Inservice Training Program

Revisiting the Independent IDR Process

And Its Impact on COVID-19 Reporting and the New Infection Control Enforcement Actions

Part 1

Instructor Presentation Slides and Notes

Provided Courtesy of

TEAMTSI

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Revisiting the IIDR Process

And Its Impact on COVID-19 Reporting and the New Infection Control Enforcement Actions

Instructor Presentation Slides & Notes

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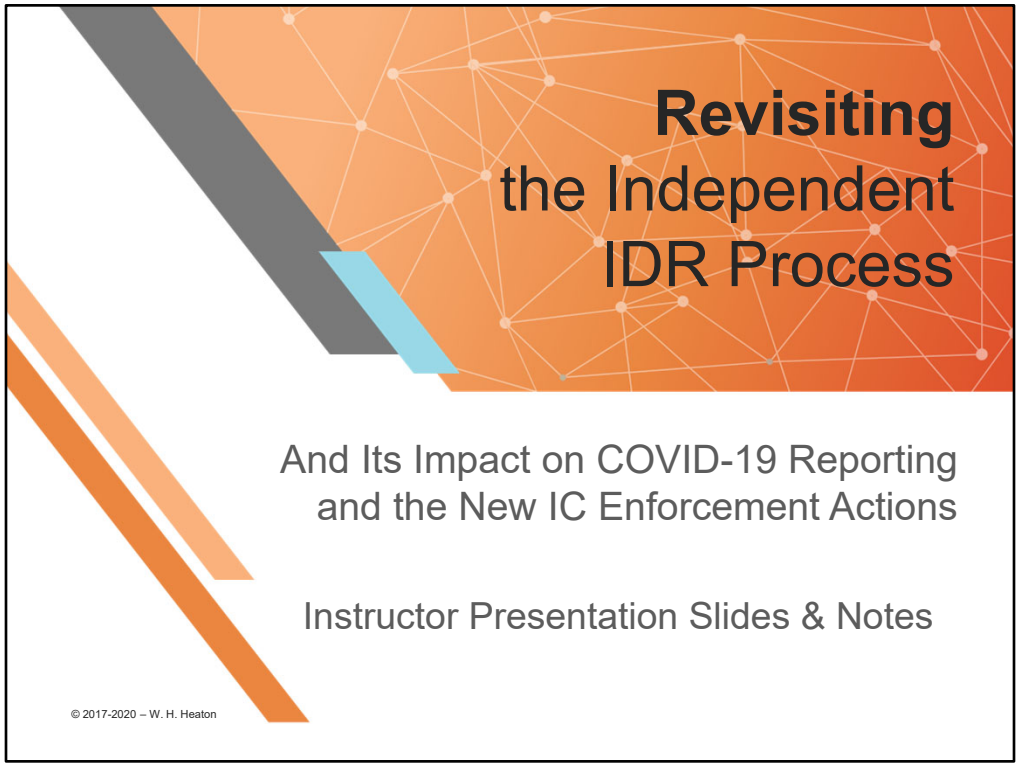


- **Sources** used in the development of this training session:

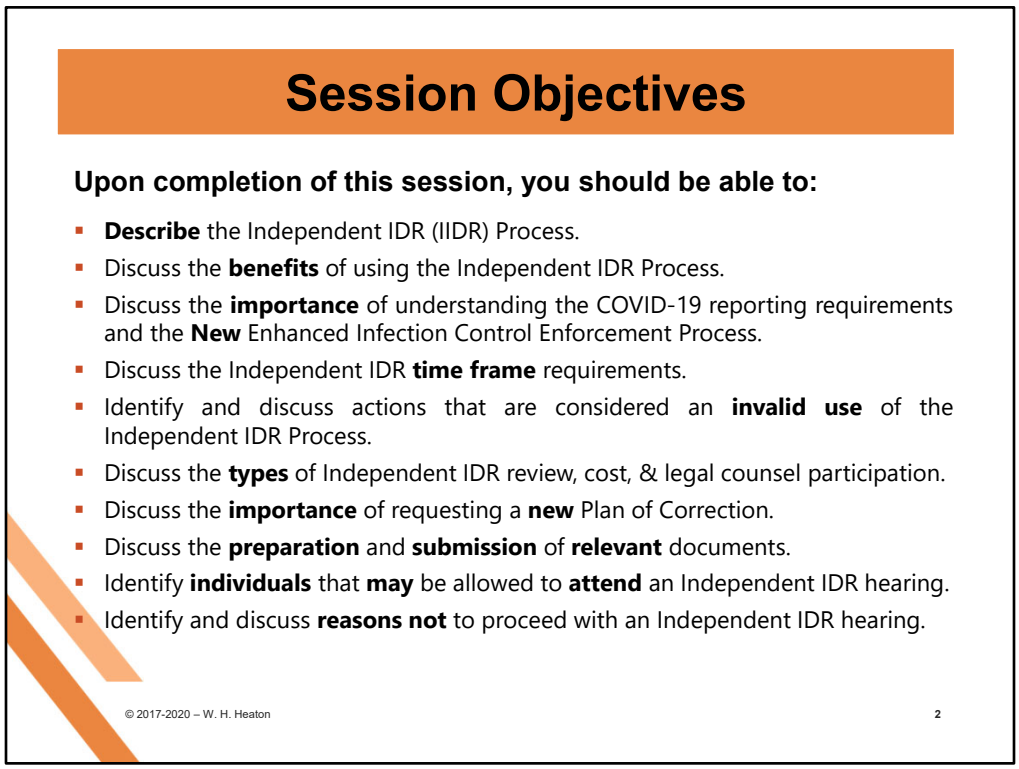
  SOM Chapter 7 – Survey and Enforcement Process for SNFs and NFs:
  - **§7213** – Independent IDR.
  - **§7500** – Directed Plan of Correction.
  - **§7904** – Information Furnished to the LTC Ombudsman.
  - **§488.431** – CMPs Imposed by CMS and Independent IDR.

- **Handouts**: The following handouts are included as a part of this training session and are located in **Part 2**. Use at your discretion.

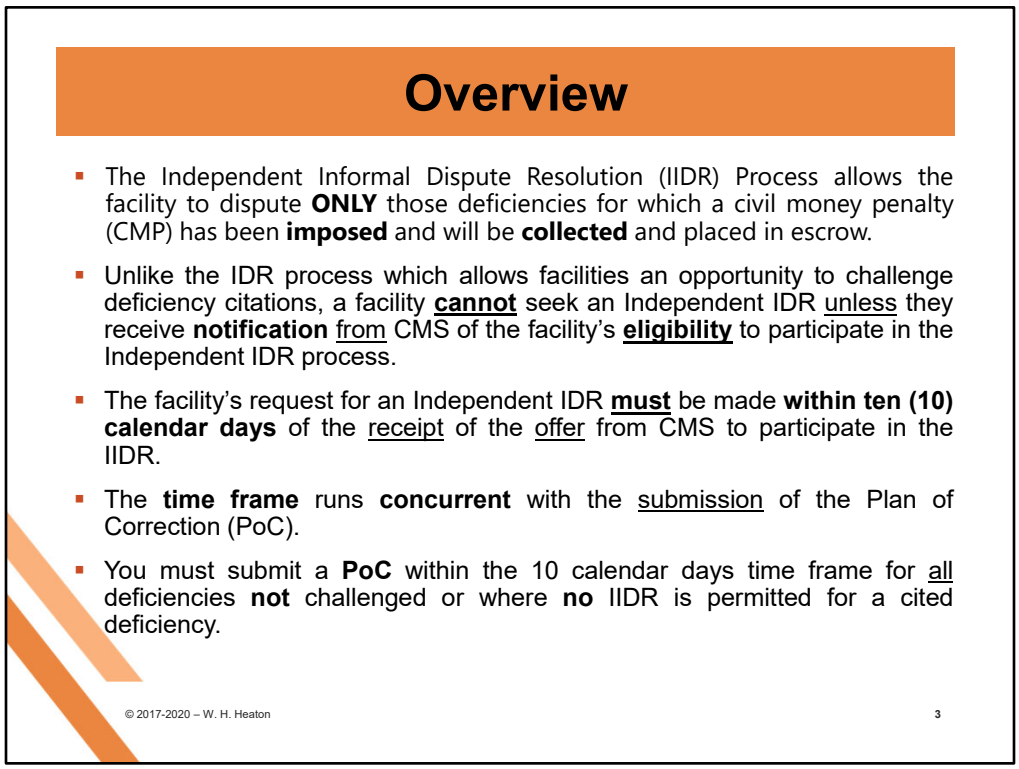
  ✓ **Handout #1** – Participant Session Outline.
  ✓ **Handout #2** – Independent IDR Regulatory Resources.
  ✓ **Handout #3** – QSO Letter 20-29: COVID-19 Reporting Requirements.
  ✓ **Handout #4** – QSO Letter 20-31: COVID-19 Survey Activities, Enhanced Enforcement for IC Deficiencies.
  ✓ **Handout #5** – ALJ Case Ruling: Hearing Denial Based on Independent IDR.
  ✓ **Handout #6** – Sample Independent IDR Worksheet.

- **Training Session and Documentation**: Modify this training session to meet your facility's specific Independent IDR process. **Note**: Be sure all participants sign the Record of Attendance Form located in **Part 3**.

- **OPTIONAL**: Provide participants with a copy of **Handout #1** – Participant Session Outline.

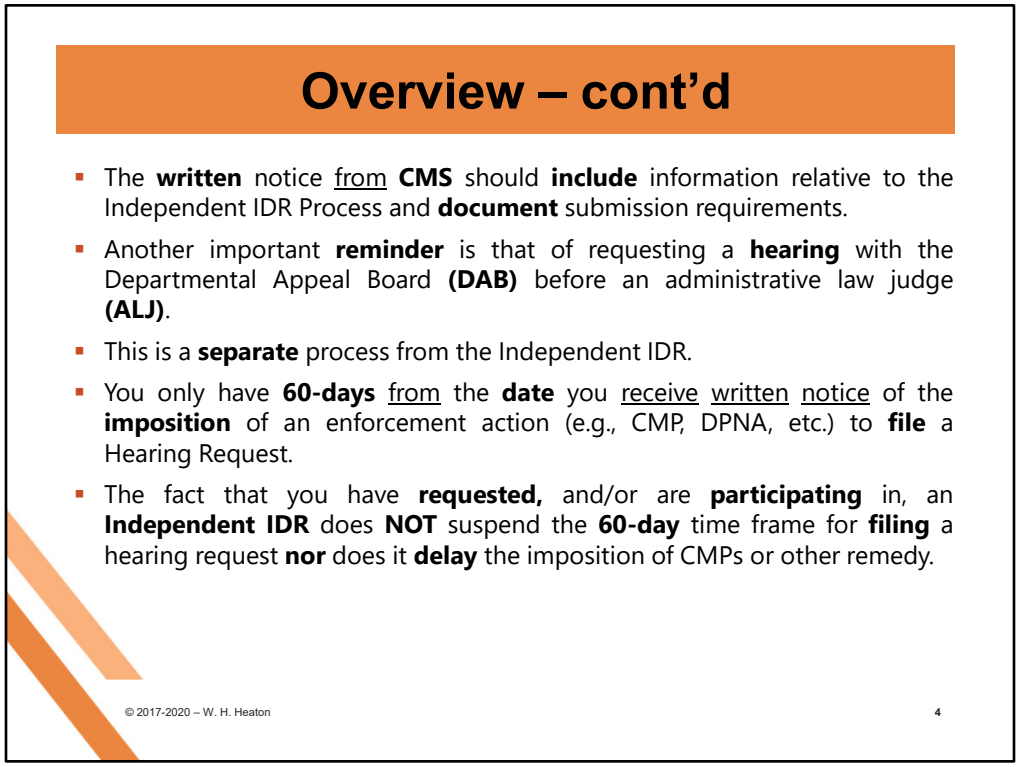


- Each of these session objectives are discussed during the training session.



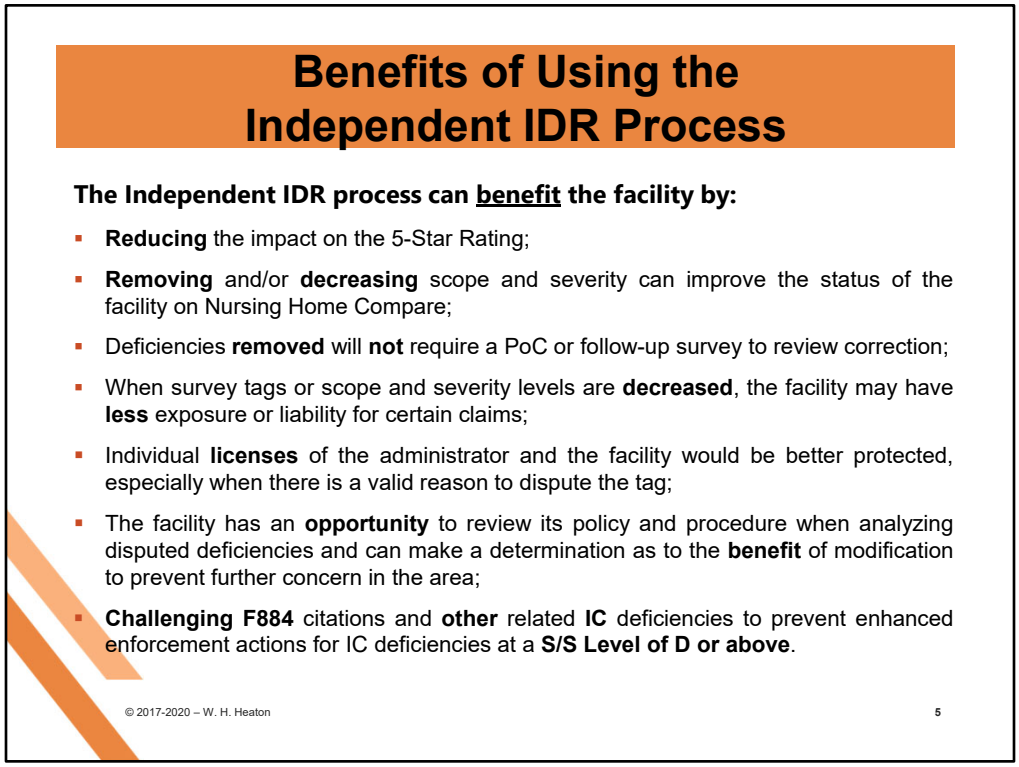
- States have the **option** to allow an Independent IDR process for imposed remedies **other** than a CMP.

- Your State's Independent IDR notice will most likely contain information about the **types** of remedies that **can** be used in the Independent IDR process.



- **OPTIONAL**: Provide participants with a copy of **Handout #5** – ALJ Case Ruling: Hearing Denial Based on Independent IDR process.

- This is an **ACTUAL** case on the **dismissal** of the facility's request for a hearing before an Administrative Law Judge (ALJ) **because** the facility failed to file a **timely** request as it was **participating** in an Independent IDR process.



- With the advent of **COVID-19** reporting, infection control focused surveys, and the **new** enhanced enforcement actions for **ANY** infection control associated deficiency makes it critical for facilities to review their past compliance history to determine their **risk potential** for increased CMPs and other enforcement remedies.

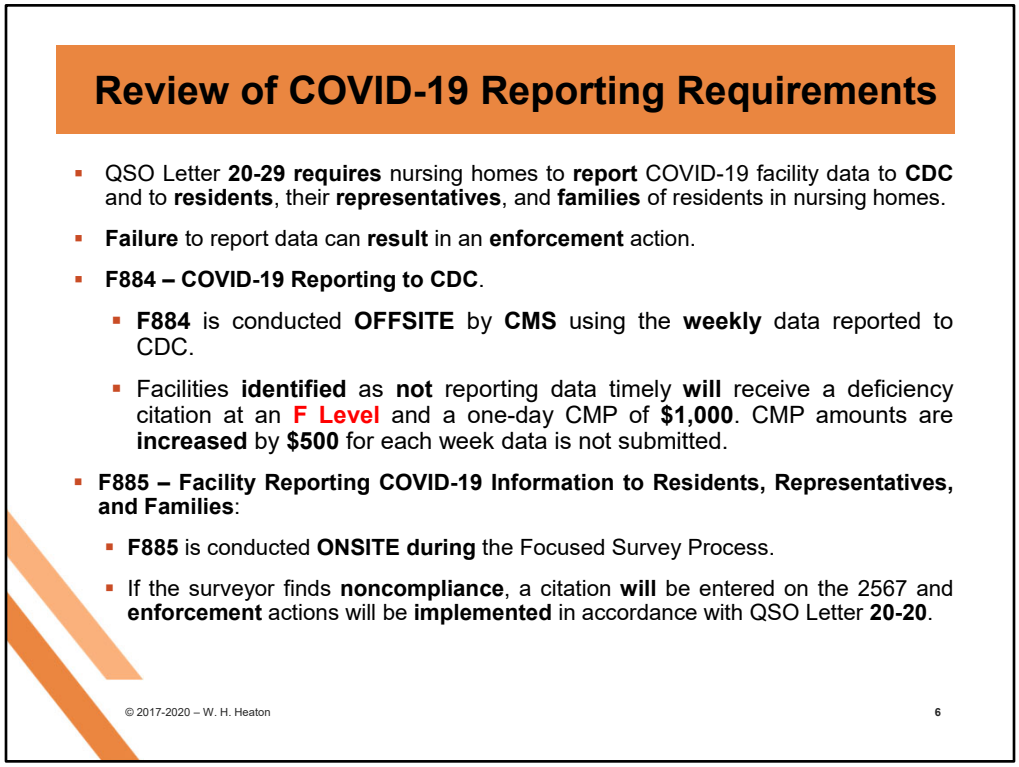
- Research indicates providers are **TWICE** as likely to receive **favorable** results from an Independent IDR over an IDR. However, CMS routinely **refuses** to accept the Independent IDR rulings.

- **CMS** has the **final** authority to accept or reject the findings of the Independent IDR.

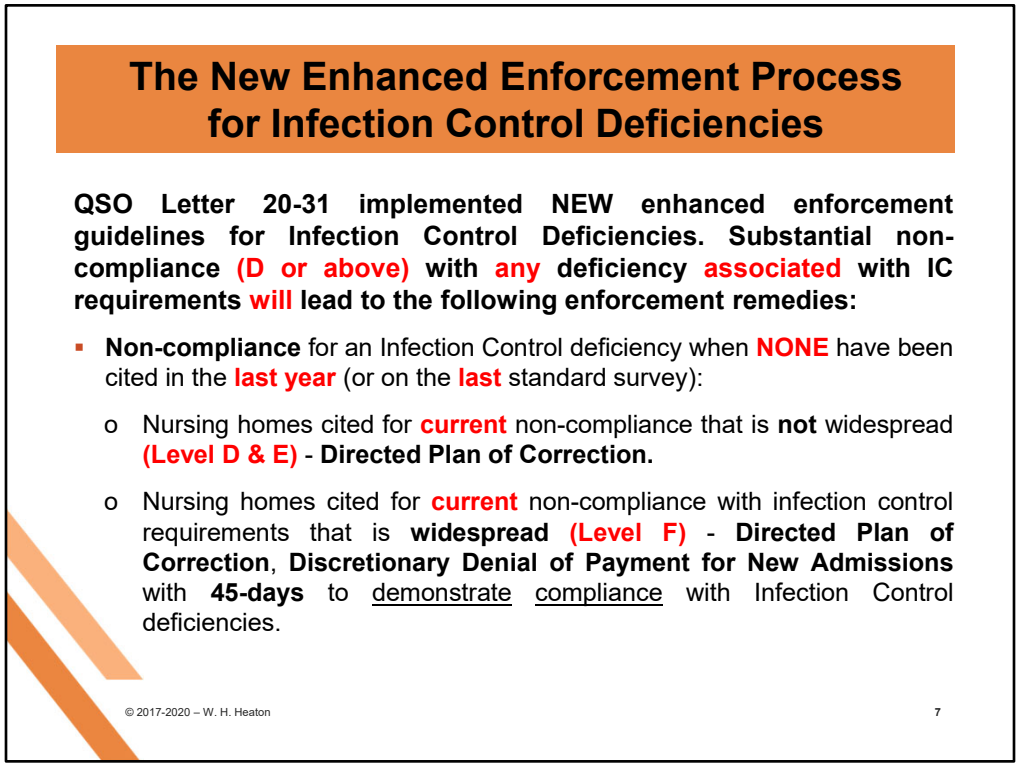
- A **proposed** rule change (July 18, 2019 Federal Register) will **require** CMS to provide the **rationale** (in writing) for their decision.

- This Independent IDR overview will provide you with **essential** information on **how** to use the process to **benefit** the facility.

- Be sure your **QAPI/QAA** program is **involved** in the decision-making process and review of support materials to present in disputing a cited deficiency.



- **Only** CMS can **cite** a facility at **F884**.
- Failure to timely report COVID-19 data (every Sunday), will result in an **"F" level** citation with a **$1,000 CMP**.
- Citations are **automatically** generated and sent to the facility's **CASPER** file.
- **CMPs** are issued for **one-day for the failure to report that week**. For **each subsequent** week the facility fails to submit the required report, the noncompliance will result in an **additional** one-day CMP imposed at an amount **increased** by $**500**.
- **Example**: **$1,000 for Week 1**; **$1,500 for Week 2**; and so forth. If you **file** for Week 3, but **fail** to report on **Week 4**, the **CMP** would be **$2,000** for **Week 4**. (See **Handout #3** – QSO Letter 20-29, page 5).
- **F885** review is conducted **onsite** during the focused infection control survey. Failure to report findings to residents, families, and representatives, **can** result in enforcement actions.
- **CMS** and **CDC** have indicated there have been issues with the **F884** data submission. Citations have been **erroneously** issued and CMS is working to correct those. Be sure you are reviewing your **CASPER** file often and challenge unsubstantiated citation through your Independent IDR process.
- The **NEXT** four (4) slides discuss the **NEW** enhanced enforcement actions for Infection Control deficiencies. It is **imperative** that facilities prepare for this process and use the Independent IDR process to help reduce the facility's liability.



- **OPTIONAL**: Provide participates with a copy of **Handout #4** – QSO Letter 20-31 – COVID-19 Survey Activities and IC Enforcement Actions.
- **Current** IC Survey Tags: **F880, F881, F883 (SQC Tag), F884, F885**.
- An "**Associated IC Requirement**" most likely includes **F945** – IC Training.
- A "Directed Plan of Correction" **(DPoC)** is a **Category 1** enforcement action. (Refer to **§7500** – Directed Plan of Correction.) **(See Handout #2)**
- A **DPoC** is a plan that the State or the Regional Office, or temporary manager, develops to **require** a facility to **take** action within specified time frames.
- A **DPoC requires** the facility's use of a **Root Cause Analysis** as part of the facility's **corrective** action process. (This involves your QAPI program.)
- A **Root Cause Analysis** is a process designed to **identify** root causes of an event that resulted in an **undesired** outcome and **develop** corrective actions.
- The **purpose** of the Root Cause Analysis is to find out **what** happened, **why** it happened, and determine **what changes** need to be made to correct the issue.
- It is **VERY** important that you review your **past three years** compliance history to identify **ANY** infection control deficiency citations.

The New Enhanced Enforcement Process for Infection Control Deficiencies – cont'd

Non-compliance for an Infection Control deficiency cited **ONCE** in the **last year** (or on the **last** standard survey):

- Nursing Homes cited for **current** non-compliance with infection control requirements that is **not** widespread **(Level D & E)-Directed Plan of Correction, Discretionary Denial of Payment for New Admissions** with **45-days** to demonstrate compliance with Infection Control deficiencies, Per Instance Civil Monetary Penalty (**CMP**) up to **$5000** (at State/CMS discretion).
- Nursing Homes cited for **current** non-compliance with infection control requirements that is **widespread (Level F)-Directed Plan of Correction, Discretionary Denial of Payment for New Admissions** with **45-days** to demonstrate compliance with Infection Control deficiencies; **$10,000** Per Instance CMP.

- If you have been cited for **F884**, these enforcement actions will **automatically** apply to the facility if CMS has **not** removed the citation, or if the facility participated in a **successful** Independent IDR process.
- **Remember**, F884 citations are **sent** to your **CASPER** file. You may **not receive** any other **notice**. Be sure to **check** your CASPER file often as CMS and CDC have indicated errors in the reporting process.
- CMPs of **$10,000** or more will **automatically** result in the **loss** of your Nurse Aide Training Program (NATP).

The New Enhanced Enforcement Process for Infection Control Deficiencies – cont'd

Non-compliance that has been cited for Infection Control Deficiencies **TWICE** or MORE **in the last two years** (or **twice** since **second** to **last** standard survey)

- Nursing homes cited for **current** non-compliance with Infection Control requirements that is **not** widespread (**Level D & E**)-**Directed Plan of Correction, Discretionary Denial of Payment for New Admissions**, **30-days** to demonstrate compliance with Infection Control deficiencies; **$15,000** Per Instance CMP (**or** per day CMP may be imposed, as long as the total amount **exceeds** $15,000)
- Nursing homes cited for **current** non-compliance with Infection Control requirements that is **widespread** (**Level F**)-**Directed Plan of Correction, Discretionary Denial of Payment for New Admissions**, **30-days** to demonstrate compliance with Infection Control deficiencies; **$20,000** Per Instance CMP (**or** per day CMP may be imposed, as long as the total amount **exceeds** $20,000).

The New Enhanced Enforcement Process for Infection Control Deficiencies – cont'd

- Nursing Homes cited for **current** non-compliance with Infection Control Deficiencies at the **Harm Level** (**Level G, H, I**), **regardless** of **past history-Directed Plan of Correction, Discretionary Denial of Payment for New Admissions** with **30 days** to demonstrate compliance with Infection Control deficiencies. **Enforcement imposed** by CMS Location per current policy, but **CMP** imposed at **highest** amount option within the appropriate (non-Immediate Jeopardy) range in the CMP analytic tool.
- Nursing Homes cited for **current** non-compliance with Infection Control Deficiencies at the **Immediate Jeopardy Level (Level J, K, L)**, **regardless** of **past history** – In **addition** to the **mandatory remedies** of **Temporary Manager or Termination, imposition of Directed Plan of Correction, Discretionary Denial of Payment for New Admissions**, **15-days** to demonstrate compliance with Infection Control deficiencies. **Enforcement imposed** by CMS Location per current policy, but **CMP** imposed at **highest** amount option within the appropriate (IJ) range in the CMP analytic tool.

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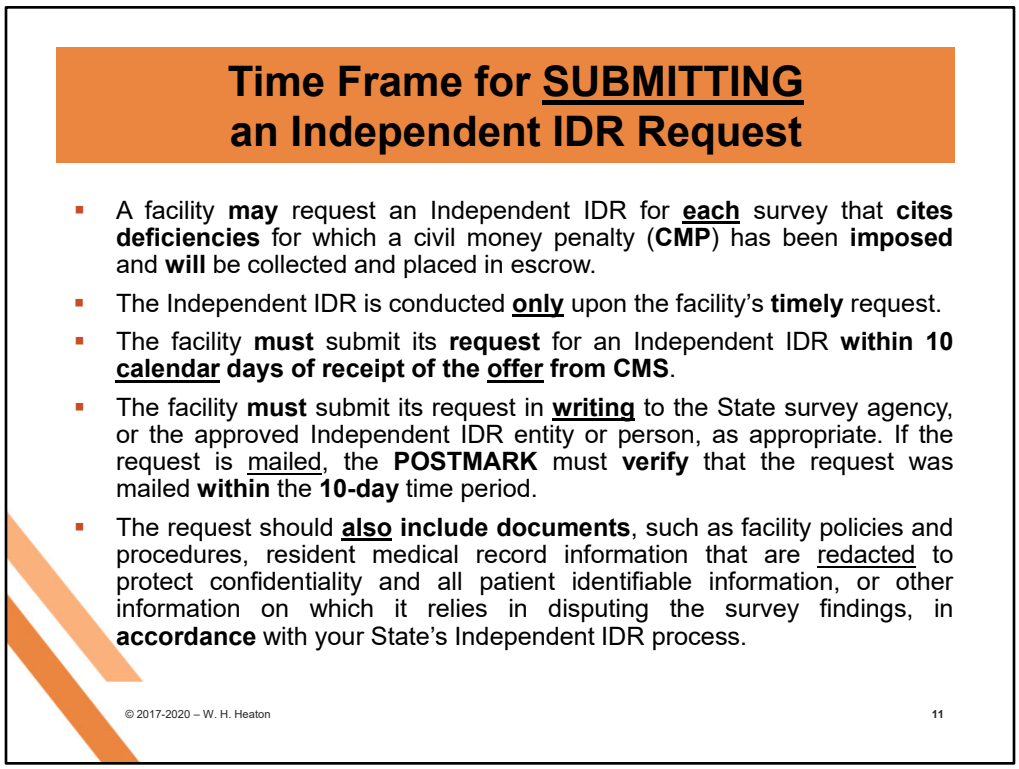
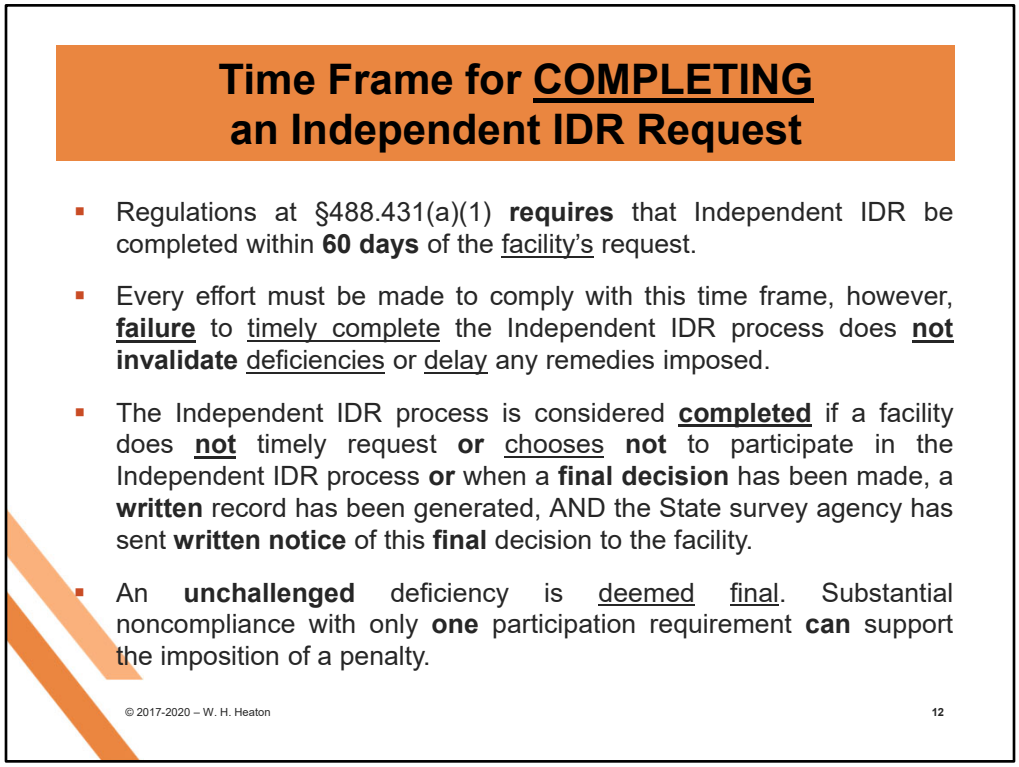
- Now that we have reviewed the **COVID-19** Reporting Requirements and the **NEW** Infection Control enforcement actions, let's **review** the importance of **Independent IDR** process.



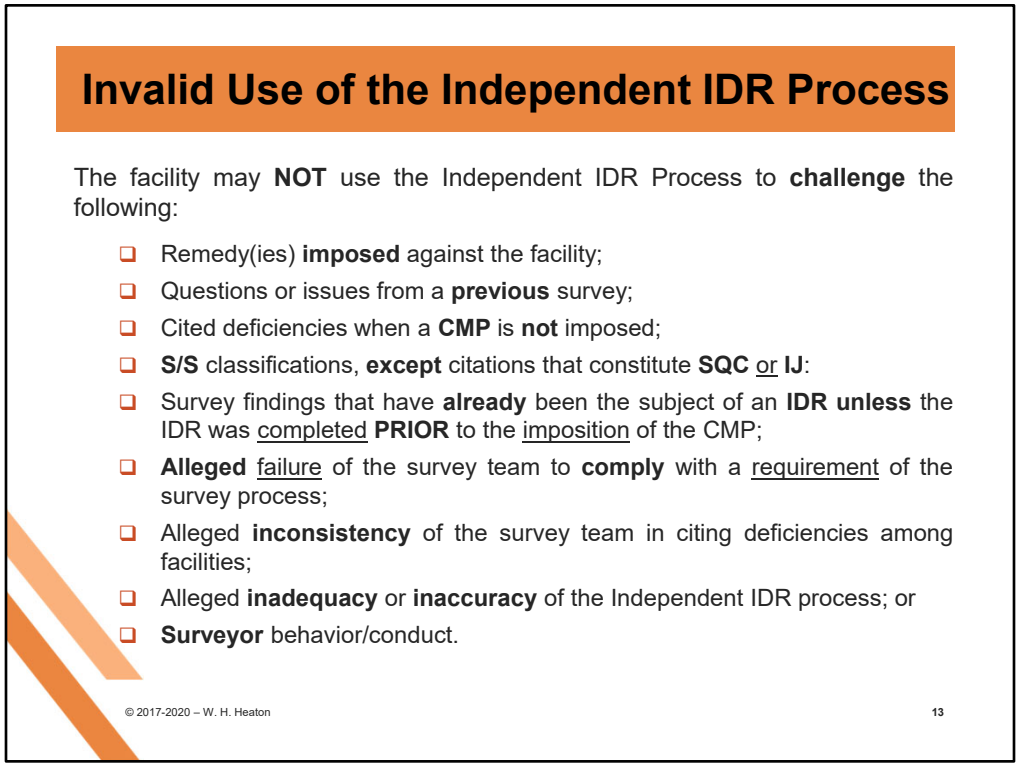
- The time frame for **submitting** a **request** for an Independent IDR is **critical**.
- Time frame is **10 calendar days**, **NOT 10 business days**.
- Your Independent IDR **notice** will contain information relative to the request **dates** and **data** to be submitted. **Follow** those **instructions carefully**.



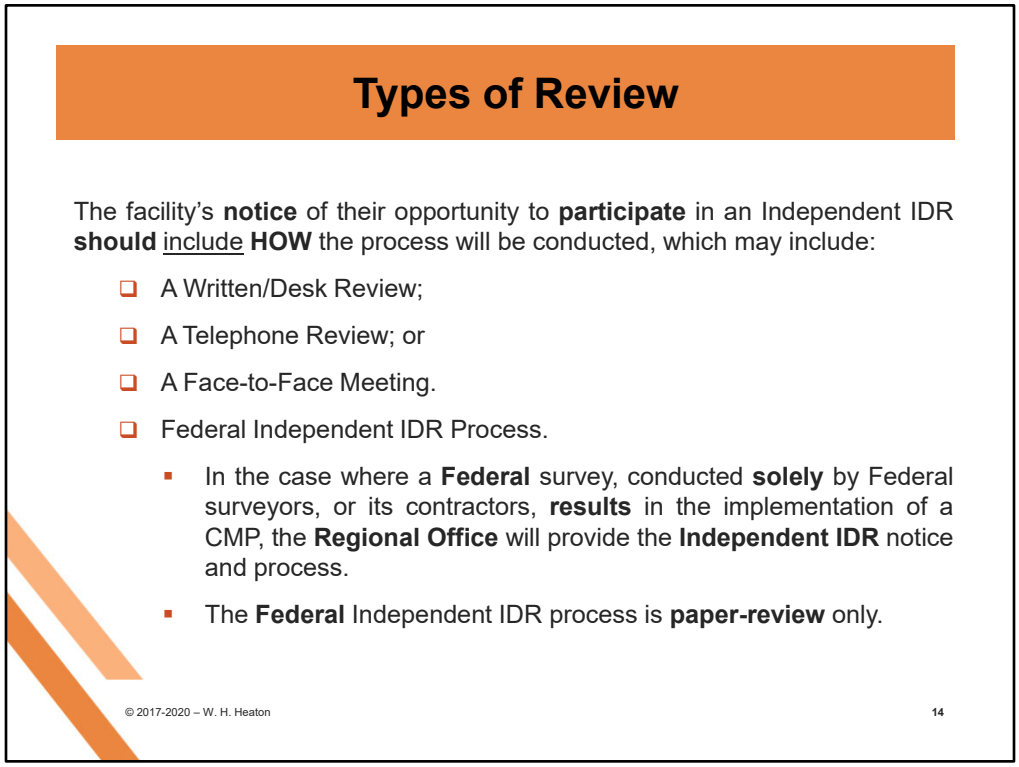
- An Independent IDR process does **NOT delay** the **imposition** of **any** remedies, including CMPs.

- You **cannot** ADD any challenges to your Independent IDR request **after** the 10 calendar days have passed. Be sure all challenges are included in the written request.

- Even if you request a **DAB** appeal hearing, you will **NOT** be permitted to include deficiency challenges **not** included in the Independent IDR process UNLESS permitted by the Administrative Law Judge (ALJ) or civil court action.



- Other State-specific reasons may apply. Be sure to check your State's Independent IDR process guidelines.
- Be sure to follow the instructions outlined in your Independent IDR notice.



- Since **F884** is conducted **solely** by CMS, it is considered a **Federal** Independent IDR Process.
- Your Independent IDR notice will come from the **CMS** Regional Office and will be **posted** to your **CASPER** file. It will be a paper only review.

Cost to the Facility

- 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.

Participation of Legal Counsel

- The **attendance** of the facility's legal counsel, or his/her representatives, at an Independent IDR review is an **individual** State **decision**.
- **Should** the State **permit** the facility's legal counsel to participate in the Independent IDR, the facility must **notify** the State of their legal counsel's participation to **ensure** that the State's legal counsel is **present**.
- The **cost** of the State's legal counsel's attendance is the responsibility of the State.
- The **cost** of the facility's legal counsel's attendance is the responsibility of the facility.

Notifying Involved Resident/Ombudsman

- 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** concerning the facility's Independent IDR request.
- The State is **encouraged** to **request** from the Ombudsman **specific** information based on **direct** involvement or **knowledge** about the **issues** being **disputed** by the facility.
- **Information** about the facility or provider in **general**, but **not related** to the deficiency(ies) at issue, are **not** relevant to the Independent IDR and should **not** be **considered** by the State or the Independent IDR process.

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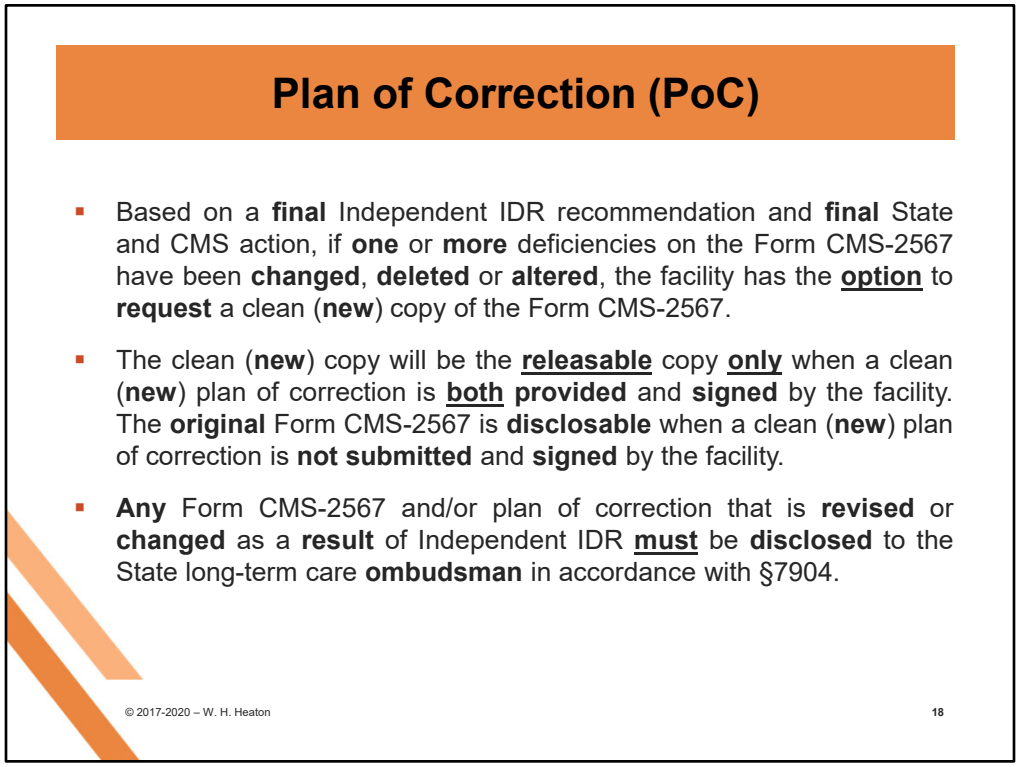
- An "**Involved Resident**" is a resident who was the subject of a complaint or who filed a complaint that led to a deficiency finding that is the subject of Independent IDR.
- "**Representative**" means either the resident's legal representative or an individual filing a complaint involving or on behalf of a resident.



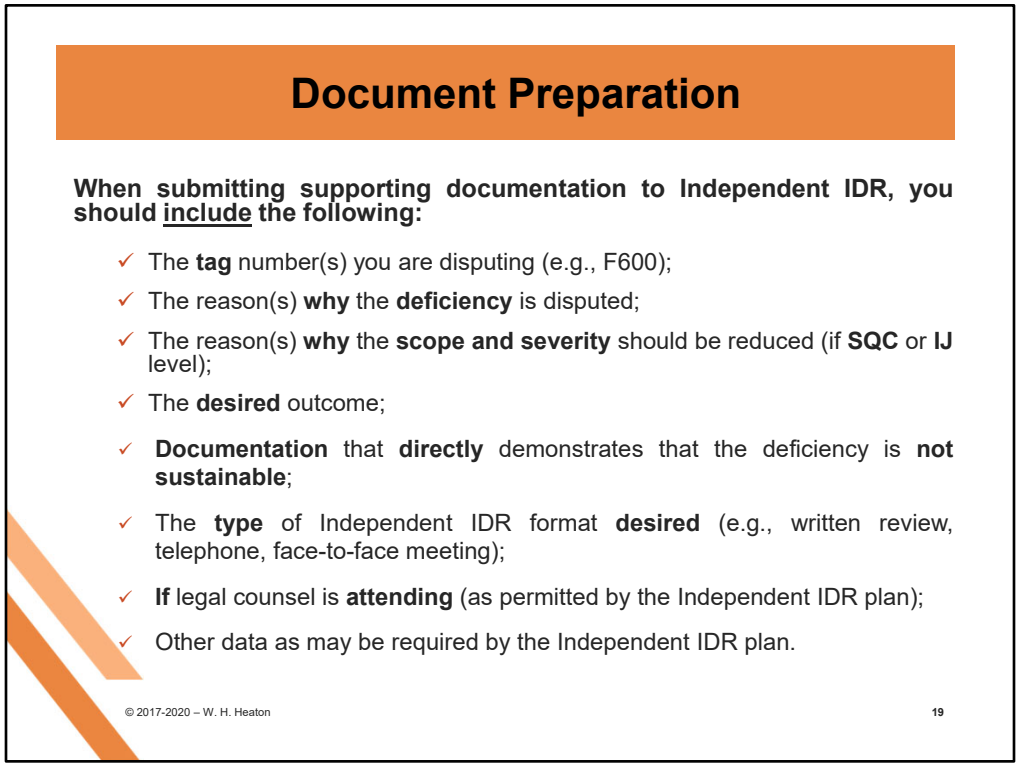
- The Plan of Correction **(PoC)** is one of the most **CRITICAL** elements of the Independent IDR process, and one that is most often **overlooked**.

- If you are **successful** in your Independent IDR, but do **NOT** request a **NEW** 2567 and submit a new **signed** and **dated** PoC, the **ORIGINAL** 2567 Statement of Deficiencies and Plan of Correction (PoC) will be the information that will be **posted** to ASPEN and to Nursing Home Compare.

- The **10-day** PoC submission **applies** to the NEW Plan of Correction.

- If you are successful in your Independent IDR, be sure you request a **new** 2567. You **cannot remove** or **change** those deficiencies once they have been **entered** into ASPEN as they are considered by CMS as **FINAL**.

- An **F884** citation is a prime **example** of this issue. If you requested and was **successful** in removing the deficiency and CMP, and did **NOT** request a new 2567, the "F" level citation and CMP are **posted** to ASPEN and Nursing Home Compare as a **final** determination.

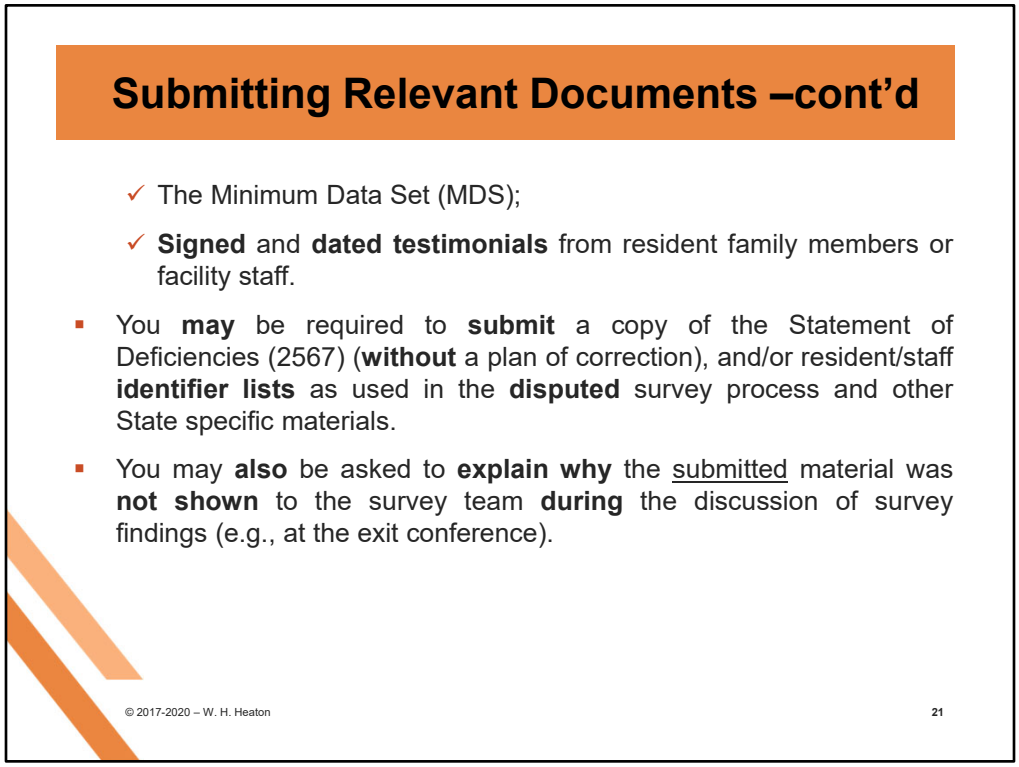


- **Document** preparation is another **critical** element of the Independent IDR process.
- Be sure you are **only** submitting documents that are **relevant** to the tag you are disputing.
- Documents that do **not** pertain to the challenged tag citation will **NOT** be considered in the Independent IDR process.
- Even if you request and are granted a **DAB** hearing, you will **not** be permitted to use data that was **not included** in the **Independent IDR** process.
- Be sure to **follow** your Independent IDR notice instructions for **how** documents are to be submitted (e.g., digital, paper copy, etc.).

Submitting Relevant Documents

Documentation should be relevant to the disputed survey findings. Examples include:

- ✓ A **facility** form that is **specific** to the **disputed** findings. **Blank** forms should **only** be submitted to **prove** that a form **existed** at the time of the survey;
- ✓ **Documents** from appropriate facility **records** (i.e., if the dispute regards a care plan that a surveyor found deficient, submit that care plan).
- ✓ Nurse's notes, physician's notes, medication orders, assessments, etc.;
- ✓ **Applicable** policies and procedures;
- ✓ **Inservice** training records (e.g., curriculum summary, signature lists, etc., to indicate the training context and attendance at the training session.)



- **Follow** your Independent IDR notice instructions on **how** documents are to be **assembled** and **arranged** (e.g., cover page, index, page numbers, exhibits, etc.).

- **Remember**, don't send documents that are **not** relevant. If documents are not relevant, it may create issues with the Independent IDR process and could result in the **rejection** of information and **end** the Independent IDR process.

Submitting Relevant Documents –cont'd

- Documents should be in its **original** form and content as of the survey date. Do **not** submit documentation that was prepared **after** the survey date (i.e., revised policies and procedures, care plans, in-service training records, etc.).
- The **wording** on the documents must be **legible**. If the document or portions are **illegible**, provide a **typed** version or a neatly **written** transcript of the section of the document. **Illegible** documentation will **not** be reviewed.
- Follow your State's process for **redacting** resident identification information.

Determining Relevant Information

Evidence which is almost never relevant includes such items as:

- ✓ Time, event, or person **other** than identified on the Statement of Deficiencies (SOD);
- ✓ Events occurring **after** the date of the SOD;
- ✓ **Subsequent** remedial measures (e.g., policy change **after** the alleged deficiency);
- ✓ **Offers** to pay medical expenses;
- ✓ **Past** determinations of deficiencies (e.g., presenting an exhibit which shows a **previous** survey from **another** facility in which the **same** deficiency was **removed** during an Independent IDR.);
- ✓ Evidence **relating** to the SOD which are **not** disputed.

- Be sure to **review** information with your legal counsel or facility management to ensure you are **submitting** only information that pertains to the disputed tag(s).

Burden of Proof

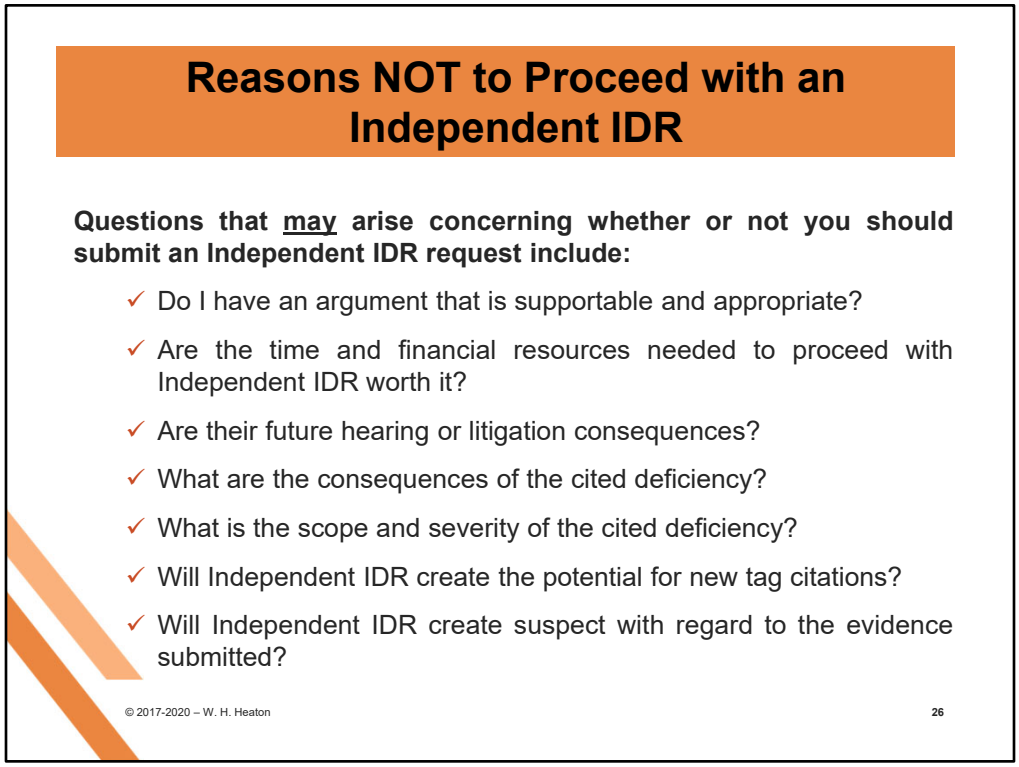
- The **standard** of **proof** is the **level** of **proof** required.
- Because the **purpose** of the Independent IDR is to **provide** the facility with an **opportunity** to **refute** certain cited deficiencies, **it is the facility** that **has** the **burden** of **proof** of presenting **evidence** which can **persuade** the Independent IDR entity that the **necessary elements** of the regulations **were met**.

Attendance at Independent IDR

Attendance at an Independent IDR is determined by each State. Normally, the following individuals may attend:

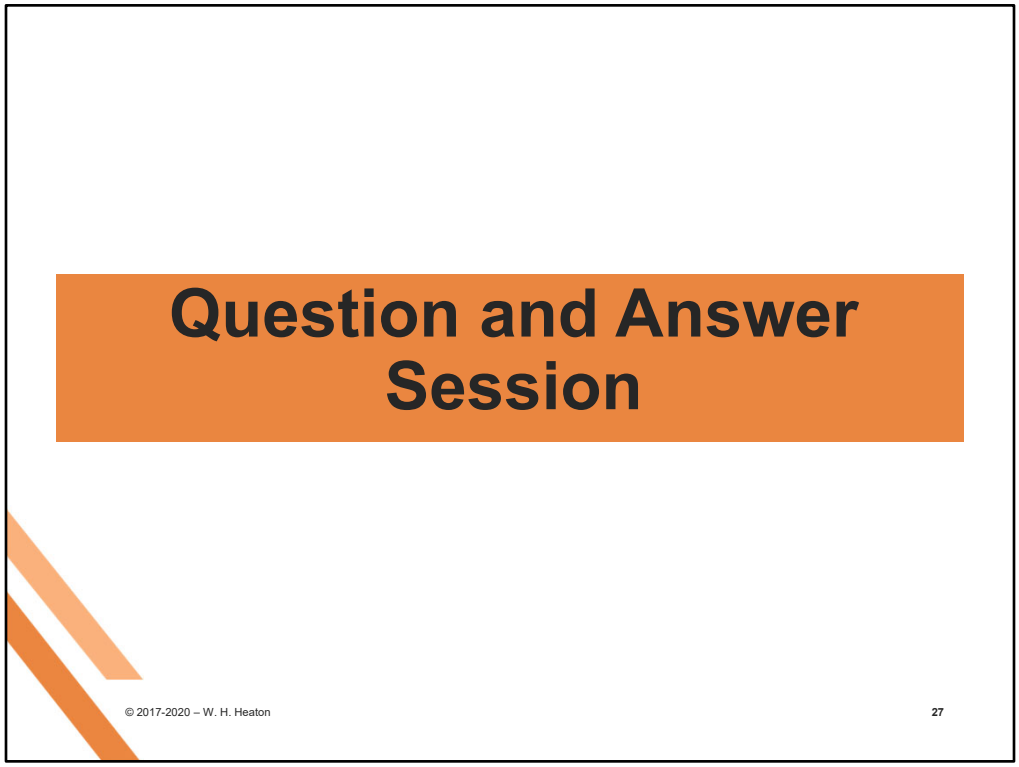
- ✓ Facility representatives and staff;
- ✓ Survey team members;
- ✓ State Long-Term Care Ombudsman;
- ✓ Involved Resident, individual or agency who is a legal guardian or has a medical power of attorney;
- ✓ Facility legal counsel and/or their representatives (if permitted by the IIDR Process);
- ✓ Others as permitted by the State's Independent IDR plan.

All persons attending the Independent IDR are **responsible** for **protecting** the **confidentiality** of resident information.



- These are only examples. Your legal counsel and management team may have other considerations during facility discussions on whether or not to proceed with an Independent IDR.

- **OPTION**: Review **Handout #6** – Sample Independent IDR Worksheet.



- **Encourage** participants to ask questions to ensure they have a working understanding of **how** the Independent IDR process is conducted.
- It is very important for **all** who are **involved** in the Independent IDR process to be **familiar** with the process from beginning to end.
- Remind participants to sign the **Record of Attendance Form**. Be sure to complete all required recordkeeping documentation. (**See Part 3**).

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Part 2

Participant Handouts

Provided Courtesy of

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Part 2 – Participant Handouts

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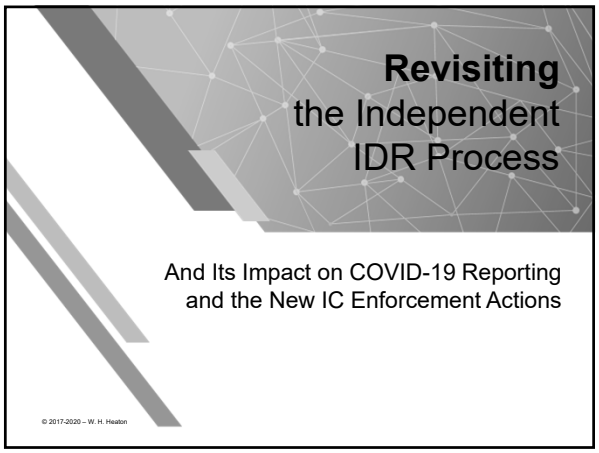

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Session Objectives

Upon completion of this session, you should be able to:

- **Describe** the Independent IDR (IIDR) Process.
- Discuss the **benefits** of using the Independent IDR Process.
- Discuss the **importance** of understanding the COVID-19 reporting requirements and the **New** Enhanced Infection Control Enforcement Process.
- Discuss the Independent IDR **time frame** requirements.
- Identify and discuss actions that are considered an **invalid use** of the Independent IDR Process.
- Discuss the **types** of Independent IDR review, cost, & legal counsel participation.
- Discuss the **importance** of requesting a **new** Plan of Correction.
- Discuss the **preparation** and **submission** of **relevant** documents.
- Identify **individuals** that **may** be allowed to **attend** an Independent IDR hearing.
- Identify and discuss **reasons not** to proceed with an Independent IDR hearing.

 2

2

Overview

- The Independent Informal Dispute Resolution (IIDR) Process allows the facility to dispute **ONLY** those deficiencies for which a civil money penalty (CMP) has been **imposed** and will be **collected** and placed in escrow.
- Unlike the IDR process which allows facilities an opportunity to challenge deficiency citations, a facility **cannot** seek an Independent IDR unless they receive **notification** from CMS of the facility's **eligibility** to participate in the Independent IDR process.
- The facility's request for an Independent IDR **must** be made **within ten (10) calendar days** of the receipt of the offer from CMS to participate in the IIDR.
- The **time frame** runs **concurrent** with the submission of the Plan of Correction (PoC).
- You must submit a **PoC** within the 10 calendar days time frame for all deficiencies **not** challenged or where **no** IIDR is permitted for a cited deficiency.

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Overview – cont'd

- The **written** notice from **CMS** should **include** information relative to the Independent IDR Process and **document** submission requirements.
- Another important **reminder** is that of requesting a **hearing** with the Departmental Appeal Board **(DAB)** before an administrative law judge **(ALJ)**.
- This is a **separate** process from the Independent IDR.
- You only have **60-days** from the **date** you receive written notice of the **imposition** of an enforcement action (e.g., CMP, DPNA, etc.) to **file** a Hearing Request.
- The fact that you have **requested,** and/or are **participating** in, an **Independent IDR** does **NOT** suspend the **60-day** time frame for **filing** a hearing request **nor** does it **delay** the imposition of CMPs or other remedy.

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Benefits of Using the Independent IDR Process

The Independent IDR process can benefit the facility by:

- **Reducing** the impact on the 5-Star Rating;
- **Removing** and/or **decreasing** scope and severity can improve the status of the facility on Nursing Home Compare;
- Deficiencies **removed** will **not** require a PoC or follow-up survey to review correction;
- When survey tags or scope and severity levels are **decreased**, the facility may have **less** exposure or liability for certain claims;
- Individual **licenses** of the administrator and the facility would be better protected, especially when there is a valid reason to dispute the tag;
- The facility has an **opportunity** to review its policy and procedure when analyzing disputed deficiencies and can make a determination as to the **benefit** of modification to prevent further concern in the area;
- **Challenging F884** citations and **other** related **IC** deficiencies to prevent enhanced enforcement actions for IC deficiencies at a **S/S Level of D or above**.

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Review of COVID-19 Reporting Requirements

- QSO Letter **20-29 requires** nursing homes to **report** COVID-19 facility data to **CDC** and to **residents**, their **representatives**, and **families** of residents in nursing homes.
- **Failure** to report data can **result** in an **enforcement** action.
- **F884 – COVID-19 Reporting to CDC**.
  - **F884** is conducted **OFFSITE** by **CMS** using the **weekly** data reported to CDC.
  - Facilities **identified** as **not** reporting data timely **will** receive a deficiency citation at an **F Level** and a one-day CMP of **$1,000**. CMP amounts are **increased** by **$500** for each week data is not submitted.
- **F885 – Facility Reporting COVID-19 Information to Residents, Representatives, and Families**:
  - **F885** is conducted **ONSITE during** the Focused Survey Process.
  - If the surveyor finds **noncompliance**, a citation **will** be entered on the 2567 and **enforcement** actions will be **implemented** in accordance with QSO Letter **20-20**.

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The New Enhanced Enforcement Process for Infection Control Deficiencies

QSO Letter 20-31 implemented NEW enhanced enforcement guidelines for Infection Control Deficiencies. Substantial non-compliance (D or above) with any deficiency associated with IC requirements will lead to the following enforcement remedies:

- **Non-compliance** for an Infection Control deficiency when **NONE** have been cited in the **last year** (or on the **last** standard survey):
  - Nursing homes cited for **current** non-compliance that is **not** widespread **(Level D & E)** - **Directed Plan of Correction.**
  - Nursing homes cited for **current** non-compliance with infection control requirements that is **widespread (Level F)** - **Directed Plan of Correction**, **Discretionary Denial of Payment for New Admissions** with **45-days** to demonstrate compliance with Infection Control deficiencies.

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The New Enhanced Enforcement Process for Infection Control Deficiencies – cont'd

Non-compliance for an Infection Control deficiency cited **ONCE** in the **last year** (or on the **last** standard survey):

- Nursing Homes cited for **current** non-compliance with infection control requirements that is **not** widespread (**Level D & E**)-**Directed Plan of Correction, Discretionary Denial of Payment for New Admissions** with **45-days** to demonstrate compliance with Infection Control deficiencies, Per Instance Civil Monetary Penalty (**CMP**) up to **$5000** (at State/CMS discretion)**.**
- Nursing Homes cited for **current** non-compliance with infection control requirements that is **widespread (Level F)-Directed Plan of Correction, Discretionary Denial of Payment for New Admissions** with **45-days** to demonstrate compliance with Infection Control deficiencies; **$10,000** Per Instance CMP.

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The New Enhanced Enforcement Process for Infection Control Deficiencies – cont'd

Non-compliance that has been cited for Infection Control Deficiencies **TWICE** or MORE **in the last two years** (or **twice** since **second** to **last** standard survey)

- Nursing homes cited for **current** non-compliance with Infection Control requirements that is **not** widespread (**Level D & E**)-**Directed Plan of Correction, Discretionary Denial of Payment for New Admissions**, **30-days** to demonstrate compliance with Infection Control deficiencies; **$15,000** Per Instance CMP (**or** per day CMP may be imposed, as long as the total amount **exceeds** $15,000)
- Nursing homes cited for **current** non-compliance with Infection Control requirements that is **widespread** (**Level F**)-**Directed Plan of Correction, Discretionary Denial of Payment for New Admissions**, **30-days** to demonstrate compliance with Infection Control deficiencies; **$20,000** Per Instance CMP (**or** per day CMP may be imposed, as long as the total amount **exceeds** $20,000).

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The New Enhanced Enforcement Process for Infection Control Deficiencies – cont'd

- Nursing Homes cited for **current** non-compliance with Infection Control Deficiencies at the **Harm Level** (**Level G, H, I**), **regardless** of **past history-Directed Plan of Correction, Discretionary Denial of Payment for New Admissions** with **30 days** to demonstrate compliance with Infection Control deficiencies. **Enforcement imposed** by CMS Location per current policy, but **CMP** imposed at **highest** amount option within the appropriate (non-Immediate Jeopardy) range in the CMP analytic tool.
- Nursing Homes cited for **current** non-compliance with Infection Control Deficiencies at the **Immediate Jeopardy Level (Level J, K, L)**, **regardless** of **past history** – In **addition** to the **mandatory remedies** of **Temporary Manager or Termination, imposition of Directed Plan of Correction, Discretionary Denial of Payment for New Admissions**, **15-days** to demonstrate compliance with Infection Control deficiencies. **Enforcement imposed** by CMS Location per current policy, but **CMP** imposed at **highest** amount option within the appropriate (IJ) range in the CMP analytic tool.

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Time Frame for SUBMITTING an Independent IDR Request

- A facility **may** request an Independent IDR for **each** survey that **cites deficiencies** for which a civil money penalty (**CMP**) has been **imposed** and **will** be collected and placed in escrow.
- The Independent IDR is conducted **only** upon the facility's **timely** request.
- The facility **must** submit its **request** for an Independent IDR **within 10 calendar days of receipt of the offer from CMS**.
- The facility **must** submit its request in **writing** to the State survey agency, or the approved Independent IDR entity or person, as appropriate. If the request is mailed, the **POSTMARK** must **verify** that the request was mailed **within** the **10-day** time period.
- The request should **also include 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, in **accordance** with your State's Independent IDR process.

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Time Frame for COMPLETING an Independent IDR Request

- 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 timely complete the Independent IDR process does **not invalidate** deficiencies or delay any remedies imposed.
- 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.
- An **unchallenged** deficiency is deemed final. Substantial noncompliance with only **one** participation requirement **can** support the imposition of a penalty.

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Invalid Use of the Independent IDR Process

The facility may **NOT** use the Independent IDR Process to **challenge** the following:

- Remedy(ies) **imposed** against the facility;
- Questions or issues from a **previous** survey;
- Cited deficiencies when a **CMP** is **not** imposed;
- **S/S** classifications, **except** citations that constitute **SQC** or **IJ**:
- Survey findings that have **already** been the subject of an **IDR unless** the IDR was completed **PRIOR** to the imposition of the CMP;
- **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 facilities;
- Alleged **inadequacy** or **inaccuracy** of the Independent IDR process; or
- **Surveyor** behavior/conduct.

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Types of Review

The facility's **notice** of their opportunity to **participate** in an Independent IDR **should** include **HOW** the process will be conducted, which may include:

- A Written/Desk Review;
- A Telephone Review; or
- A Face-to-Face Meeting.
- Federal Independent IDR Process.
  - In the case where a **Federal** survey, conducted **solely** by Federal surveyors, or its contractors, **results** in the implementation of a CMP, the **Regional Office** will provide the **Independent IDR** notice and process.
  - The **Federal** Independent IDR process is **paper-review** only.

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Cost to the Facility

- 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.

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Participation of Legal Counsel

- The **attendance** of the facility's legal counsel, or his/her representatives, at an Independent IDR review is an **individual** State **decision**.
- **Should** the State **permit** the facility's legal counsel to participate in the Independent IDR, the facility must **notify** the State of their legal counsel's participation to **ensure** that the State's legal counsel is **present**.
- The **cost** of the State's legal counsel's attendance is the responsibility of the State.
- The **cost** of the facility's legal counsel's attendance is the responsibility of the facility.

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Notifying Involved Resident/Ombudsman

- 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** concerning the facility's Independent IDR request.
- The State is **encouraged** to **request** from the Ombudsman **specific** information based on **direct** involvement or **knowledge** about the **issues** being **disputed** by the facility.
- **Information** about the facility or provider in **general**, but **not related** to the deficiency(ies) at issue, are **not** relevant to the Independent IDR and should **not** be **considered** by the State or the Independent IDR process.

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Plan of Correction (PoC)

- Based on a **final** Independent IDR recommendation and **final** State and CMS action, if **one** or **more** deficiencies on the Form CMS-2567 have been **changed**, **deleted** or **altered**, the facility has the **option** to **request** a clean (**new**) copy of the Form CMS-2567.
- The clean (**new**) copy will be the **releasable** copy **only** when a clean (**new**) plan of correction is **both** **provided** and **signed** by the facility. The **original** Form CMS-2567 is **disclosable** when a clean (**new**) plan of correction is **not submitted** and **signed** by the facility.
- **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.

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Document Preparation

When submitting supporting documentation to Independent IDR, you should include the following:

- ✓ The **tag** number(s) you are disputing (e.g., F600);
- ✓ The reason(s) **why** the **deficiency** is disputed;
- ✓ The reason(s) **why** the **scope and severity** should be reduced (if **SQC** or **IJ** level);
- ✓ The **desired** outcome;
- ✓ **Documentation** that **directly** demonstrates that the deficiency is **not sustainable**;
- ✓ The **type** of Independent IDR format **desired** (e.g., written review, telephone, face-to-face meeting);
- ✓ **If** legal counsel is **attending** (as permitted by the Independent IDR plan);
- ✓ Other data as may be required by the Independent IDR plan.

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Submitting Relevant Documents

Documentation should be relevant to the disputed survey findings. Examples include:

- ✓ A **facility** form that is **specific** to the **disputed** findings. **Blank** forms should **only** be submitted to **prove** that a form **existed** at the time of the survey;
- ✓ **Documents** from appropriate facility **records** (i.e., if the dispute regards a care plan that a surveyor found deficient, submit that care plan).
- ✓ Nurse's notes, physician's notes, medication orders, assessments, etc.;
- ✓ **Applicable** policies and procedures;
- ✓ **Inservice** training records (e.g., curriculum summary, signature lists, etc., to indicate the training context and attendance at the training session.)

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Submitting Relevant Documents –cont'd

- ✓ The Minimum Data Set (MDS);
- ✓ **Signed** and **dated testimonials** from resident family members or facility staff.

- You **may** be required to **submit** a copy of the Statement of Deficiencies (2567) (**without** a plan of correction), and/or resident/staff **identifier lists** as used in the **disputed** survey process and other State specific materials.
- You may **also** be asked to **explain why** the submitted material was **not shown** to the survey team **during** the discussion of survey findings (e.g., at the exit conference).

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Submitting Relevant Documents –cont'd

- Documents should be in its **original** form and content as of the survey date. Do **not** submit documentation that was prepared **after** the survey date (i.e., revised policies and procedures, care plans, in-service training records, etc.).
- The **wording** on the documents must be **legible**. If the document or portions are **illegible**, provide a **typed** version or a neatly **written** transcript of the section of the document. **Illegible** documentation will **not** be reviewed.
- Follow your State's process for **redacting** resident identification information.

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Determining Relevant Information

Evidence which is almost never relevant includes such items as:

- ✓ Time, event, or person **other** than identified on the Statement of Deficiencies (SOD);
- ✓ Events occurring **after** the date of the SOD;
- ✓ **Subsequent** remedial measures (e.g., policy change **after** the alleged deficiency);
- ✓ **Offers** to pay medical expenses;
- ✓ **Past** determinations of deficiencies (e.g., presenting an exhibit which shows a **previous** survey from **another** facility in which the **same** deficiency was **removed** during an Independent IDR.);
- ✓ Evidence **relating** to the SOD which are **not** disputed.

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Burden of Proof

- The **standard** of **proof** is the **level** of **proof** required.
- Because the **purpose** of the Independent IDR is to **provide** the facility with an **opportunity** to **refute** certain cited deficiencies, **it is the facility** that **has** the **burden** of **proof** of presenting **evidence** which can **persuade** the Independent IDR entity that the **necessary elements** of the regulations **were met**.

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Attendance at Independent IDR

Attendance at an Independent IDR is determined by each State. Normally, the following individuals may attend:

- ✓ Facility representatives and staff;
- ✓ Survey team members;
- ✓ State Long-Term Care Ombudsman;
- ✓ Involved Resident, individual or agency who is a legal guardian or has a medical power of attorney;
- ✓ Facility legal counsel and/or their representatives (if permitted by the IIDR Process);
- ✓ Others as permitted by the State's Independent IDR plan.

All persons attending the Independent IDR are **responsible** for **protecting** the **confidentiality** of resident information.

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Reasons NOT to Proceed with an Independent IDR

Questions that <u>may</u> arise concerning whether or not you should submit an Independent IDR request include:

- ✓ Do I have an argument that is supportable and appropriate?
- ✓ Are the time and financial resources needed to proceed with Independent IDR worth it?
- ✓ Are their future hearing or litigation consequences?
- ✓ What are the consequences of the cited deficiency?
- ✓ What is the scope and severity of the cited deficiency?
- ✓ Will Independent IDR create the potential for new tag citations?
- ✓ Will Independent IDR create suspect with regard to the evidence submitted?

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Question and Answer Session

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Handout #2 - Independent IDR Regulatory Resources

Independent Informal Dispute Resolution (Independent IDR)

7213 - Independent Informal Dispute Resolution (Independent IDR)
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

All regulatory references are in 42 CFR unless otherwise stated.

7213.1 - Introduction
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

Under sections 1819(h)(2)(B)(ii)(IV) and 1919(h)(2)(B)(ii)(IV) of the Act and regulations at 42 CFR 488.331 and 488.431 SNFs, NFs and 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.

NOTE: All CMP funds are subject to escrow. If the nursing home elects not to request an Independent IDR or to appeal, then after any IDR (if requested), CMP amount becomes due and payable in accordance with the process in §7528.3.

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
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

To provide facilities, under certain circumstances, an additional opportunity to informally dispute cited deficiencies through a process that is independent from the State survey agency or, in the case of Federal surveys, the CMS Regional Office.

7213.3 - Independent Informal Dispute Resolution Requirements
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The requirements and specific core elements that must be included in an acceptable Independent IDR process are specified in the 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;

   NOTE: Independent IDR is completed when a final decision from the Independent IDR process has been made, a written record has been generated and the State survey agency has sent written notice of this decision to the facility. The Independent IDR process is also considered to be completed if a facility does not timely request or chooses not to participate in the Independent IDR process.

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;

   NOTE: "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. "Representative" means either the resident's legal representative or an individual filing a complaint involving or on behalf of a resident.

4. Be approved by CMS and conducted by the State, 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, must be approved by CMS. 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 for the State's or RO's jurisdiction. 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. The Independent IDR process must be in writing and available for review upon request.

7213.4 - Applicability of the Independent Informal Dispute Resolution Process

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

The Independent IDR process must be offered to a facility when a civil money penalty is imposed and that penalty is subject to being 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. The facility's request will be considered timely if the request is dated within 10 calendar days of the receipt of the offer, and, in the case of the request being mailed, the postmark verifies that it was mailed within that same 10 day time period.

1. A facility may request an Independent IDR for each survey that cites deficiencies for which a civil money penalty has been imposed that is subject to collection and placement in an escrow account. 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. The following table indicates when independent informal dispute resolution may be requested based on the results of a revisit or as a result of the previous independent informal dispute resolution outcome.

Situation	Eligibility for Independent Informal Dispute Resolution
Continuation of same deficiency at revisit which results in the continuation of the imposed civil money penalty	Yes
New deficiency resulting in the imposition of a civil money penalty (i.e., new or changed facts, new tag) at revisit or as a result of an independent informal dispute resolution	Yes
New instance of deficiency resulting in the imposition of a civil money penalty (i.e., new facts, same tag) at revisit or as a result of an informal dispute resolution.	Yes
Different tag but same facts at revisit or as a result of an informal dispute resolution	No, unless the new tag constitutes substandard quality of care and results in the imposition of a civil money penalty

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 that led to the imposition of a civil money penalty that is subject to being 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 is not 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 42 CFR 498.3(b). The Independent IDR results are recommendations to the State and CMS and are not subject to a formal appeal.

7213.5- Key Elements of Independent Informal Dispute Resolution
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

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 is subject to being 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 CMS notice will provide the State survey agency contact information, including the name, address, and telephone number of the person and/or agency or office that the facility must contact to request an Independent IDR. The Notice of Imposition of a Penalty may 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, i.e. the name, address, phone number and e-mail of the person(s) who will be conducting the Independent IDR, if appropriate.

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. IDR and Independent IDR are part of the survey and certification process.

2. Timing: 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's request will be considered timely if the request is dated within 10 calendar days of the receipt of the CMS offer, and, in the case of the request being mailed, the postmark verifies that it was mailed within that same 10 day time period. The facility must 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 refuting the survey findings.

§488.431(a)(1) require that the 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 cited 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. The State should request information from the long-term care ombudsman program, asking for specific information based on the ombudsman program's direct involvement or knowledge and directly related to the deficiency (ies) being disputed by the facility. Information about the facility or provider in general, but not related to the deficiency (ies) at issue, is not relevant to the Independent IDR process. This notification must be done before the Independent IDR review begins and with sufficient time for the resident 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 ID, a statement about the CMP imposed based on these findings, 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 within 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 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 Independent IDR 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 justification 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, taking care to protect confidentiality and protected health information.

7213.6 - Qualifications of an Independent Informal Dispute Resolution Entity or Person(s)

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

In order to be approved as an Independent IDR entity or person, whether it is a State agency or an outside organization contracted by the State agency, 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) Have a family member who is either a resident or an employee of the facility involved in the Independent IDR;

c) Is currently employed by the facility or organization involved in the Independent IDR;

d) Have worked within the past year as an employee, consultant or volunteer for the facility or a related corporation, involved in the Independent IDR;

e) Have ownership interest or currently serves or within the past year has served on the Board of Directors or Governing Body of a facility or organization involved in the Independent IDR; or

f) Have acted within the past year as legal counsel for or against the facility involved in the Independent IDR.

7213.7 - Approval of an Independent Informal Dispute Resolution Process

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

A State's Independent IDR process must be approved by CMS. The State must submit all proposed processes, including any process that may have been used by or already existed in the State prior to January 1, 2012, 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 meets 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 the Independent IDR, including the results of the Independent IDR review.

7213.8 - State Budget and Payment for Expenses
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

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.

7213.9 - Independent Informal Dispute Resolution Recommendation and Final Decision
(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

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

   (a) 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.

   (b) 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 identify the portion(s) of the Independent IDR recommendation with which it disagrees, the basis for its disagreement including any relevant survey documents that support its recommendation to the CMS RO. As soon as practicable, but no later than 10 calendar days, the CMS RO will review the Independent IDR ecommendation 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 CMS review will be conducted by persons familiar with LTC requirements but who have not had any input or activity with respect to the survey or deficiencies at issue. 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. The Independent IDR process is also considered completed if a facility does not timely request or chooses not to participate in the Independent IDR process.

2. 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 , within 10 calendar days of receiving the written record:

   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 recommendations from the Independent IDR regarding the deficiency(ies);

   c) Annotate deficiency(ies) citations as "deleted or amended as recommended", where appropriate;

   d) Have a State survey agency manager or supervisor sign and date the revised CMS Form-2567;

   e) Promptly recommend to CMS that any enforcement action(s) imposed solely because of deleted or altered deficiency citations be reviewed, changed or rescinded as appropriate; and

   f) Provide written notification of the final decision to the facility.

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 been changed, deleted or altered, the facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Any Form CMS-2567 and/or plan of correction that is revised or changed as a result of informal dispute resolution must be disclosed to the ombudsman in accordance with §7904.

Deficiencies pending Independent IDR should be entered into the Automated Survey Processing Environment (ASPEN) and the ASPEN Informal Dispute Resolution (IDR) Manager within ten (10) calendar days of receiving the request for an independent informal dispute resolution. This information however will not be uploaded to the Certification and Survey Provider Enhanced Reporting System (CASPER) for posting to the Nursing Home Compare website until the Independent IDR has been completed. .

IDR or Independent IDR requests from the facility should be entered in the ASPEN system within 10 working days of the IDR or Independent IDR request 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.

7213.10 - Additional Elements for Federal Independent Informal Dispute Resolution Process

(Rev. 118, Issued: 06-12-14, Effective: 01-01-12, Implementation: 01-01-12)

In the case where a Federal survey, conducted solely by Federal surveyors, or its contractors, results in the imposition of a civil money penalty (CMP) that is subject to being collected and placed in escrow, the Regional Office will offer the facility the opportunity for an Independent IDR. The Regional Office will follow the applicable elements cited in §7213. The Regional Office should advise the facility that all requests for an Independent IDR should be directed in writing to the Regional Office and an electronic copy of the request should also be sent to the CMS mailbox at CMSQualityAssurance@cms.hhs.gov. The facility should send any and all documentation, such as facility policies and procedures, resident medical record information or other information on which it relies in disputing the survey findings directly to the entity contracted by CMS to provide the Federal Independent IDR process. The facility must also send a copy of the supporting documentation to the CMS Regional Office with its request.

The Regional Office must also inform the involved resident or resident representative as well as the State's long term care ombudsman to submit any written comments directly to the Federal Independent IDR entity. This Independent IDR will be a paper review performed by the Federal Independent IDR entity under contract with CMS, Survey & Certification Group, Division of Nursing Homes. The Independent IDR will be completed within 60 calendar days of the facility's timely request. Upon completion of the review the Federal Independent IDR entity will send all documents submitted by the facility and any comments submitted by the State's long term care ombudsman and/or residents or resident representatives to the respective Regional Office along with its final written record/report.

In the event that any conflict of interest exists between the facility and the contracted Federal Independent IDR entity, or in the event that the Federal Independent IDR entity is unavailable, the Independent IDR will be conducted by CMS Central Office. In this case, the facility should be instructed to send all documentation to:

Centers for Medicare & Medicaid Services
Survey and Certification Group - Division of Nursing Homes
7500 Security Blvd - Mailstop C2-21-16
Baltimore, MD 21244

This Independent IDR will be a paper review performed by a panel of CMS Central Office employees who meet the criteria for an Independent IDR entity. The Independent IDR will be completed within 60 calendar days of the facility's timely request. Upon completion of the review, CMS Central Office will send all documents submitted by the facility and any comments submitted by the State's long term care ombudsman and/or residents or resident representatives to the respective Regional Office along with their final written record/report.

Upon receipt of a facility's request for an Independent IDR the Regional Office should enter the appropriate information into the Automated Survey Processing Environment (ASPEN).

Upon receipt of the Independent IDR written record, the Regional Office, will review the Independent IDR recommendation(s) and:

1. If the Regional Office agrees with the Independent IDR recommendation(s) and no changes will be made to the disputed survey findings, the Regional Office 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.

2. If the Regional Office disagrees with one or more of the recommendations of the Independent IDR entity or person, the complete written record will be sent to CMS Central Office for review and final decision. The Regional Office should identify the Independent IDR recommendation with which it disagrees, the basis for its disagreement and any relevant survey documents to the CMS Central Office. As soon as practicable, but no later than 10 calendar days, the CMS Central Office will review the Independent IDR recommendation and corresponding records along with the Regional Office's written disagreement of the Independent IDR's recommendation and will provide written notification to the CMS Regional Office of the final decision. The CMS Regional Office will then send written notification of the final decision to the facility within 10 calendar days of receiving the final decision from the CMS Central Office.

NOTE: The 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 CMS Regional Office has sent written notice of the Independent IDR recommendation to the facility.

3. If the CMS Regional Office agrees with the Independent IDR recommendation(s) or has received a final decision from the CMS Central Office and changes are to be made to the disputed survey findings, the CMS Regional Office will, within 10 calendar days of receiving the written record:

    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 or amended as recommended "where appropriate;

    d) Have a CMS Regional Office manager or supervisor sign and date the revised CMS Form-2567;

    e) Ensure that any enforcement action(s) imposed solely because of deleted or altered deficiency citations will be reviewed, changed or rescinded, as appropriate; and

    f) Provide written notification of the final decision to the facility.

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 been revised or removed, the facility has the option to request a clean (new) copy of the Form CMS-2567. However, the clean copy will be the releasable copy only when a clean (new) plan of correction is both provided and signed by the facility. The original Form CMS-2567 is disclosable when a clean plan of correction is not submitted and signed by the facility. Any Form CMS-2567 and/or plan of correction that is revised or changed as a result of IDR must be disclosed to the ombudsman in accordance with §7904.

Deficiencies pending Independent IDR should be entered into the Automated Survey Processing Environment (ASPEN) and the ASPEN Informal Dispute Resolution (IDR) Manager but will not be uploaded to the Certification and Survey Provider Enhanced Reporting System (CASPER) for posting to the Nursing Home Compare website until the Independent IDR has been completed.

IDR or Independent IDR requests from the facility and necessary changes should be entered in the ASPEN system within 10 working days of the IDR or Independent IDR request 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 Guide.

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.

7500 - Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7500.1 - Introduction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

These procedures implement the regulatory requirements in 42 CFR 488.424 for imposing a directed plan of correction. A directed plan of correction is one of the category 1 remedies the State or regional office can select when it finds a facility out of compliance with Federal requirements.

7500.2 - Purpose
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

The purpose of the directed plan of correction is to achieve correction and continued compliance with Federal requirements. A directed plan of correction is a plan that the State or the regional office, or the temporary manager (with State or regional office approval), develops to require a facility to take action within specified time frames.

Achieving compliance is ultimately the facility's responsibility, whether or not a directed plan of correction is followed. If the facility fails to achieve substantial compliance after complying with the directed plan of correction, the State or regional office may impose another remedy until the facility achieves substantial compliance or is terminated from the Medicare or Medicaid programs.

7500.3 - Elements of a Directed Plan of Correction

A directed plan of correction should address all of the elements required for a facility-developed plan of correction. (See §7304)

7500.4 - Causes
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

Use of a directed plan of correction should be dependent upon causes identified by the State, regional office, or temporary manager. For example, a directed plan of correction may be appropriate when a facility's heating system fails. The directed plan of correction would specify that the heating system must be repaired or replaced within a specific time frame. If the cause of the noncompliance was a specific structural problem, the facility could be directed to implement identified structural repairs such as a new roof, or renovations such as replacement of rusted sinks in common bathrooms.

7500.5 - Notice of Imposition of Directed Plan of Correction
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

A directed plan of correction may be imposed 15 calendar days after the facility receives notice in non-immediate jeopardy situations and 2 calendar days after the facility receives notice in immediate jeopardy situations. The date the directed plan of correction is imposed does not mean that all corrections must be completed by that date.

Information Furnished to State's LTC Ombudsman

7904 - Information Furnished to State's Long Term Care Ombudsman
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

7904.1 -Information Given to Long Term Care Ombudsman
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

In accordance with §1819(g)(5)(B), §1919(g)(5)(B) of the Act, and 42 CFR 488.325(f), the State survey agency must provide the State's long-term care ombudsman with the following:

- A Statement of Deficiencies reflecting facility noncompliance and, if applicable, a separate list of isolated deficiencies that constitute no actual harm with the potential for minimal harm;
- Reports of adverse actions specified in 42 CFR 488.406 imposed on a facility;
- Any written response by the facility, including plans of correction and facility requests for informal dispute resolution; and
- A facility's request for an appeal and the results of any appeal.

7904.2 - Federal Surveys
(Rev. 63, Issued: 09-10-10, Effective: 09-10-10, Implementation: 09-10-10)

For Federal surveys, CMS will contact the State survey agency and provide the information needed for the State to notify the ombudsman on CMS's behalf.

§488.431
Civil Money Penalties Imposed by CMS and Independent Informal Dispute Resolution for SNFs, Dually Participating SNFs/NFs, and NF only Facilities

(a) *Opportunity for independent review.* CMS retains ultimate authority for the survey findings and imposition of civil money penalties, but provides an opportunity for independent informal dispute resolution within 30 days of notice of imposition of a civil money penalty that will be placed in escrow in accordance with paragraph (b) of this section. An independent informal dispute resolution will—

(1) Be completed within 60 days of facility's request if an independent informal dispute resolution is timely requested 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 dispute resolution process is not used, and which has no conflict of interest, such as:

(i) A component of an umbrella State agency provided that the component is organizationally separate from the State survey agency.

(ii) An independent entity with a specific understanding of Medicare and Medicaid program requirements selected by the State and approved by CMS.

(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.

(b) *Collection and placement in escrow account.*

(1) For both per day and per instance civil money penalties, CMS may collect and place the imposed civil money penalties in an escrow account on whichever of the following occurs first:

(i) The date on which the independent informal dispute resolution process is completed under paragraph (a) of this section.

(ii) The date that is 90 days after the date of the notice of imposition of the penalty.

(2) For collection and placement in escrow accounts of per day civil money penalties, CMS may collect the portion of the per day civil money penalty that has accrued up to the time of collection as specified in paragraph (b)(1) of this section. CMS may make additional collections periodically until the full amount is collected, except that the full balance must be collected once the facility achieves substantial compliance or is terminated from the program and CMS determines the final amount of the civil money penalty imposed.

(3) CMS may provide for an escrow payment schedule that differs from the collection times of paragraph (1) of this subsection in any case in which CMS determines that more time is necessary for deposit of the total civil money penalty into an escrow account, not to exceed 12 months, if CMS finds that immediate payment would create substantial and undue financial hardship on the facility.

(4) If the full civil money penalty is not placed in an escrow account within 30 calendar days from the date the provider receives notice of collection, or within 30 calendar days of any due date established pursuant to a hardship finding under paragraph (b)(3), CMS may deduct the amount of the civil money penalty from any sum then or later owed by CMS or the State to the facility in accordance with §488.442(c).

(5) For any civil money penalties that are not collected and placed into an escrow account under this section, CMS will collect such civil money penalties in the same manner as the State in accordance with §488.432.

(c) *Maintenance of escrowed funds.* CMS will maintain collected civil money penalties in an escrow account pending the resolution of any administrative appeal of the deficiency findings that comprise the basis for the civil monetary penalty imposition. CMS will retain the escrowed funds on an on-going basis and, upon a final administrative decision, will either return applicable funds in accordance with paragraph (d)(2) of this section or, in the case of an unsuccessful administrative appeal, will periodically disburse the funds to States or other entities in accordance with §488.433.

(d) *When a facility requests a hearing.*

(1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty as specified in §498.40 of this chapter.

(2) If the administrative law judge reverses deficiency findings that comprise the basis of a civil money penalty in whole or in part, the escrowed amounts continue to be held pending expiration of the time for CMS to appeal the decision or, where CMS does appeal, a Departmental Appeals Board decision affirming the reversal of the pertinent deficiency findings. Any collected civil money penalty amount owed to the facility based on a final administrative decision will be returned to the facility with applicable interest as specified in section 1878(f)(2) of the Act.

[*Source*: 76 FR 15126, Mar. 18, 2011]

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

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-29-NH

DATE: **May 6, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On May 8, 2020, CMS will publish an interim final rule with comment period.
- **COVID-19 Reporting Requirements**: CMS is requiring nursing homes to report COVID-19 facility data to the Centers for Disease Control and Prevention (CDC) and to residents, their representatives, and families of residents in facilities.
- **Enforcement:** Failure to report in accordance with 42 CFR §483.80(g) can result in an enforcement action.
- **Updated Survey Tools:** CMS has updated the COVID-19 Focused Survey for Nursing Homes, Entrance Conference Worksheet, COVID-19 Focused Survey Protocol, and Summary of the COVID-19 Focused Survey for Nursing Homes to reflect COVID-19 reporting requirements.
- **COVID-19 Tags**: F884 and F885.
- **Transparency:** CMS will begin posting data from the CDC National Healthcare Safety Network (NHSN) for viewing by facilities, stakeholders, or the general public. The COVID-19 public use file will be available on https://data.cms.gov/.

Background

On April 19, 2020, CMS released memo QSO-20-26, "Upcoming Requirements for Notification of Confirmed COVID-19 (or COVID-19 Persons under Investigation) Among Residents and Staff in Nursing Homes," summarizing new facility reporting requirements that would soon be released through rulemaking.

On May 8, 2020, CMS will publish an interim final rule with comment period, titled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of

Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program". The unpublished rule is available for public inspection at the Federal Register website (Agency Docket: CMS-5531-IFC and Regulation ID Number (RIN): 0938-AU32).

Prior to the COVID-19 PHE and this interim final rule, regulations at 42 CFR §483.80(a)(2)(ii), already required LTC facilities (i.e., skilled nursing facilities and/or nursing facilities) to have written standards, policies and procedures regarding infection control, to include when and to whom possible incidents of communicable disease or infections should be reported, such as to local/state health authorities. In an effort to support surveillance of COVID-19 cases and increase transparency for residents, their representatives, and families, we have added to the infection control requirements provisions to establish reporting for confirmed or suspected COVID-19 cases at new §483.80(g), as follows:

§ 483.80 Infection control.

(g) *COVID-19 Reporting*. The facility must—

(1) Electronically report information about COVID-19 in a standardized format specified by the Secretary. This report must include but is not limited to--

(i) Suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19;
(ii) Total deaths and COVID-19 deaths among residents and staff;
(iii) Personal protective equipment and hand hygiene supplies in the facility;
(iv) Ventilator capacity and supplies in the facility;
(v) Resident beds and census;
(vi) Access to COVID-19 testing while the resident is in the facility;
(vii) Staffing shortages; and
(viii) Other information specified by the Secretary.

(2) Provide the information specified in paragraph (g)(1) of this section at a frequency specified by the Secretary, but no less than weekly to the Centers for Disease Control and Prevention's National Healthcare Safety Network. This information will be posted publicly by CMS to support protecting the health and safety of residents, personnel, and the general public.

(3) Inform residents, their representatives, and families of those residing in facilities by 5 p.m. the next calendar day following the occurrence of either a single confirmed infection of COVID-19, or three or more residents or staff with new-onset of respiratory symptoms occurring within 72 hours of each other. This information must—

(i) Not include personally identifiable information;
(ii) Include information on mitigating actions implemented to prevent or reduce the risk of transmission, including if normal operations of the facility will be altered; and
(iii) Include any cumulative updates for residents, their representatives, and families at least weekly or by 5 p.m. the next calendar day following the subsequent occurrence of either: each time a confirmed infection of COVID-19 is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occur within 72 hours of each other.

We understand that state and local health departments may currently require nursing homes to report certain COVID-19 related information to them. A key difference between the state/local reporting and this new national reporting requirement is that reporting to state/local health departments allows them to understand the status of their local environment and intervene (e.g., direct staffing and supplies), whereas this national requirement provides standardized information to assist with national surveillance on the status of COVID-19 in all nursing homes. State and local health departments are also able to submit the required data on behalf of a nursing homes, although this does not relieve facilities of their accountability to report in accordance with the regulation.

Reporting COVID-19 Information to CDC's NHSN

The NHSN Long-Term Care Facility COVID-19 Module is available. Facilities should immediately gain access to the NHSN system and visit the home page for important information, including how to register: https://www.cdc.gov/nhsn/. The following provides an overview of the registration process:

Step 1 – Prepare your computer to interact with NHSN

You may need to change your email and internet security settings to receive communications from NHSN during the enrollment process

Step 2A – Register Facility with NHSN

The person who will serve as the NHSN Facility Administrator must access and read the NHSN Facility/Group Administrator Rules of Behavior from https://nhsn.cdc.gov/RegistrationForm/index

Step 2B – Register with SAMS (Security Access Management System)

After CDC receives your completed registration, you will receive an ***Invitation to Register with SAMS*** via email

Step 3 – Complete NHSN Enrollment

On the SAMS homepage, click the link to the NHSN labeled **NHSN Enrollment** and Complete Facility Contact Information

Step 4 – Electronically Accept the NHSN Agreement to Participate and Consent

After successfully completing enrollment, the NHSN Facility Administrator and Component Primary Contact (may be the same person) will receive an NHSN email with instructions on how to electronically accept the *NHSN Agreement to Participate and Consent*.

Please note: It is critical for facilities to ensure their CMS Certification Number (CCN) is entered correctly into the NHSN system, so CMS can confirm the facility has met the reporting requirement.

For NHSN questions, please email: NHSN@cdc.gov and add "LTCF" in the subject header.

Facilities must submit their first set of data by 11:59 p.m. Sunday, May 17, 2020. To be compliant with the new requirement, facilities must submit the data through the NHSN reporting system at least once every seven days. Facilities may choose to submit multiple times a week. CMS is not prescribing which day of the week the data must be submitted, although reporting should remain consistent with data being submitted on the same day(s) each week. The collection period should also remain consistent (e.g., Monday through Sunday). Each Monday,

CMS will review the data submitted to assess if each facility submitted data at least once in the previous seven days. The data pulled each Monday will also be used to update the data that is publicly reported.

Updates to the COVID-19 Focused Survey for Nursing Homes

CMS has updated the "COVID-19 Focused Survey for Nursing Homes," "Entrance Conference Worksheet," "COVID-19 Focused Survey Protocol," and "Summary of the COVID-19 Focused Survey for Nursing Homes" to include an updated assessment of the new requirements for facilities to report to the NHSN and to residents, their representatives, and their families. These updated forms are posted to the Survey Resources folder in the COVID-19 Focused Survey sub-folder on the CMS Nursing Homes website. Surveyors should begin using these revised documents immediately, and facilities should also begin using the revised "COVID-19 Focused Survey for Nursing Homes" to perform their self-assessment. The documents include the following new deficiency tags for citing noncompliance with the new requirements:

F884: COVID-19 Reporting to CDC as required at §483.80(g)(1)-(2)

Review for F884 will be conducted offsite by CMS Federal surveyors (state surveyors should not cite this F-tag). Following an initial reporting grace period granted to facilities, CMS will receive the CDC NHSN COVID-19 reported data and review for timely and complete reporting of all data elements. Facilities identified as not reporting will receive a deficiency citation at F884 on the CMS-2567 with a scope and severity level at an F (no actual harm with a potential for more than minimal harm that is not an Immediate Jeopardy [IJ] and that is widespread; this is a systemic failure with the potential to affect a large portion or all of the residents or employees), and be subject to an enforcement remedy imposed as described below.

F885: COVID-19 Reporting to Residents, their Representatives, and Families as required at §483.80(g)(3)(i)-(iii)

Review for F885 is included in the "COVID-19 Focused Survey Protocol" and will occur onsite by State and/or Federal surveyors. If the survey finds noncompliance with this requirement, a deficiency citation at this tag will be recorded on the CMS-2567 and enforcement actions will follow the memo QSO-20-20-All. We note that there are a variety of ways that facilities can meet this requirement, such as informing families and representatives through email listservs, website postings, paper notification, and/or recorded telephone messages. We do not expect facilities to make individual telephone calls to each resident's family or responsible party to inform them that a resident in the facility has laboratory-confirmed COVID-19. However, we expect facilities to take reasonable efforts to make it easy for residents, their representatives, and families to obtain the information facilities are required to provide.

In addition, when the State Survey Agency is planning to conduct these surveys, the COVID-19 Focused Survey should be coded in the Automated Survey Process Environment (ASPEN) under "Survey Type" as U=COVID-19. If the survey is taking place with an IJ complaint investigation, the survey should be coded in ASPEN under "Survey Type" as A=complaint and U=COVID-19. This will help ensure consistent, accurate reporting.

Enforcement for F884

A determination that a facility failed to comply with the requirement to report COVID-19 related information to the CDC pursuant to §483.80(g)(1)-(2) (tag F884) will result in an enforcement action. These regulations require a minimum of weekly reporting, and noncompliance with this requirement will receive a deficiency citation and result in a civil money penalty (CMP) imposition.

CMS will provide facilities with an initial two-week grace period to begin reporting cases in the NHSN system (which ends at 11:59 p.m. on May 24, 2020). Facilities that fail to begin reporting after the third week (by 11:59 p.m. on May 31st) will receive a warning letter reminding them to begin reporting the required information to CDC. For facilities that have not started reporting in the NHSN system by 11:59 p.m. on June 7th, ending the fourth week of reporting, CMS will impose a per day (PD) CMP of $1,000 for one day for the failure to report that week. For each subsequent week that the facility fails to submit the required report, the noncompliance will result in an additional one-day PD CMP imposed at an amount increased by $500. For example, if a facility fails to report in week four (following the two week grace period and receipt of the warning letter), it will be imposed a $1,000 one-day PD CMP for that week. If it fails to report again in week five, the noncompliance will lead to the imposition of another one-day PD CMP in the amount of $1,500 for that failure to report (for a CMP total of $2,500). In this example, if the facility complies with the reporting requirements and submits the required report in week six, but then subsequently fails to report as required in week seven, a one-day PD CMP amount of $2,000 will be imposed (which is $500 more than the last imposed PD CMP amount) for a total of $4,500 imposed CMPs.

For enforcement-related questions, please email: DNH_Enforcement@cms.hhs.gov

Posting Facility-Level COVID-19 Data

Reporting COVID-19 data supports CMS's responsibility to protect and ensure the health and safety of residents and is necessary to ensure the appropriate tracking, response, and mitigation of the spread and impact of COVID-19 on our most vulnerable citizens, personnel who care for them, and the general public. The information provided may be used to inform residents, families, and communities of the status of COVID-19 infections in their area. We believe that this action strengthens CMS's response to the COVID-19 pandemic, and reaffirms our commitment to transparency and protecting the health and safety of nursing home residents. CMS anticipates publicly posting CDC's NHSN data (including facility names, number of COVID-19 suspected and confirmed cases, deaths, and other data as determined appropriate) weekly on https://data.cms.gov/ by the end of May.

Contact: For questions or concerns regarding this memo, please contact DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Branch training coordinators immediately.

/s/
David R. Wright

Attachments:
COVID-19 Focused Survey for Nursing Homes
Long-term Care Facility Notification Frequently Asked Questions

cc: Survey & Operations Group (SOG) Management

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

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-31-All

DATE: **June 1, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: COVID-19 Survey Activities, CARES Act Funding, Enhanced Enforcement for Infection Control deficiencies, and Quality Improvement Activities in Nursing Homes

Memorandum Summary

- ***CMS is committed*** *to taking critical steps to protect vulnerable Americans to ensure America's health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).*
- ***CMS has implemented*** *a new COVID-19 reporting requirement for nursing homes and is partnering with CDC's robust federal disease surveillance system to quickly identify problem areas and inform future infection control actions.*
- ***Following the March 6, 2020 survey prioritization,*** *CMS has relied on State Survey Agencies to perform Focused Infection Control surveys of nursing homes across the country. We are now initiating a performance-based funding requirement tied to the Coronavirus Aid, Relief and Economic Security (CARES) Act supplemental grants for State Survey Agencies. Further, we are providing guidance for the limited resumption of routine survey activities.*
- ***CMS is also enhancing the penalties for noncompliance*** *with infection control to provide greater accountability and consequence for failures to meet these basic requirements. This action follows the agency's prior focus on equipping facilities with the tools they needed to ensure compliance, including 12 nursing home guidance documents, technical assistance webinars, weekly calls with nursing homes, and many other outreach efforts. The enhanced enforcement actions are more significant for nursing homes with a history of past infection control deficiencies, or that cause actual harm to residents or Immediate Jeopardy.*
- ***Quality Improvement Organizations*** *have been strategically refocused to assist nursing homes in combating COVID-19 through such efforts as education and training, creating action plans based on infection control problem areas and recommending steps to establish a strong infection control and surveillance program.*

Background

The coronavirus presents a unique challenge for nursing homes. Therefore, CMS is using every tool at our disposal to protect our nation's most vulnerable citizens and aid the facilities that care for them. Since the pandemic began, CMS, in coordination with the Centers for Disease Control and Prevention (CDC), has provided ongoing technical guidance and assistance to all Medicare and Medicaid certified providers and suppliers, including nursing homes. Nursing homes have been ground zero for COVID-19. As the data from our required COVID-19 reporting from nursing homes indicates, additional immediate action is necessary to safeguard the health and safety of residents.

Further, to complement our technical assistance efforts, States and CMS have completed Focused Infection Control surveys in approximately 53% of the nation's nursing homes. We are calling on States to ensure that all Medicare and Medicaid certified nursing homes receive this onsite, targeted review and access to the new CARES Act funding will be tied to a state's progress on completing these surveys.

Guidance

Focused Infection Control Nursing Home Surveys and CARES Act Supplemental Funding

Currently, States receive over $397 million to perform oversight surveys and certification of Medicare and Medicaid certified providers and suppliers.

On March 4, 2020, CMS called for States to focus surveys on infection control and on March 23, 2020 provided a streamlined tool to facilitate these efforts. There is currently wide variation in the number of Focused Infection Control surveys of nursing homes performed by States, between 11%-100% (with a national average of approximately 54.1%). Based on the COVID-19 nursing home data being reported to the CDC, CMS believes further direction is needed to prioritize completion of focused infection control surveys in nursing homes.

Therefore, States that have not completed 100% of their focused infection control nursing home surveys by July 31, 2020 will be required to submit a corrective action plan to their CMS location outlining the strategy for completion of these surveys within 30 days. If, after the 30-day period, States have still not achieved surveys in 100% of their nursing homes, their CARES Act FY2021 allocation may be reduced by up to10%. Subsequent 30-day extensions could result in an additional reductions up to 5%. These funds would then be redistributed to those States that completed 100% of their focused infection control surveys by July 31.

Access to FY 2020 CARES Act allocations will be based on the following:

- All States may request FY 2020 CARES Act supplemental funding, up to their FY 2020 proportional allocation cap.
- States that have completed 100% of their nursing home focused infection control surveys will be able to request their entire FY 2020-FY2023 CARES ACT funding allocation (at their discretion) and can also apply for redistributed funding from States that failed to meet performance goals.

COVID-19 Survey Activities

In addition to completing the Focused Infection Control surveys of nursing homes, CMS is also requiring States to implement the following COVID-19 survey activities:

1. Perform on-site surveys (*within 30 days of this memo)* of nursing homes with previous COVID-19 outbreaks, defined as:
    - Cumulative confirmed cases/bed capacity at 10% or greater; **or**
    - Cumulative confirmed plus suspected cases/bed capacity at 20% or greater; **or**
    - Ten or more deaths reported due to COVID-19.
2. Perform on-site surveys (*within three to five days of identification*) of any nursing home with 3 or more new COVID-19 suspected and confirmed cases in the since the last National Healthcare Safety Network (NHSN) COVID-19 report, **or** 1 confirmed resident case in a facility that was previously COVID-free. State Survey Agencies are encouraged to communicate with their State Healthcare Associated Infection coordinators prior to initiating these surveys.
3. Starting in FY 2021, perform annual Focused Infection Control surveys of 20 percent of nursing homes based on State discretion or additional data that identifies facility and community risks.

States that fail to perform these survey activities timely and completely could forfeit up to 5% of their CARES Act Allocation, annually.

Additional COVID Activities

CARES Act funds may also be used for State-specific interventions (such as Strike Teams, enhanced surveillance, or monitoring of nursing homes). In addition, in August 2020, State Survey Agency priorities may also be informed by recommendations from the *Coronavirus Commission for Safety and Quality in Nursing Homes*.

Expanded Survey Activities

Finally, to transition States to more routine oversight and survey activities, once a state has entered Phase 3 of the Nursing Homes Re-opening guidance (https://www.cms.gov/files/document/nursing-home-reopening-recommendations-state-and-local-officials.pdf), or earlier, at the state's discretion, States are authorized to expand beyond the current survey prioritization (Immediate Jeopardy, Focused Infection Control, and Initial Certification surveys) to perform (**for all provider and supplier types**):

- Complaint investigations that are triaged as Non-Immediate Jeopardy-High
- Revisit surveys of any facility with removed Immediate Jeopardy (but still out of compliance),
- Special Focus Facility and Special Focus Facility Candidate recertification surveys, and
- Nursing home and Intermediate Care Facility for individuals with Intellectual Disability (ICF/IID) recertification surveys that are greater than 15 months.

When determining the order in which to schedule more routine surveys, States should prioritize providers based on those with a history of noncompliance, or allegations of noncompliance, with the below items:

- Abuse or neglect;
- Infection control;
- Violations of transfer or discharge requirements;
- Insufficient staffing or competency; or
- Other quality of care issues (e.g., falls, pressure ulcers, etc.).

Accrediting organizations may resume normal survey activities based on state reopening criteria. Any variations from the approved reaccreditation survey process must receive CMS-approval prior to implementation

Enhanced Enforcement for Infection Control Deficiencies

While CMS infection control deficiencies have been an ongoing compliance concern, the COVID-19 pandemic highlights the imperative that nursing home staff adhere to these fundamental health and safety protocols. Due to the heightened threat to resident health and safety for even low-level, isolated infection control citations (such as proper hand-washing and use of personal protective equipment (PPE), CMS is expanding enforcement to improve accountability and sustained compliance with these crucial practices. In addition to enhanced enforcement, CMS is also providing Directed Plans of Correction, including use of Root Cause Analysis, to facilitate lasting systemic changes within facilities to drive sustained compliance.

Therefore, substantial non-compliance (D or above) with any deficiency associated with Infection Control requirements will lead to the following enforcement remedies:

- Non-compliance for an Infection Control deficiency when none have been cited in the last year (or on the last standard survey):
    - Nursing homes cited for current non-compliance that is not widespread (Level D & E) - *Directed Plan of Correction*
    - Nursing homes cited for current non-compliance with infection control requirements that is widespread (Level F) - *Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **45**-days to demonstrate compliance with Infection Control deficiencies.*

- Non-compliance for Infection Control Deficiencies cited once in the last year (or last standard survey):
    - Nursing Homes cited for current non-compliance with infection control requirements that is not widespread (Level D & E) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **45**-days to demonstrate compliance with Infection Control deficiencies, Per Instance Civil Monetary Penalty (CMP) up to $5000 (at State/CMS discretion)*
    - Nursing Homes cited for current non-compliance with infection control requirements that is widespread (Level F) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **45**-days to*

demonstrate compliance with Infection Control deficiencies, $10,000 Per Instance CMP

- Non-compliance that has been cited for Infection Control Deficiencies twice or more in the last two years (or twice since second to last standard survey)
    - Nursing homes cited for current non-compliance with Infection Control requirements that is not widespread (Level D & E) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions, **30**-days to demonstrate compliance with Infection Control deficiencies, $15,000 Per Instance CMP (or per day CMP may be imposed, as long as the total amount exceeds $15,000)*
    - Nursing homes cited for current non-compliance with Infection Control requirements that is widespread (Level F) -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions, **30**-days to demonstrate compliance with Infection Control deficiencies, $20,000 Per Instance CMP (or per day CMP may be imposed, as long as the total amount exceeds $20,000)*

- Nursing Homes cited for current non-compliance with Infection Control Deficiencies at the Harm Level (Level G, H, I), regardless of past history -*Directed Plan of Correction, Discretionary Denial of Payment for New Admissions with **30** days to demonstrate compliance with Infection Control deficiencies.* Enforcement imposed by CMS Location per current policy, but CMP imposed at highest amount option within the appropriate (non-Immediate Jeopardy) range in the CMP analytic tool.

- Nursing Homes cited for current non-compliance with Infection Control Deficiencies at the Immediate Jeopardy Level (Level J, K, L) regardless of past history –In addition to the mandatory remedies of Temporary Manager or Termination, *imposition of Directed Plan of Correction, Discretionary Denial of Payment for New Admissions, **15**-days to demonstrate compliance with Infection Control deficiencies.* Enforcement imposed by CMS Location per current policy, but CMP imposed at highest amount option within the appropriate (IJ) range in the CMP analytic tool.

Quality Improvement Organization Support

While we have taken these important actions at a regulatory level, we have also strategically refocused the approach of the Quality Improvement Organizations (QIO) to assist in combating COVID-19 within these facilities.

In November 2019, CMS took a major step toward improving quality for Medicare beneficiaries in nursing homes as well as rural and underserved communities by awarding contracts to 12 experienced, community-based organizations to serve as QIOs and focus on areas of immediate need as well as urgent healthcare priorities. With varying degrees of intensity, QIOs provide education and training to every nursing home in the country. All nursing homes across the country can take advantage of weekly National Infection Control Training that focuses on all aspects of infection control, prevention and management to help nursing homes prevent the transmission of COVID-19 in facilities and keep residents safe. Additionally, as part of their ongoing work, the

QIOs provide more direct assistance to around 6000 small, rural nursing homes and those serving vulnerable populations in areas where access to care is limited with helping them understand and comply with CMS and CDC reporting requirements, sharing best practices related to infection control, testing and patient transfers.

Lastly, the QIOs are being deployed to provide technical assistance to nursing homes, which includes a targeted focus on approximately 3,000 low performing nursing homes who have a history of infection control challenges. Further, States may request QIO technical assistance specifically targeted to nursing homes that have experienced an outbreak. These requests should be sent to Anita Monteiro, Acting Director of the iQuality Improvement and Innovation Group at CMS: anita.monteiro@cms.hhs.gov. The QIOs help nursing homes identify what their greatest areas of infection control problems are, then create an action plan, and implement specific steps to establish a strong infection control and surveillance program in the nursing home. For instance, they train staff on proper use of personal protective equipment (PPE), cohorting residents appropriately and transferring residents safely. They monitor compliance with infection control standards and practices in the nursing home.

Nursing homes can locate the QIO responsible for their state here: http://www.qioprogram.org/locate-your-qio.

Contact

Questions about this memorandum should be addressed to DNH_Enforcement@cms.hhs.gov.

Effective Date

Effective immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately. This guidance will cease to be in effect when the Secretary determines there is no longer a Public Health Emergency due to COVID-19. At that time, CMS will send public notice that this guidance has ceased to be effective via its website.

/s/
David R. Wright

cc: Survey and Operations Group Management

Handout #5

Independent IDR Case History
ABC Nursing and Rehabilitation Center v. CMS

This is a **factual** hearing request. The name was **changed** to protect the identity of the facility.

DECISION

The request for hearing of Petitioner, ABC Nursing and Rehabilitation Center, LLC, is dismissed pursuant to 42 C.F.R. § 498.70(c).1 Petitioner's request for hearing was not timely filed and Petitioner has not shown good cause to extend the time for filing the request for hearing.

I. Background and Facts

The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated September 13, 2017, that a survey of Petitioner's facility completed on August 11, 2017, found Petitioner was not in substantial compliance with program participation requirements. CMS advised Petitioner regarding mandatory termination if Petitioner did not return to substantial compliance within six months of the end of the survey. CMS also advised Petitioner that it was imposing a discretionary denial of payments for new admissions effective September 28, 2017, and a per instance civil money penalty of $12,005. CMS advised Petitioner that it had the right to request informal dispute resolution (**IDR**) or independent IDR (**IIDR**). CMS Exhibit (Ex.) 8 at 1-2. The CMS notice stated:

> **Please note, furthermore, that an incomplete IDR or Independent IDR process will not delay any deadline listed below under "Appeal Rights" for requesting a hearing, or for requesting a waiver of hearing rights.**

CMS Ex. 8 at 3 (emphasis in original). The CMS notice advised Petitioner that, if it disagreed with the enforcement remedies imposed, Petitioner could request a hearing before an administrative law judge (ALJ). CMS advised that a request for hearing must be filed no later than 60 days from receipt of the CMS notice. CMS Ex. 8 at 3.

Petitioner filed its request for hearing (RFH) by delivering it to the United Parcel Service (UPS) on April 23, 2018. Petitioner requested that the time for filing the request for hearing be extended. RFH at 2-3.

Petitioner's request for hearing was docketed and assigned to me on May 4, 2018. I issued an Acknowledgement and Prehearing Order on May 4, 2018 (Prehearing Order). Paragraph II.D.1 of the Prehearing Order required that any motion to dismiss for untimely filing of the request for hearing be filed not later than June 4, 2018. On August 2, 2018, CMS filed a motion to dismiss Petitioner's request for hearing on grounds it was not timely filed (CMS Motion).2 Petitioner filed a response in opposition to the motion to dismiss on August 21, 2018 (P. Response).3

II. Issues, Conclusions of Law, and Discussion

A. Issues

Whether good cause exists to extend the time for filing the request for hearing in this case; and

Whether the request for hearing should be dismissed because it was untimely filed.

B. Applicable Law

A provider or supplier notified of an initial, reconsidered, or reopened and revised decision that results in an enforcement remedy has the right to request a hearing by ALJ in accordance with the procedures set forth at 42 C.F.R. pt. 498. 42 C.F.R. §§ 488.408(g), 498.3(b)(13), and 498.5(b). The regulations are clear regarding the requirements for timely filing a request for hearing:

> The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended . . . .

42 C.F.R. § 498.40(a)(2). The 60-day period runs from the date of receipt by the affected party, which is presumed to be five days after the date of the notice, unless it is shown that the notice was received earlier or later. 42 C.F.R. §§ 498.40(a)(2) and 498.22(b)(3).

I have the discretion to extend the period for filing a request for hearing if the petitioner files a "written request for extension of time stating the reasons why the request was not filed timely," and I find good cause for the late filing is shown. 42 C.F.R. § 498.40(c). Although the legislative history for 42 C.F.R. § 498.40 is not helpful in understanding the application of these regulatory provisions in this case, the requirement for timely filing a written request for hearing is commonly viewed as the means by which administrative finality can be achieved, i.e., if there is no deadline for filing and an affected party may file at any time, the record on an action may never be closed.

I may dismiss an untimely request for hearing, if I do not grant an extension of the time to file. 42 C.F.R. § 498.70(c).

C. Conclusions of Law and Analysis

My conclusions of law are set forth in bold followed by my findings of fact and discussion.

1. **Petitioner failed to file its request for hearing within the 60-day period provided by the regulation. 42 C.F.R. § 498.40(a)(2).**
2. **Petitioner has not shown good cause to extend the period for filing its request for hearing by 157 days. 42 C.F.R. § 498.40(c).**
3. **Dismissal of Petitioner's request for hearing pursuant to 42 C.F.R. § 498.70(c) is appropriate.**

The CMS notice of initial determination in this case is dated September 13, 2017. CMS Ex. 8. Pursuant to 42 C.F.R. §§ 498.40(a)(2) and 498.22(b)(3), it is presumed that Petitioner received the CMS notice on September 18, 2017.

Petitioner had 60 days from receipt of the CMS notice to file its request for hearing. Therefore, Petitioner had until Friday, November 17, 2017, to file its request for hearing. Petitioner did not file its request for hearing until it was delivered to UPS on April 23, 2018. Petitioner missed the

deadline for filing its request for hearing by 157 days and there is no dispute that Petitioner's request for hearing was filed late.

I am granted discretion by 42 C.F.R. § 498.70(c) to dismiss a request for hearing that is not timely filed and for which the time for filing has not been extended. Therefore, dismissal is permitted in this case if I determine not to extend the period for filing the request for hearing by 157 days.

Pursuant to 42 C.F.R. § 498.40(c)(2), I may only extend the period for filing a request for hearing for good cause. Petitioner urges me to find good cause in this case but I conclude good cause for an extension has not been shown under any reasonable definition of the term.

The regulations do not define the term "good cause." Furthermore, the Departmental Appeals Board (Board) has never provided a precise or complete definition of "good cause." *West Side House LTC Facility*, DAB No. 2791 at 6 (2017) (citing *Rutland Nursing Home*, DAB No. 2582 at 5 (2014)). Relevant Board decisions turn on evaluation of the facts and determination on a case-by-case basis whether the facts fit within any reasonable definition of good cause. *See, e.g.*, *West Side*; *Rutland*; *Nursing Inn of Menlo Park*, DAB No. 1812 (2002); *Cary Health & Rehab. Ctr.*, DAB No. 1771 at 27 (2001). Various appellate panels of the Board have commented that the IDR or IIDR process established by 42 C.F.R. § 488.331 does not toll the federal administrative appeal process because it is a separate procedure in addition to the appeal rights provided to facilities under federal regulations. The Board noted in *Cary*, "[i]f approaching the deadline for termination to go into effect and/or choosing to participate in an IDR process were sufficient to excuse the failure to file a timely request for a federal hearing, the time frame for such appeals would become almost meaningless." *Cary* at 29.

Petitioner argues good cause exists because:

- Petitioner timely requested IIDR;
- The IIDR decision was not issued until December 20, 2017 (more than a month after the 60-day period for requesting a hearing had expired);
- The IIDR decision was partially favorable to Petitioner;
- CMS did not respond to the IIDR recommendation until February 27, 2018; and
- The CMS response to the IIDR was partially favorable to Petitioner but CMS failed to issue a revised notice of initial determination to reflect the impact of the IIDR.

RFH at 2-3; P. Response at 2-3. Petitioner admits that a pending IIDR is not good cause for extending the period for requesting a hearing. The regulation is clear that failure of the state or CMS to complete IDR or IIDR timely cannot delay the effective date of enforcement actions and Petitioner may not seek to delay enforcement action on grounds that IDR or IIDR was not completed before the effective date of the enforcement action. 42 C.F.R. § 488.331(b). Petitioner asserts, however, that it was CMS' failure to timely respond to the IIDR recommendation and issue a reopened and revised initial determination that constitutes good cause. Petitioner argues, without citation to any authority, that CMS must issue a reopened and revised determination if CMS accepts a recommendation of IDR or IIDR, even if the enforcement remedy is unchanged. I find no authority that imposes such a due process requirement on CMS and conclude Petitioner's argument is meritless. Furthermore, Petitioner's argument must fail because the 60-day period for requesting a hearing actually expired more than 30 days before issuance of the IIDR recommendation. Therefore, when the time to request a hearing expired, Petitioner had no idea

that the IIDR recommendation would be favorable, and Petitioner had no reason to think CMS might take favorable action.

I conclude that Petitioner's election to invoke the IIDR process does not constitute good cause for extending the time for Petitioner to file its request for hearing. Petitioner provides no acceptable explanation for why it did not simultaneously file both its request for IIDR and a request for hearing. Accordingly, Petitioner's request for extension is denied. Petitioner's request for hearing was filed 157 days late and no extension has been granted. I conclude that exercising my discretion to permit this case to proceed is not appropriate. Accordingly, the request for hearing is dismissed.

III. Conclusion

For the foregoing reasons, Petitioner's request for hearing is dismissed.

/s/

Keith W. Sickendick
Administrative Law Judge

Footnotes

1. References are to the 2016 revision of the Code of Federal Regulations (C.F.R.), unless otherwise indicated.
2. The CMS Motion was not filed timely pursuant to my Prehearing Order. The purpose for requiring the parties to file motions to dismiss shortly after the issuance of the Prehearing Order is to permit resolution of the motion quickly and potentially avoid the parties incurring unnecessary litigation expenses associated with making prehearing exchanges. CMS failed to comply with the Prehearing Order and both parties incurred unnecessary litigation expenses in this case. Counsel for CMS is cautioned that they must comply with ALJ orders or face potential sanctions. However, in this case, resources have been wasted and further sanctioning CMS will not remedy that waste.
3. CMS filed CMS Exs. 1 through 28 and Petitioner filed Petitioner Exs. 1 through 3 in preparation for hearing on the merits. Only CMS Ex. 8, to which Petitioner has made no objection, is admitted and considered for purposes of this decision.

Handout #6

Confidential QAPI/QAA Program Work Document

SAMPLE Independent IDR (IIDR) Preliminary Worksheet

Important Reminder: Request for an Independent IDR must be submitted within **ten (10) calendar days** of the **receipt** of the offer from CMS

Date CMS Offer Received: 07/15/2020 **Date Independent IDR Materials Due**: 07/25/2020

Purpose: This worksheet has been designed to be used solely as a tool to gather preliminary information relative to your dispute of a regulatory citation. It is not intended to replace any specific form your State may require when submitting an Independent IDR request or supporting evidence. The Independent IDR process allows you to challenge cited deficiencies for each survey in which a civil money penalty (CMP) has been imposed and will be collected and placed in an escrow account [see §488.331; §488.431; §7213]. Use this worksheet to prepare your supporting claim and documentation. Complete a worksheet for each tag you are disputing. Use additional sheets as necessary. Upon completion of this worksheet, you can then make your determination on whether or not to proceed with Independent IDR and what supporting evidence you wish to submit.

Disputed Data From: [X] Current Survey [ ] Revisit Survey [ ] Complaint Survey [ ] IDR Decision

Disputed Tag Number

Federal/State Tag	Which Survey Tag on the 2567 are You Disputing?	CMP Imposed	Scope & Severity Level Cited	Identify the Regulatory Reference Number for the Disputed Tag	Regulatory Grouping	Regulatory Description	What Facts and/or Findings are You Disputing?
Federal Tag	F583	$3,500	F	483.10(h)(1)	Resident Rights	Privacy & Confidentiality	Failure to provide privacy while providing personal care.

- Are you challenging the **S/S Level** of this citation? [ ] Yes [X] No [**Note**: S/S may only be challenged **if** the cited deficiency **constitutes** substandard quality of care or immediate jeopardy (§7213.4)].
- Is there an **ongoing IDR process** for any of the disputed **federal tags** you are including in this **IIDR** request? [ ] Yes [X] No. (**Note**: An **IIDR** request **replaces** an **IDR** in progress for disputed federal tags).
- **Important Note**: Survey findings that have been subject to an IDR are **not** eligible for an IIDR, **UNLESS** the IDR was completed **PRIOR** to the imposition of the CMP (§7213.3.5).

Survey Facts and/or Findings

Which Element of the Regulation Are You Disputing?	What Facts and/or Findings from the Statement of Deficiencies Are You Disputing?	Why Are You Disputing This Fact and/or Finding?	What, if any, documents are you using to support your dispute?	
			Document / Exhibit ID #	Identify the document and the reason you are using this document for dispute of the citation.
The resident has the right to personal privacy and confidentiality of his or her personal and clinical records. (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;…	Based on observation, interview and record review the facility failed to provide full visual privacy while providing **personal care** to two of 16 sampled residents. (Resident #2 and Resident #15). The resident census was 88.	Both residents reside in private rooms that include private bath and shower facilities. Showers were given in the residents' private bathroom and visual privacy was not compromised during the procedure. In accordance with facility policy, the bathroom door does not have to be closed if the room door is closed. The room entrance door was closed. The surveyor did not ask for or review the facility's policy and procedure governing showers.	**#1** **#2** **#3**	**Facility Policy & Procedure regarding Showers**. Note that paragraph 3 describes bathing the resident in his/her private bath which contains a shower. Facility policy does not require the bathroom door to be closed **if** the room door is closed. The caregiver did not shut the bathroom door during the shower given to Resident 2 or Resident 15 *because* the room entrance door was closed. The only persons in the room during the procedure were the resident, the caregiver, and the surveyor. **Caregiver's Statement:** Note that the caregiver's statement indicates she provided showers to both residents in accordance with the facility's policy and procedure and that the Surveyor did not comment on her leaving the bathroom door open nor did the Surveyor ask to see the facility's policy governing showers. **Care Plans:** Note the highlighted portion of each resident's care plan which specifically indicates a personal choice of receiving a shower in their respective rooms.

Is there sufficient evidence to support the dispute of this tag citation? [X] Yes [ ] No **Proceed to Independent IDR [X] Yes [ ] No**

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Independent IDR (IIDR) Preliminary Worksheet

Important Reminder: Request for an Independent IDR must be submitted within **ten (10) calendar days** of the **receipt** of the offer from CMS

Date CMS Offer Received: _____ **Date Independent IDR Materials Due**: _____

Purpose: This worksheet has been designed to be used solely as a tool to gather preliminary information relative to your **dispute** of a regulatory citation. It is not intended to replace any specific form your State may require when submitting an Independent IDR request or supporting evidence. The Independent IDR process allows you to challenge cited deficiencies for each survey in which a civil money penalty (CMP) has been imposed and will be collected and placed in an escrow account [see §488.331; §488.431; §7213]. Use this worksheet to prepare your supporting claim and documentation. Complete a worksheet for each tag you are disputing. Use additional sheets as necessary. Upon completion of this worksheet, you can then make your determination on whether or not to proceed with Independent IDR and what supporting evidence you wish to submit.

Disputed Data From: [ ] Current Survey [ ] Revisit Survey [ ] Complaint Survey [ ] IDR Decision

Disputed Tag Number

Federal/State Tag	Which Survey Tag on the 2567 are You Disputing?	CMP Imposed	Scope & Severity Level Cited	Identify the Regulatory Reference Number for the Disputed Tag	Regulatory Grouping	Regulatory Description	What Facts and/or Findings are You Disputing?
Federal Tag							

- Are you challenging the **S/S Level** of this citation? [ ] Yes [ ] No [**Note**: S/S may only be challenged **if** the cited deficiency **constitutes** substandard quality of care or immediate jeopardy (§7213.4)].
- Is there an **ongoing IDR process** for any of the disputed **federal tags** you are including in this **IIDR** request? [ ] Yes [ ] No. (**Note**: An **IIDR** request **replaces** an **IDR** in progress for disputed federal tags).
- **Important Note**: Survey findings that have been subject to an IDR are **not** eligible for an IIDR, **UNLESS** the IDR was completed **PRIOR** to the imposition of the CMP (§7213.3.5).

Survey Facts and/or Findings

Which Element of the Regulation Are You Disputing?	What Facts and/or Findings from the Statement of Deficiencies Are You Disputing?	Why Are You Disputing This Fact and/or Finding?	What, if any, documents are you using to support your dispute?	
			Document / Exhibit ID #	Identify the document and the reason you are using this document for dispute of the citation.

Is there sufficient evidence to support the dispute of this tag citation? [ ] Yes [ ] No **Proceed to Independent IDR [ ] Yes [ ] No**

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Inservice Training Program

Revisiting the Independent IDR Process

And Its Impact on COVID-19 Reporting and the New Infection Control Enforcement Actions

Part 3

Recordkeeping Documents

Provided Courtesy of

TEAMTSI

Revisiting the IIDR Process

And Its Impact on COVID-19 Reporting and the New Infection Control Enforcement Actions

Part 3 – Recordkeeping Documents

Table of Contents

Click on Description Title to Advance to Recordkeeping Form

Record of In-Service Training Session

The Independent Informal Dispute Resolution (IIDR) Process

Date of Training Session: _____

Time Started: _____ (am / pm)

Instructor(s): _____

Personnel Attending: See Attached *"Session Attendance Record*

Purpose of Training Session:

To provide our facility's survey management team with information relative to the Independent Informal Dispute Resolution Process (IIDR).

Method of Presentation – Provide a brief summary of how the session was presented (e.g., lecture, self-study, PowerPoint presentation, handouts provided, etc.).

Participant Participation – Provide a brief summary of how participants participated. (e.g., Q & A session, review of §7213, §7500, §7904, and 42 CFR §488.431 regulatory requirements, facility policies, etc.):

Critical Analysis (List any recommendations/suggestions you believe would be beneficial for future presentation of this topic):

Comparative Analysis (Was there an improvement in staff's knowledge of the Independent IDR process after completing the training session? If yes, what process was used to measure staff's improvement?

Time Adjourned: (am / pm)

Signature of Instructor(s): _____

_____

_____

In-Service Training Session – Record of Attendance

The Independent Informal Dispute Resolution (IIDR) Process

Date Session Conducted: _____ Time Started: _____ [am/pm] Time Ended: _____ [am/pm]

Location: _____

Instructor(s): _____

Personnel Attending

Signature	Printed Name	License Number [as required]	Job Position

Use additional sheets as necessary. Be sure this document is attached to the Record of Training Session.

In-Service Training Session – Participant Evaluation Form

Independent Informal Dispute Resolution (IIDR) Process

Date:		**Instructor(s):**	

Please indicate with a check (√) mark your level of agreement with the following statements:

Statement	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. The objectives of the training session were clearly defined.					
2. The instructor(s) were knowledgeable about the topics.					
3. Attendee participation and interaction were encouraged.					
4. The topics covered were relevant.					
5. The content was organized and easy to follow.					
6. The materials (handouts) were helpful.					
7. The instructor(s) were well prepared.					
8. The training objectives were met.					
9. The time allotted for the session was sufficient.					
10. The meeting room was clean and comfortable.					
11. The training session will be useful in my work.					

What did you like MOST about this training session?

What did you like LEAST about this training session?

What aspects of the training session could be improved?

What information would you like to see added?

Please share additional comments or information here:

CERTIFICATE of COMPLETION

THIS ACKNOWLEDGES THAT

_____

ATTENDED AND SUCCESSFULLY COMPLETED OUR FACILITY'S

Independent Informal Dispute Resolution (IIDR) Process

In-Service Training Program

On the _____ day of _____, 20____

_____

Signature/Title - Instructor