing homes.

The Centers for Medicare & Medicaid Services (CMS) is in the process of updating the SOM to reflect the new regulations found at 42 CFR Sections 488.331 and 488.431. An advance copy of the interim guidance is attached. The final version of this document, when published in the online SOM may differ slightly from this interim advanced copy.

This memorandum replaces Survey and Certification memorandum S&C: 12-02-NH dated October 14, 2011, which discusses Federal requirements for the Independent IDR process for nursing homes. Please disregard the October 14, 2011 version.

B. Estimated State Budget and Payment for Expenses of an Independent IDR

Costs incurred by the State survey agency for conducting Independent IDRs are eligible for Federal funding using standard cost allocation principles. If the State has a State law or regulation that obliges the State to offer an Independent IDR, or specifies the manner in which an Independent IDR is to be provided or who must provide the Independent IDR, then the State must use the existing cost allocation methodology and proportions in place for the State's surveys of Skilled Nursing Facilities (SNF)/Nursing Facilities (NF), with costs allocated between Medicare, Medicaid, and State-only sources, as appropriate. In all other cases, the costs should be allocated between Medicare and Medicaid using the existing cost allocation methodology and proportions in place for the State's surveys of SNFs/NFs but adjusted for the absence of a State-only share (that is, there would not need to be State-only funds beyond the requirement for State match for the Medicaid portion).

States may not charge facilities for the Independent IDR process required under 42 C.F.R. §488.431. For deficiencies that are the basis for a civil money penalty which is not collected and placed in escrow under §488.431(b), or for deficiencies that lead to the imposition of another remedy that is not a civil money penalty, a State is not required to provide Independent IDR. In situations where the Independent IDR process is not required but is provided by the State directly at its option, the State may choose to charge a facility a user fee for those processes.

If you have additional questions or concerns, please contact Lorelei Chapman at (410) 786-9254 or via email at <u>lorelei.chapman@cms.hhs.gov</u>.

Effective Date: January 1, 2012. Please ensure that all appropriate staff is fully informed within 28 days of the date of this memorandum.

Training: The information contained in this memorandum should be shared with all nursing home surveyors and supervisors.

/s/ Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management

CMS Manual System	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Pub. 100-07 State Operations Provider Certification	
Transmittal INTERIM ADVANCE GUIDELINES	Date:

SUBJECT: New Interim Advance Guidance Added to Chapter 7 – Independent Informal Dispute Resolution (Independent IDR)

I. SUMMARY OF CHANGES:

NEW MATERIAL - EFFECTIVE DATE*: 01/01/2012 IMPLEMENTATION DATE: 01/01/2012

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	7/7213 - Independent Informal Dispute Resolution (Independent IDR)
N	7/7213/7213.1 - Introduction
N	7/7213/7213.2 - Purpose
N	7/7213/7213.3 – Definitions
N	7/7213/7213.4 - Independent IDR Requirements
N	7/7213/7213.5 - Applicability of the Independent IDR Process
N	7/7213/7213.6 - Key elements of Independent IDR
N	7/7213/7213.7 - Qualifications of an Independent IDR Entity or Person(s)
N	7/7213/7213.8 - Approval of an Independent IDR process
N	7/7213/7213.9 – State Budget and Payment for Expenses
N	7/7213/7213.10 - Independent IDR Recommendation and Final Decision
N	7/7213/7213.11 - Additional Elements for Federal Independent IDR process

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2012 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification

^{*}Unless otherwise specified, the effective date is the date of service.

7213 - Independent Informal Dispute Resolution (Independent IDR)

All regulatory references are in 42 Code of Federal Regulations (CFR) unless otherwise stated.

7213.1 - Introduction

Under sections 1819(h)(2)(B)(ii)(IV) and 1919(h)(2)(B)(ii)(IV) of the Social Security Act (the Act) and regulations at 42 CFR 488.331 and 488.431 skilled nursing facilities (SNF), nursing facilities (NF) and dually participating facilities (SNF/NFs) are provided the opportunity to request and participate in an Independent IDR if CMS imposes civil money penalties against the facility and these penalties are subject to being collected and placed in an escrow account pending a final administrative decision.

A State survey agency does not need to create any new or additional processes for Independent IDR if its existing process meets the requirements at 42 CFR 488.331 and 488.431 and described throughout §7213.

7213.2 - Purpose

Independent IDR is an informal administrative procedure intended to provide facilities, under certain circumstances, the opportunity to dispute cited deficiencies through a process independent from the State survey agency.

7213.3 - Definitions

Completed means that a final decision from the Independent IDR process has been made, a written record generated AND the State survey agency has sent written notice of this decision to the facility. For purposes of the traditional Informal Dispute Resolution (IDR) process completed is when the State survey agency has sent written notice of the final IDR decision to the facility.

Involved Resident is a resident who was the subject of a complaint, or who filed a complaint that led to a deficiency finding that is the subject of Independent IDR.

Organizationally Separate means a distinct office or division that functions independently from the office or division that conducts survey or certification activities of nursing homes.

Resident representative means either the resident's legal representative or the individual filing a complaint involving or on behalf of a resident.

7213.4 - Independent IDR Requirements

The requirements and specific core elements that must be included in an acceptable Independent IDR process are specified in regulations at 42 CFR 488.331 and 488.431. CMS retains ultimate authority for the survey findings and imposition of civil money penalties. However, an opportunity for an Independent IDR is provided within 30 calendar days of the notice of imposition of a civil money penalty that is subject to being collected and placed in escrow. An Independent IDR will —

- 1. Be completed within 60 calendar days of a facility's request, if an Independent IDR is requested timely by the facility;
- 2. Generate a written record prior to the collection of the penalty;
- 3. Include notification to an involved resident or resident representative, as well as the State's long term care ombudsman, to provide opportunity for written comment;
- 4. Be approved by CMS and conducted by the State under section 1864 of the Act, or by an entity approved by the State and CMS, or by CMS or its agent in the case of surveys conducted only by Federal surveyors where the State Independent IDR process is not used, and which has no conflict of interest, such as:
 - a. A component of an umbrella State agency provided that the component is organizationally separate from the State survey agency, or
 - b. An independent entity with a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS, and,
- 5. Not include the survey findings that have already been the subject of an informal dispute resolution under §488.331 for the particular deficiency citations at issue in the independent process under §488.431, unless the informal dispute resolution under §488.331 was completed prior to the imposition of the civil money penalty.

The Independent IDR process, as established by the State survey agency and approved by CMS must be in writing and available for review upon request. If an Independent IDR entity or person provides services in multiple States and/or CMS Regions, each State and its CMS Regional Office (RO) must approve the Independent IDR entity's or person's process and procedures. In order to ensure compliance of the Independent IDR process with Federal statute and regulations, each State survey agency will submit its written process and procedures, including any subsequent changes, to the applicable CMS RO for review and prior approval.

7213.5 - Applicability of the Independent IDR Process

The Independent IDR process will only apply to all standard and/or complaint surveys begun on or after January 1, 2012 that initiate an enforcement action for which a civil money penalty is imposed and is subject to being placed in escrow. Any revisit survey conducted on or after January 1, 2012 that is associated with a standard or complaint survey completed before January 1, 2012 for which an enforcement action was initiated before January 1, 2012, will not be subject to the Independent IDR process, even if a civil money penalty is imposed after January 1, 2012.

The Independent IDR process must be offered to a facility when a civil money penalty is imposed and that penalty is to be collected and placed in escrow under 42 CFR 488.431(b). Beginning on January 1, 2012, CMS may collect and place imposed civil money penalties in an escrow account on whichever of the following occurs first:

- The date on which the Independent IDR process is completed, or
- The date which is 90 calendar days after the date of the notice of imposition of the civil money penalty.

The Independent IDR is conducted only upon the facility's timely request. The facility must request an Independent IDR within 10 calendar days of receipt of the offer.

In order to phase in the new civil money penalty collection and escrow provisions, CMS initially intends to collect and escrow only those penalties which are imposed as a result of the most serious deficiencies. Beginning January 1, 2012, and until further notice, only civil money penalties which are imposed for surveys in which a deficiency or deficiencies were cited for actual harm or immediate jeopardy to resident health or safety (i.e., at a scope and severity level of G or above) will be subject to the combined civil money penalty collection and escrow provisions and Independent IDR. For surveys in which all of the deficiencies were cited at a scope and severity level that are less than G (i.e., at a scope and severity level of D, E, and F), any civil money penalty imposed for those deficiencies will continue to be collected under the current IDR process without a requirement for Independent IDR.

A facility may request an Independent IDR for each survey that cites deficiencies (at a scope and severity level of G or above) for which a civil money penalty has been imposed and will be collected and placed in escrow. However, when a facility requests an Independent IDR for a survey, the facility cannot raise questions or issues regarding a previous survey, and consideration of such previous survey results is beyond the scope of the independent IDR. Each Independent IDR is specific to the survey for which the facility either received Independent IDR or had an opportunity for it and did not request it.

The Independent IDR process does not delay the imposition of any remedies, including a civil money penalty. During the Independent IDR process a facility may dispute the factual basis of the cited deficiencies for which it requested Independent IDR. During the Independent IDR process, a facility may not challenge other aspects of the survey process, such as:

- Scope or severity classifications, with the exception of assessments that constitute substandard quality of care or immediate jeopardy;
- *Remedy(ies) imposed;*
- Alleged failure of the survey team to comply with a requirement of the survey process;
- Alleged inconsistency of the survey team in citing deficiencies among other facilities;
- Alleged inadequacy or inaccuracy of the IDR or Independent IDR process.

The focus of the Independent IDR process is the deficiency or deficiencies from a survey for which CMS imposed a civil money penalty that will be collected and placed in escrow under §488.431(b). However, while such factors as the scope and severity classification, and the amount of the penalty, are not the subjects of the Independent IDR, State survey agencies and CMS, will take into consideration any changes in deficiency findings that result pursuant to State or CMS review of the completed Independent IDR process. Based on such review, States and CMS will assess whether any changes to scope and severity or civil money penalty amount are warranted.

While States have discretion to limit participation in the Independent IDR process by attorneys or other parties, notice to the facility should indicate that the Independent IDR, including face-

to-face meetings, constitutes an informal administrative process that in no way is to be construed as a formal evidentiary hearing.

Independent IDR is not intended to be a formal or evidentiary hearing nor are the results of the Independent IDR process an initial determination that gives rise to appeal rights pursuant to regulations at 42 CFR 498.3(b). As such, the the Independent IDR process provides recommendations to the State and CMS and are not subject to appeal. Further the documents and written report created by the Independent IDR entity, the State and CMS, other than the final decision of the Independent IDR process, are pre-decisional and deliberative, and therefore are protected from disclosure under the deliberative process privilege. See EPA v. Mink, 410 U.S. 73, 88 (1973); see also 5 U.S.C. § 522(b)(5) (inter-agency and intra-agency memoranda and letters generated before adoption of final agency policy or decision are protected from disclosure under Exemption 5 of the Freedom of Information Act).

7213.6 - Key elements of Independent IDR

At a minimum, the Independent IDR process must provide for the following:

1. Offer of Independent IDR: The opportunity for Independent IDR must be provided within 30 calendar days of CMS's notice of imposition of a civil money penalty that will be collected and placed in an escrow account. The CMS RO will communicate the offer for an Independent IDR in its initial Notice of Imposition of a Penalty letter to a facility. In addition, the notice will provide the State survey agency contact information, including the name, address, and telephone number of the person and/or agency or office, the facility must contact to request an Independent IDR. The Notice of Imposition of a Penalty letter must be sent to the facility by certified mail return receipt requested and may also be sent by e-mail and/or fax. The Statement of Deficiencies (Form CMS-2567) may be included with the Notice of Imposition of a Penalty letter. The CMS RO must confirm receipt by the facility of such notice letter. A copy of this letter will also be sent to the State survey agency.

Upon a facility's timely request for an Independent IDR, the State survey agency, or the Independent IDR entity or person (as appropriate) will provide the following information to the facility:

- Information on the Independent IDR process including where, when and how the process may be accomplished, e.g., by telephone, in writing, or in a face-to-face meeting, and
- Contact information, including the name, address, phone number and e-mail of the person(s) who will be conducting the Independent IDR, if known.

As with the current IDR process, the Independent IDR process will be available to a facility at no charge. Collected civil money penalty funds may not be used to cover State expenses for IDR or Independent IDR. Under §488.433, a portion of collected CMP funds may be used for activities that protect or improve the quality of care for residents and "may not be used for survey and certification operations but must be used entirely for activities that protect or improve the quality

of care for residents." IDR and Independent IDR are part of the survey and certification process.

2. <u>Timing:</u> The Independent IDR is conducted only upon the facility's timely request. The facility must request an Independent IDR within 10 calendar days of receipt of the offer. The facility should submit its request in writing to the State survey agency, or the approved Independent IDR entity or person, as appropriate. The facility's request should also include copies of any documents, such as facility policies and procedures, resident medical record information that are redacted to protect confidentiality and all patient identifiable information, or other information on which it relies in disputing the survey findings.

Regulations at §488.431(a)(1) requires that Independent IDR be completed within 60 days of the facility's request. Every effort must be made to comply with this time frame, however, failure to comply with the Independent IDR process does not invalidate any deficiencies or any remedies imposed.

The Independent IDR process should be completed as soon as practicable but no later than 60 calendar days of receipt of the facility's request. The Independent IDR process is considered completed if a facility does not timely request or chooses not to participate in the Independent IDR process or when a final decision has been made, a written record has been generated, AND the State survey agency has sent written notice of this final decision to the facility.

3. Opportunity to Comment:

Once a facility requests an Independent IDR, the State must notify the involved resident or resident representative, as well as the State's long term care ombudsman, that they have an opportunity to submit written comment. This notification must be done before the Independent IDR review process begins and with sufficient time for the resident and/or their representative to provide comment. At a minimum, this notification must include:

- A brief description of the findings of noncompliance for which the facility is requesting Independent IDR and reference to the relevant survey date;
- Contact information for the State survey agency, or the approved Independent IDR entity or person as appropriate regarding when, where and how potential commenters must submit their comments;
- A designated contact person to answer questions/concerns;
- For residents and/or resident representatives, contact information for the State's long term care Ombudsman.
- 4. Written Record: The Independent IDR entity or person must generate a written record as soon as practicable but no later than 10 calendar days of completing its review. The Independent IDR entity or person will forward the written record to the State survey agency, for retention by the surveying entity. The State survey agency, will make a decision based on this written record and will provide the final decision to the facility as soon as practicable but no later than 10 calendar days of its receipt of the written record. The final decision to the facility shall contain the result for each deficiency

challenged and a brief summary of the rationale for that result. The written record from the Independent IDR entity or person shall include:

- List of each deficiency or survey finding that was disputed;
- A summary of the Independent IDR recommendation for each deficiency or finding at issue and the rationale for that result;
- Documents submitted by the facility to dispute a deficiency, to demonstrate that a deficiency should not have been cited, or to demonstrate a deficient practice should not have been cited as immediate jeopardy or substandard quality of care; and,
- Any comments submitted by the State's long term care ombudsman and/or residents or resident representatives, as appropriate.

7213.7 - Qualifications of an Independent IDR Entity or Person(s)

In order to be approved as an Independent IDR entity or person, whether it is a State agency or contracted outside organization, the entity or person must meet the following requirements:

Expertise and Training: The entity or person has an understanding of:

- Medicare and Medicaid program requirements including, but not limited to:
 - a) 42 CFR Part 483, Subpart B, and Part 488, Subparts A, E and F;
 - b) The State Operations Manual (SOM), including;
 - 1) Chapter 7, Definitions and §§ 7212, 7213 and 7900;
 - 2) Appendix P, Appendix PP, Appendix Q; and
- Applicable health care standards of practice, health care management, and/or life safety code knowledge and experience, relevant to the disputed issues.

Independence: The entity or person -

- *Has no financial or other conflict of interest;*
- May be a component of an umbrella State agency provided that the component is organizationally separate from the State survey agency;
- May be an independent entity or person with an understanding of specific Medicare and Medicaid program requirements selected by the State and approved by CMS.

Examples of possible conflict of interest include, but are not limited to, individuals who:

a) Were employed by the State survey agency or the State Ombudsman program within the past year.

- b) Were employed by CMS, Survey and Certification, Division of Nursing Homes within the past year.
- c) Have a family member who is either a resident or an employee of the facility involved in the Independent IDR.
- d) Is currently employed by the facility or organization involved in the Independent IDR.
- e) Have worked within the past year as an employee, consultant or volunteer for the facility or a related corporation, involved in the Independent IDR.
- f) Have ownership interest or currently serves or has served within the past year on the Board of Directors or Governing Body of a facility or organization involved in the Independent IDR.
- g) Have acted within the past year as counsel for or against the facility involved in the Independent IDR.

7213.8 - Approval of an Independent IDR process

A State's Independent IDR process must be approved by CMS. The State must submit its proposed process, whether existing or new, to the CMS RO for approval.

The CMS RO will review and approve all written policies and procedures of the State's Independent IDR process. Any subsequent changes to an approved Independent IDR process must be submitted as soon as possible to the applicable CMS RO for review and approval prior to these changes taking effect.

The State survey agency and the Independent IDR entity or person must enter into a written contract or Memorandum of Understanding (MOU) which ensures that the Independent entity or person meet all of the qualifications and responsibilities set forth in regulations and guidelines specified in Chapter 7, §7213.7 of the SOM and will comply with all applicable Federal record laws and regulations concerning protected health information and the survey process or the Independent IDR process. An Independent IDR entity or person must not disclose to the public any information related to the facility that requested Independent IDR, including the results of the Independent IDR review.

A copy of the signed contract or MOU must be provided to the applicable CMS RO.

7213.9 - State Budget and Payment for Expenses

Costs incurred by the State survey agency for conducting Independent IDRs are eligible for federal funding using standard cost allocation principles. If the State has a State law or regulation that obliges the State to offer an Independent IDR, or specifies the manner in which an Independent IDR is to be provided or who must provide the Independent IDR, then the State must use the existing cost allocation methodology and proportions in place for the State's surveys of Skilled Nursing Facilities (SNF)/Nursing Facilities (NF), with costs allocated between Medicare, Medicaid, and State-only sources, as appropriate. In all other cases, the costs should be allocated between Medicare and Medicaid using the existing cost allocation methodology and

proportions in place for the State's surveys of Skilled Nursing Facilities (SNF)/Nursing Facilities (NF), but adjusted for the absence of a State-only share (that is, there would not need to be State-only funds beyond the requirement for State match for the Medicaid portion).

States may not charge facilities for the Independent IDR process required under 42 C.F.R. §488.431. For deficiencies that are the basis for a CMP which is not collected and placed in escrow under §488.431(b), or for deficiencies that lead to the imposition of another remedy that is not a CMP, a State is not required to provide Independent IDR. In situations where the Independent IDR process is not required but is provided by the State directly at its option, the State may choose to charge a facility a user fee for those processes.

7213.10 - Independent IDR Recommendation and Final Decision

Upon receipt of the Independent IDR written record, the State survey agency, will review the Independent IDR recommendation(s) and:

- If the State survey agency, agrees with the Independent IDR recommendation(s) and no changes will be made to the disputed survey findings, the State survey agency will send written notification of the final decision to the facility within 10 calendar days of receiving the written record from the Independent IDR entity or person.
- If the State survey agency disagrees with one or more of the recommendations of the Independent IDR entity or person, the complete written record will be sent to the applicable CMS RO for review and final decision. The State survey agency should provide the portion(s) of the Independent IDR recommendation with which it disagrees, the basis for its disagreement and any relevant survey documents to the CMS RO. As soon as practicable, but no later than 10 calendar days, the CMS RO will review the Independent IDR recommendation and records along with the State's written disagreement of the Independent IDR's recommendation and will provide written notification to the State survey agency of the final decision. The State survey agency will then send written notification of the final decision to the facility within 10 calendar days of receiving the final decision from the CMS RO.

NOTE: Regulations at §488.431(a)(1) require that an Independent IDR will be completed within 60 days of a facility's timely request. **Completed** means that a final decision from the Independent IDR process has been made, a written record generated AND the State survey agency has sent written notice of the Independent IDR recommendation to the facility.

- If the State survey agency agrees with the Independent IDR recommendation(s) or has received a final decision from the CMS RO and changes will need to be made to the disputed survey findings, the State survey agency will provide written notification of the results and final decision to the facility within 10 calendar days of receiving the written record and will:
 - a) Change deficiency(ies) citation content findings, as recommended.
 - b) Adjust the scope and severity assessment for deficiencies, if warranted by CMS policy after taking into consideration approvable recommendations from the Independent IDR regarding the deficiency(ies).

- c) Annotate deficiency(ies) citations as "deleted as recommended."
- d) A State survey agency manager or supervisor will sign and date the revised CMS Form-2567.
- e) The State survey agency will promptly recommend to CMS that any enforcement action(s) imposed solely because of deleted or altered deficiency citations be reviewed, changed or rescinded.

NOTE: Based on a final Independent IDR recommendation and final State and CMS action, if one or more deficiencies on the Form CMS-2567 have changed, the State survey agency must provide a revised Form CMS-2567 to the facility, and the facility must submit and sign a new plan of correction with changes that address the deficiencies cited. Any Form CMS-2567 and/or plan of correction that is revised or changed as a result of Independent IDR must be disclosed to the State long term care ombudsman in accordance with §7904.

Deficiencies pending IDR or Independent IDR should be entered into the Automated Survey Processing Environment (ASPEN) system in a timely fashion but will not be used to calculate the 5-Star score, posted to Nursing Home Compare, or available for public reporting until the IDR and/or Independent IDR is fully processed and all related work is completed and successfully uploaded to the national repository.

IDR or Independent IDR requests from the facility and necessary changes should be entered in the ASPEN system within 10 working days of completion of the IDR or Independent IDR process. Specific instructions are provided in the current ASPEN Users Guides

The ASPEN Enforcement Manager (AEM) will be enabled to include the Independent IDR process for enforcement actions with survey cycles that begin on or after January 1, 2012.

7213.11 - Additional Elements for Federal Independent IDR process

In addition to those elements cited in §7213, CMS is working on establishing a single process for Independent IDR for Federal surveys conducted solely by Federal surveyors or its contractors.