

Regulatory Roundup

Weekly Webinar for Long-Term Care Professionals

(🏠) IHCA.org/regulatory-roundup

PRESENTERS

Lori Davenport Indiana Health Care Association

Team Members from Indiana Department of Health

October 3, 2024



Today's Agenda

(A) IHCA.org/regulatory-roundup

- Upcoming IDOH Leadership Conference Suzanne Williams – IDOH
- Access to Medical Records Jordan Stover IDOH
- Updated CMS Memos ABN Updated and Voting Brenda Buroker - IDOH
- Mandatory Provider Enrollment Off-Cycle Revalidation for All SNFs, MDS 1.19.1 -- Lori Davenport - IHCA
- Clinical Updates Guy Crowder, MD., MPHTM, Chief Medical Officer - IDOH

Upcoming Education



- Oct 9, webinar: Substance Use Disorders
- Oct 15, webinar: <u>Documentation for ADL Care</u>, <u>Declines & Restorative Nursing</u>
- · Oct 16, webinar: Behavior Management Programs
- Oct 24-25, in-person: <u>LSC Bootcamp</u>
- Oct 29-30, in-person: SNF DON Workshop
- Oct 28-Nov 14, in-person : Activities Director certification course
- Dec 5, in-person: Assisted Living Symposium

Questions? Email kniehoff@ihca.org

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Mandatory Provider Enrollment Off-Cycle Revalidation for All SNFs



- CMS made an announcement in the MLN Connects newsletter
 - All skilled nursing facility will receive off-cycle provider enrollment revalidation notices from their Medicare Administration Contractor (MAC)
 - Additional data requested on the following
 - 1. Ownership
 - 2. Managerial
 - 3. Related party information
 - Information to be submitted in a new Appendix on the Form CMS 855A (9/24) version

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What You Need To Know

- A letter from your MAC sometime between October through December 2024 regarding a mandatory off-cycle revalidation.
- You will have 90 days from the date of the letter to respond and submit the newly required information into the Medicare Provider Enrollment, Chain and Ownership Systems (PECOS) system to keep your provider enrollment status active.
- The additional request of information is complex and affects every SNF, regardless of size or ownership characteristics.

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What You Need To Know

- SNF providers no longer report in Sections 5 and 6 of the provider enrollment from, but now in a new SNF-specific appendix.
- The Instructions for the new SNF Appendix are a handout today and can be found here.
- List of IHCP Provider Enrollment Type and Specialty Matrix https://www.in.gov/medicaid/providers/files/matrix.pdf
- Link to download Due dates through December

https://www.in.gov/medicaid/providers/provider-enrollment/maintaining-your-ihcp-provider-enrollment/provider-enrollment-revalidation/

What You Need To Know

- In addition to SNF revalidation timeline discussed above, the new Form CMS-855A must be used for all the following provider enrollment transactions effective October 1, 2024:
 - a. Initial Enrollment
 - b. Revalidations
 - c. Reactivations
 - d. CHOW

Note: if the status of any SNF transaction for a-d above prior to October 1 is "pending" in PECOS as of October 1, the MAC will request the new Appendix be completed by the SNF provider.

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To Do List

- Review the new Form CMS-855A and the Guidance (handout and link to guidance provided today)
- CMS and AHCA/NCAL suggests providers seek counsel from an attorney to help interpret the new SNF reporting requirements.
- · Start compiling the information ASAP
- · Be on the lookout for your letter from your MAC
- AHCA webinar will be announced

Note: Notices are mailed to the mail-to address indicated on the provider's service location profile.

MDS 2024 Changes

- Changes to the MDS went into effect this week on Oct 1.
- This year's changes are small compared to last October.
- Appendix B of the RAI User's Manual is available

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MDS 1.19.1 Changes

- Section GG: Self-care and Mobility Now exclude the discharge goal column in the 5-day Medicare MDS
- Section O: Immunizations Updated to include items for gathering information on the resident's COVID vaccination status.
- Section N: High-Risk Medications and Indication for Use Includes an item for collecting information on the use of anticonvulsant medications

Next Regulatory Roundups

- November 7th Guest Speaker Behaviors/Dementia Care
- November 14th Guest Speaker Life Safety Update

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Q & A



CLINICAL UPDATES

GUY CROWDER, M.D., MPHTMCHIEF MEDICAL OFFICER

10/3/2024

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OUR MISSION:

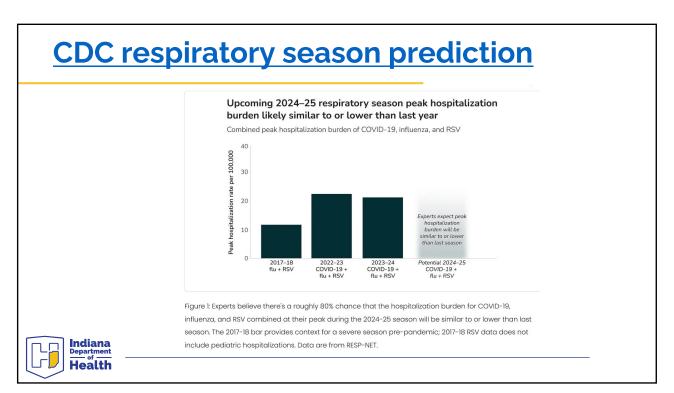
To promote, protect, and improve the health and safety of all Hoosiers.

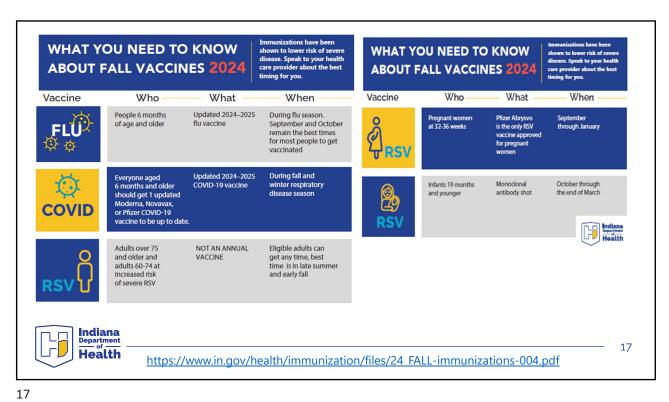
OUR VISION:

Every Hoosier reaches optimal health regardless of where they live, learn, work, or play.









RSV maternal vaccine and infant monoclonal antibody <u>recommendations</u> from CDC

Infants and young children

 To prevent severe RSV disease in infants, CDC recommends either maternal RSV vaccination or infant immunization with RSV monoclonal antibodies. Most infants will not need both.

Vaccination for pregnant women

• 1 dose of maternal RSV vaccine during weeks 32 through 36 of pregnancy, administered **September through January.** Pfizer Abrysvo is the only RSV vaccine recommended during pregnancy.

Immunization for infants and young children (monoclonal antibodies)

- 1 dose of nirsevimab is recommended for infants <u>younger than 8 months of age</u> who were born shortly before or are entering their first RSV season (**typically October through March**)
- •1 dose of nirsevimab for infants and children aged 8–19 months who are at increased risk for severe RSV disease and entering their second RSV season.
- Note: A different monoclonal antibody, palivizumab, is limited to children aged 24 months and younger with certain conditions that place them at high risk for severe RSV disease. It must be given once a month during RSV season.



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Older Adult RSV Recommendation

- ACIP recommends adults 75 years and older receive a single dose of RSV vaccine
 - Removes shared clinical decision-making language
 - Includes the new Moderna RSV vaccine
- ACIP recommends adults 60-74 who are at increased risk of severe RSV disease receive a single dose of RSV vaccine
 - Shared clinical decision-making recommendation versus a riskbased recommendation
 - Adults that have already received a dose of RSV do not need to receive another dose in the 2024-25 season



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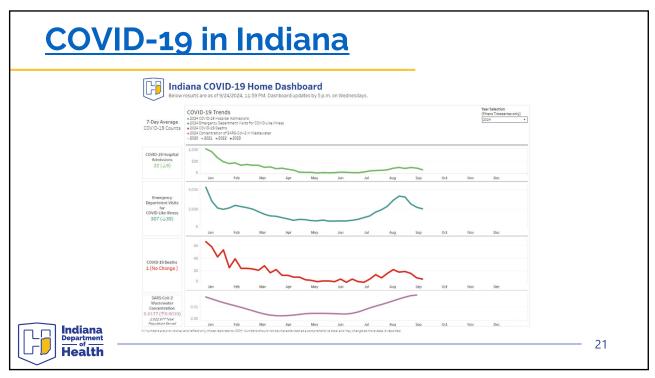
RSV vaccine effectiveness for adults

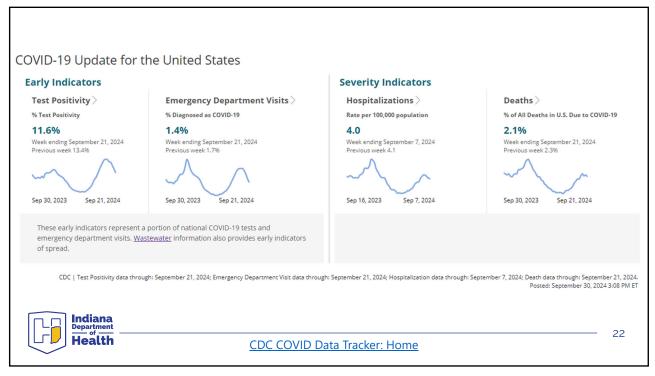
- GSK Arexvy
 - 77% prevention of ED visits, 83% preventing hospitalization
- Pfizer Abrysvo
 - 79% prevention of ED visits, 73% preventing hospitalization
- Moderna mResvia
 - Real world effectiveness not yet evaluated
 - Study efficacy against symptomatic RSV infection approximately 80% in first 4 months, 56% in first 12 months

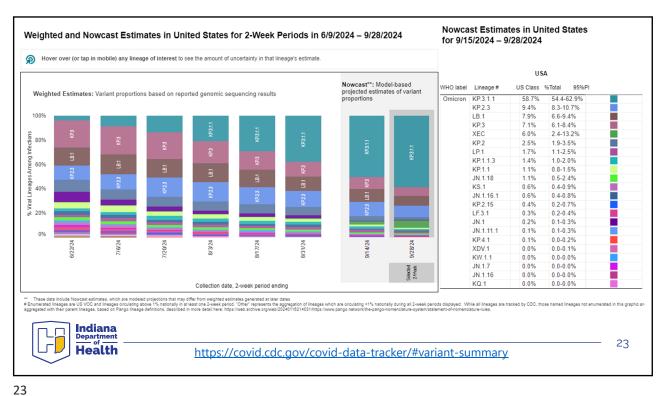


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CDC RSV vaccine clinical guidance







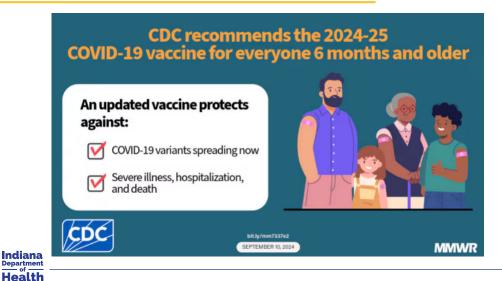
COVID-19 Recommendation

- ACIP recommends 2024-2025 COVID-19 formulation for individuals 6 months of age and older
- **COVID-19 Hospitalizations**
 - 50% of hospitalized children and adolescents have no underlying conditions
 - 2/3 of all COVID-19 associated hospitalizations are in adults 65+
 - 19% of adults 65+ who were hospitalized were residents of a longterm care facility
- **COVID-19 Vaccine Effectiveness**
 - 53% effective against symptomatic infections in adults
 - 66-71% effective against ED/UC visits among children 9 mo -17 yrs



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FDA Approves updated COVID-19 vaccines

- Based on KP.2
- Monovalent

FDA Approves and Authorizes Updated mRNA COVID-19 Vaccines to Better Protect

Against Currently Circulating Variants

Unvaccinated individuals 6 months through 4 years of age are eligible to receive three doses of the updated, authorized Pfizer-BioNTech COVID-19 Vaccine or two doses of the updated, authorized Moderna COVID-19 Vaccine.

Individuals 6 months through 4 years of age who have previously been vaccinated against COVID-19 are eligible to receive one or two doses of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines (timing and number of doses to administer depends on the previous COVID-19 vaccine received).

Individuals 5 years through 11 years of age regardless of previous vaccination are eligible to receive a single dose of the updated, authorized Moderna or Pfizer-BioNTech COVID-19 vaccines; if previously vaccinated, the dose is administered at least 2 months after the last dose of any COVID-19 vaccine.

Individuals 12 years of age and older are eligible to receive a single dose of the updated, approved Comirnaty or the updated, approved Spikevax; if previously vaccinated, the dose is administered at least 2 months since the last dose of any COVID-19 vaccine.

Additional doses are authorized for certain immunocompromised individuals ages 6 months through 11 years of age as described in the Moderna COVID-19 Vaccine and Pfizer-BioNTech COVID-19 Vaccine fact sheets.



 $\frac{https://www.fda.gov/news-events/press-announcements/fda-approves-and-authorizes-updated-mrna-covid-19-vaccines-better-protect-against-currently#:~:text=The%20updated%20mRNA%20COVID%2D19.through%2011%20years%20of%20age.$

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FDA Approves Novavax COVID-19 vaccine

FDA NEWS RELEASE

JN.1

Emergency Use Authorization

FDA Authorizes Updated Novavax COVID-19 Vaccine to Better Protect Against Currently Circulating Variants

What You Need to Know

- Individuals 12 years of age and older who have never been vaccinated with any COVID-19 vaccine are eligible to receive two doses of this updated vaccine, 3 weeks apart.
- Individuals who have been vaccinated only with one dose of any Novavax COVID-19 vaccine are
 eligible to receive one dose of the updated Novavax COVID-19 vaccine at least 3 weeks after the
 previous dose.
- Those who have been vaccinated with a prior formula of a COVID-19 vaccine from another manufacturer or with two or more doses of a prior formula of the Novavax COVID-19 vaccine are eligible to receive a single dose of the updated Novavax COVID-19 vaccine at least 2 months after the last dose of a COVID-19 vaccine.



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<u>Updated CDC COVID vaccine recommendations</u>

Ages 12 years and older

COVID-19 vaccination history ⁵	2024–2025 vaccine	Number of 2024–2025 doses indicated	Dosage (mL/ug)	Interval between doses	1 dose any Novavax	Novavax	1	0.5 mL/5 ug rS	Dose 2: 3–8 week
Unvaccinated	Moderna 1 0.5 mL/50 ug — OR			,			protein and 50 ug Matrix-M		
	Novavax	2	0.5 mL/5 ug rS protein and 50 ug Matrix-M		2 or more doses any Novavax, NOT including 1 dose any 2024–2025 COVID-19 vaccine	Moderna	1	adjuvant 0.5 mL/50 ug	At least 8 weeks
	adjuvant OR					OR			
	Pfizer- BioNTech	1	0.3 mL/30 ug	-		Novavax	1	0.5 mL/5 ug rS protein and 50 ug Matrix-M	At least 8 weeks after last dose
1 or more doses any mRNA, NOT including 1 dose any 2024–2025 COVID-19 vaccine	Moderna	1	0.5 mL/50 ug	At least 8 weeks after last dose				adjuvant	
	OR					OR			
	Novavax		0.5 mL/5 ug rS protein and 50 ug	At least 8 weeks after last dose		Pfizer- BioNTech	1	0.3 mL/30 ug	At least 8 weeks after last dose
				vant	2 or more doses any Novavax, INCLUDING 1		No further doses indicated		
	OR				dose any 2024–2025 COVID-19 vaccine				
	Pfizer- BioNTech	1	0.3 mL/30 ug	At least 8 weeks					



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Order Your 4 Free At-home COVID-19 Tests

Every U.S. household is eligible to order 4 free at-home tests.

Need help placing an order for your at-home tests? Call <u>1-800-232-0233</u> (TTY <u>1-888-720-7489</u>).

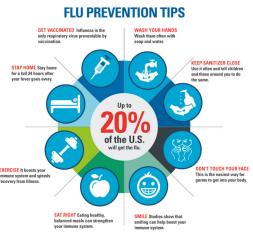
https://covidtests.gov/

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Indiana Department of Health

Seasonal Influenza Vaccine



- ACIP affirmed the recommendation for a routine annual influenza vaccination for individuals 6 months and older who do not have contraindications
- No shortages or delays in shipment expected
- Trivalent, no quadrivalent
 - A (H3N2, H1N1) and B
 - No B/Yamagata

Indiana Department Health

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FluMist now available for self or caregiver administration

FDA NEWS RELEASE

FDA Approves Nasal Spray Influenza Vaccine for Self- or Caregiver-Administration

First Influenza Vaccine That Does Not Need to be Administered by a Health Care Provider





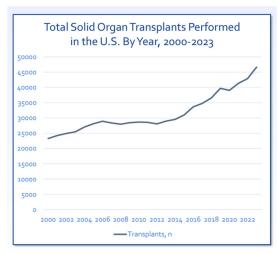
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High Dose/Adjuvanted Flu Vaccines for Solid Organ Transplant Recipients Recommendation

- New recommendation for high dose or adjuvanted flu vaccines for solid organ transplant in adults 18+
 - Previously only approved for 65+

Link to review of studies



Indiana Department Health

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CDC Study - Early Flu Antiviral Treatment Decreases Risk of Death

- FluSurv-NET 2012 2019
- Delayed initiation of antiviral treatment in patients hospitalized with influenza-associated pneumonia was associated with higher risk of death
- 30-day mortality7.5% Day 08.5% Day 1

o 10.2% - Days 2-5

CDC Link









Timing of Influenza Antiviral Therapy and Risk of Death in Adults Hospitalized With Influenza-Associated Pneumonia, Influenza Hospitalization Surveillance Network (FluSurv-NET), 2012–2019

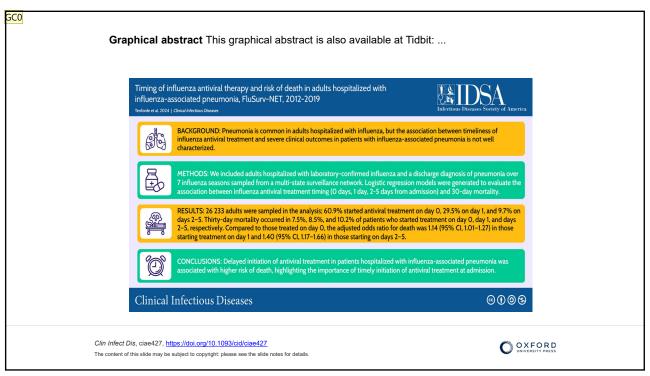
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"Influence Dissipation Control for Control



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GC0 [@Sanderson, Greta] [@Hawkins, Eric]

This slide was downloadable from the article in the previous slide. Never used an outside slide on one of these that I can remember since I started? Thoughts? I suppose we could use the graphic and put the link in. I really like the graphic. Crowder, Guy R, 2024-09-26T01:04:16.461

Increase in Mycoplasma pneumoniae

Indiana Health Alert Network Notification

Respiratory Season Updates and Recommendations



October 2, 2024

Increase in Mycoplasma pneumoniae reported among Indiana children

The Indiana Department of Health (IDOH) has received reports of increases in pediatric pneumonia cases, including those caused by *Mycoplasma pneumoniae*. This uptick has been also observed across various regions in the United States, particularly affecting young children.

- M. pneumoniae usually peaks every 3 to 7 years, with variation of strain types contributing to this pattern.
- M. pneumoniae infections began increasing in Indiana in late spring/early summer 2024, including emergency department visits across all pediatric ages.



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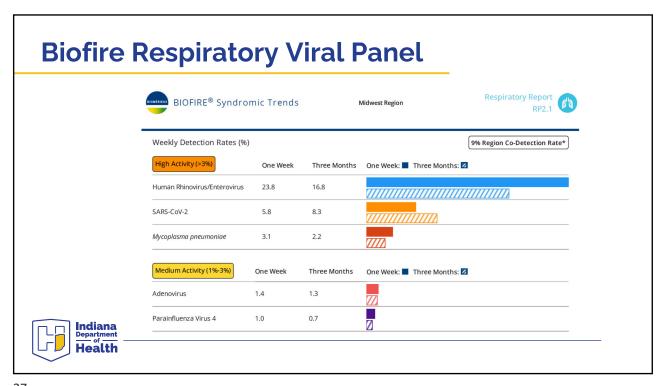
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Mycoplasma IHAN

Recommendations:

- Healthcare providers should have increased suspicion of M. pneumoniae among patients presenting with compatible symptoms or clinical presentations, including pneumonia.
 - o Children younger than 5 years of age may have a milder, subclinical illness that does not result in pneumonia
 - Complications can include asthma exacerbation, severe pneumonia, hemolytic anemia, renal dysfunction, mycoplasma induced rash and mucositis, and others.
- Diagnosis is often clinical. However, testing can be molecular (RVP), if available, or serology (IgM). Serologic testing for *M. pneumoniae* can have false positives but with the increase in cases, if pre-test probability is high, it is likely accurate.
- The preferred treatment is with macrolides, including azithromycin. Other treatment options include tetracyclines and fluoroquinolones. Mycoplasma pneumoniae does not respond to beta-lactams and should also be considered in the differential for a patient failing this therapy.
 - o Macrolide resistance is expected to be low (<10%) in Indiana, despite higher rates in other geographic areas. Reported cases have been responsive.
- Reporting: Cases of *M. pneumoniae* are not reportable however outbreaks or unusual clusters of *M. pneumoniae* should be reported to your local health department or to the IDOH Infectious Disease Epidemiology and Prevention Division at 317-233-7125.
- Prevention: Emphasize the importance of good respiratory hygiene and infection control practices to patients and their families to help prevent the spread of respiratory infections.





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Resources about Mp

- 1. CDC *Mycoplasma pneumoniae* Infection Surveillance and Trends https://www.cdc.gov/mycoplasma/php/surveillance/index.html
- 2. Clinical Care of *Mycoplasma pneumoniae* Infection https://www.cdc.gov/mycoplasma/hcp/clinical-care/index.html
- 3. Laboratory Testing for *Mycoplasma pneumoniae* https://www.cdc.gov/mycoplasma/php/laboratories/index.html
- 4. Submitting Specimens for *Mycoplasma pneumoniae* Testing https://www.cdc.gov/mycoplasma/php/laboratories/specimen-packing.html
- 5. MMWR (Notes from the Field): Reemergence of *Mycoplasma pneumoniae* Infections in Children and Adolescents After the COVID-19 Pandemic, United States, 2018-2024 https://www.cdc.gov/mmwr/volumes/73/wr/mm7307a3.htm?scid=mm7307a3 w



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GUIDANCE FOR SNF ATTACHMENT ON FORM CMS-855A

September 24, 2024

I. BACKGROUND

A. Introduction

Like other providers and suppliers, SNFs have long been required under section 1124(a) of the Social Security Act (the Act) to disclose various ownership and managerial information. This data has been reported in Sections 5 and 6 of the Form CMS-855A and is outlined in sections 10.6.7.1 and 10.6.7.2 of chapter 10 of Pub. 100-08.

On November 17, 2023, CMS published in the Federal Register a final rule titled, "Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities; Medicare Providers' and Suppliers' Disclosure of Private Equity Companies and Real Estate Investment Trusts" (88 FR 80141). This final rule implements parts of section 1124(c) of the Act. Section 1124(c) requires SNFs to disclose detailed information about their ownership and management as well as additional data regarding: (1) other parties with which the SNF is associated; and (2) the ownership structures of these other parties. Although some of the data required under section 1124(c) is already disclosed per section 1124(a), some of it is not and will therefore be newly reported. The new SNF Attachment of the Form CMS-855A therefore collects: (1) all SNF data previously disclosed in Sections 5 and 6 of the Form CMS-855A; <u>and</u> (2) additional information that section 1124(c) requires. SNFs will no longer complete Sections 5 and 6 of the Form CMS-855A.

The revised Form CMS-855A with the SNF Attachment can be found at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/enrollment-applications. (Please scroll down the page to CMS-855A link.)

The guidance in this document (including the interpretation of certain definitions and concepts) applies **only** to SNFs. It is inapplicable to all other provider and supplier types that complete the Form CMS-855A.

B. Form CMS-855A

The Form CMS-855A has been revised to collect the SNF data addressed in this guidance. It will become effective on October 1, 2024. Beginning on that date, all SNFs that are initially enrolling, revalidating, reactivating, or undergoing a change of ownership under § 489.18 must submit this version of the Form CMS-855A (i.e., the 09/24 version) with the SNF attachment completed. SNFs submitting a change of information (COI) must also use this version, though the SNF Attachment will not have to be completed in full at that time. (For example, if the SNF on October 5 is reporting a new managing employee, he/she will be disclosed on the Attachment

(rather than in Section 6). However, the SNF need not report all its current owners, managers, related parties, etc. on the Attachment in its COI submission.)

Use of the 09/24 version will also be required for initial, revalidation, reactivation, and CHOW applications that: (1) were submitted using the 09/23 prior version of the Form CMS-855A; and (2) are pending with the Medicare Administrative Contractor (MAC) or the state agency as of October 1. ("Pending" in this context means the MAC has received the application but has not yet finalized it.) For these applications --- and depending on the stage of processing the application is in --- the MAC will notify the SNF to complete and submit the SNF Attachment. CMS will ensure that SNFs that are required to submit the Attachment for such pending applications are exempt from the off-cycle SNF revalidation process (commencing in October 2024) so they do not have to submit the Attachment twice within a short period.

II. STATUTORILY REQUIRED DATA

A. Section 1124(a)/Currently Required Data

Sections 10.6.7.1 and 10.6.7.2 outline the ownership/managerial information that must currently be reported per section 1124(a) of the Act. This data is still required (though now via the SNF Attachment).

B. Section 1124(c) Data

1. Data Required Per Section 1124(c)

Section 1124(c) (which was implemented via 42 CFR § 424.516(g)) requires SNFs to disclose the following information. (Note, again, that some of this data duplicates data that was already required under section 1124(a)):

- Each member of the SNF's governing body.
- Each person or entity who is an officer, director, member, partner, trustee, or managing employee (as defined in § 424.502) of the SNF.
- Each person or entity who is an additional disclosable party (ADP) of the SNF.
- The organizational structure of each ADP of the SNF and a description of the relationship of each ADP to the facility and to one another.

2. Definitions

Section 1124(c) contains the following definitions (which have been incorporated into § 424.502) of some of the above terminology:

(i) Additional Disclosable Party: Any person or entity who:

- Exercises operational, financial, or managerial control over the SNF or a part thereof, or provides policies or procedures for any of the SNF's operations, or provides financial or cash management services to the SNF;
- Leases or subleases real property to the SNF, or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property; or
- Provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility.
- (ii) <u>Managing Employee</u> An individual (including a general manager, business manager, administrator, director, or consultant) who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the SNF. (Note that "indirect" situations typically involve a person or entity managing, advising, or supervising the SNF through another party (e.g., a president who has little day-to-day involvement with the SNF but manages the facility via her employees).
- (iii) Organizational Structure Organizational structure means:
 - For corporations The corporation's officers, directors, and 5 percent or greater shareholders
 - For limited liability companies (LLCs) The LLC's members and managers (including, as applicable, the percentage of ownership each member and manager has in the LLC)
 - For general partnerships The partners in the general partnership
 - For limited partnerships The general partners as well as any limited partners who own at least 10 percent of the limited partnership.
 - For trusts The trustees of the trust

III. EXPLANATION OF NEW DATA TO BE FURNISHED

Given the foregoing, the new or additional categories of data that SNFs will have to report --- **above and beyond what is currently required** --- are generally as follows:

- **A.** All Governing Body Members SNFs that are corporations must currently disclose all members of their board of directors. SNFs must now report all members of their governing body irrespective of their business type (e.g., LLC, corporation, etc.). For example, a SNF that is a partnership or LLC must report all their governing body's members. This applies: (1) to forprofit and non-profit entities; and (2) regardless of the body's specific title (e.g., "governing board," "leadership council"). (See § 424.516(g)(1)(i).)
- **B.** All Owners of an LLC If the SNF is an LLC, all individual and organizational owners of the LLC must be reported <u>regardless of their percentage of ownership</u>. (Previously, when only section 1124(a) applied, there was a 5 percent threshold for LLCs. Now, with the addition of 1124(c), all LLC owners must be reported.) (See § 424.516(g)(1)(ii).)

- C. All Trustees of the SNF if the SNF is Established as a Trust The trustee can be a person or entity. Note that the trustee's beneficiaries need not be reported unless they qualify for disclosure under another category (e.g., managing employee). (See § 424.516(g)(1)(ii).)
- **D.** All ADPs This includes all parties described in the ADP definition above, such as persons and entities that:
 - (i) Provide policies or procedures for <u>any</u> of the SNF's operations
 - (ii) Exercise financial control over the SNF or any part thereof
 - (iii) Provide financial or cash management services to the SNF
 - (iv) Lease or sublease real property to the SNF
 - (v) Own a 5 percent or greater interest in the total value of the SNF's real property

(NOTE: Items (iv) and (v) differ from the current requirement in section 1124(a)(3)(A)(ii) to report a 5 percent or greater ownership interest in any mortgage, deed of trust, note, or other obligation wholly or partly secured by the provider or any property or assets thereof. Section 1124(a)(3)(A)(ii) deals with mortgages and securities; Items (iv) and (v) focus on the leasing and actual ownership of real property).

(vi) Provide management or administrative services, management or clinical consulting services, or accounting or financial services to the SNF

E. Persons/Entities Within the ADP

For each ADP, the SNF must also report the following persons/entities:

- (i) If the ADP is a corporation:
 - The officers and directors of the ADP; or
 - Any person or entity with a 5 percent or greater direct or indirect ownership interest in the ADP

(The terms "officer" and "director" have the same meaning as that in § 424.502.)

- (ii) If the ADP is an LLC:
 - Any person or entity that manages the LLC; or
 - Any person or entity that has a direct or indirect ownership interest in the LLC, regardless of the percentage.

(For purposes of this requirement, the term "manages" has the same general meaning as "managing employee" and "managing organization" in § 424.502.)

- (iii) If the ADP is a general partnership, all persons and entities with a partnership/ownership interest in the ADP, regardless of the percentage.
- (iv) If the ADP is a limited partnership:

- All persons and entities with a general partnership/ownership interest the ADP, regardless of the percentage.
- All persons and entities with a limited partnership interest in the ADP of at least 10 percent.
- (v) If the ADP is a trust, the trustees of the trust.

IV. EXAMPLES

A. Introduction

Sections (II) and (III) above identified the parties that must be reported pursuant to section 1124(c). This subsection (IV) lists several examples of these parties; they are grouped by the specific section 1124(c) disclosure category/term (e.g., cash management services).

Note that:

- The parties listed within each example do not represent a minimum threshold of influence for required disclosure. That is, if a chief executive officer (CEO) is cited as an example of a reportable party, this does not mean that a person with less influence within an organization than a CEO need not be reported. The CEO is merely cited as an illustration.
- Certain persons and entities may fall within multiple required categories of disclosure. For instance, a company the SNF hires to run its operations could involve managing control, management services, operational control, accounting services, etc.
- It is unnecessary for a party to have an ownership interest in the SNF to qualify for disclosure. A person/entity can have, for example, operational control without being an owner of the SNF.
- It does not matter whether the disclosable party is an employee, an independent contractor, or even a volunteer. Moreover, an individual's specific occupational title is not solely determinative as to whether he/she must be reported. It is the nature of the service, function, ownership, oversight, etc., that is pertinent, not the party's employment/contractual status.
- There is no minimum threshold for disclosure in terms of: (1) the length of time the party must have furnished the services, served on an ADP's governing board, etc.; (2) the degree and extent of involvement with the SNF's day-to-day operations; and (3) the volume of the furnished services, functions, etc. As an illustration, it is unnecessary for a person's dealings with the SNF to be equivalent to at least 0.33 full-time employees (FTEs) to qualify for disclosure. Even if certain services were furnished for only a very brief period, by a temporary employee, and only one time (rather than, for example, for three-month periods every 18 months), disclosure is required. Likewise, suppose the party helped establish clinical policies. The assistance need not have involved <u>all</u> the SNF's clinical policies for all aspects of its operations. If it only pertained to a portion

(even a small one) of the facility's entire clinical policies, this is sufficient to require disclosure.

• We respectfully note that CMS in its various guidance will be unable to address all conceivable factual scenarios within and among organizations or to individually identify every potential disclosable party and associated occupational title (e.g., whether individuals X and Y – who perform Functions A and B for the SNF, furnish Services C and D to the SNF, or have Relationships E and F — must be reported). This is because there could be hundreds of such scenarios given the vast variety of organizational structures, relationships, personnel functions, services, occupations, etc. If the SNF is uncertain as to whether a certain party must be reported, it should disclose said party. As we stated in the November 17, 2023, final rule: "In general, this rule should be construed towards disclosure and, if in doubt about whether additional information should be released, SNFs should disclose it." (88 FR 80142).

We recommend that SNFs contact their legal counsel or other professional advisor (e.g., provider enrollment business advisor) with questions regarding whether specific persons or entities within their organization should be disclosed.

B. Categories of Potentially Disclosable Parties

- 1. Examples of Each ADP Category
- (i) <u>Accounting Services</u> Can include an accountant or accounting company the SNF hires/contracts with to perform <u>any</u> accounting activity (e.g., preparation of cost reports) for the SNF. (This can include in-house and outside auditors the SNF hires). The person need not be a Certified Public Accountant to qualify for disclosure. It is the provision of the accounting service itself, rather than the professional status or title of the party furnishing it, that is determinative.
- (ii) <u>Administrative Services</u> Can involve services such as, but not limited to, compliance/oversight, human resources, public relations/outreach/advertising, technical assistance to the SNF's main information system, etc. (This category does <u>not</u> include custodial, building security, and similar services.)
- (iii) <u>Cash Management Services</u> Can include parties that give guidance/advice on cash flow and other financial matters; handling the SNF's financial transactions, such as ACH payments and mobile banking; etc. (To reiterate, this short list is not exhaustive. There are many types of services that could fall within the category of cash management.)
- (iv) <u>Clinical Consulting Services</u> Can involve assessing or advising how to improve or modify any aspect of the SNF's provision of health care. (Note that the person/entity need not have a medical license or have the formal title of "clinical consultant" or "clinical consulting" firm to qualify for disclosure. It is the <u>type</u> of service involved (not the person's title or medical certification) that is critical.)

- (v) <u>Financial Control</u> Can include monitoring or managing the SNF's finances; authority to approve the expenditure of SNF funds; an owning organization of the SNF that funds part of the SNF's operations; banks that have given the SNF a line of credit; etc.
- (vi) <u>Financial Services</u> Can include investment banking, investment management, asset management, financial advice, accounting, etc.
- (vii) Managerial Control Includes parties falling within the definition of "managing employee" or "managing organization" in § 424.502, such as: (1) supervisors; or (2) non-supervisors who nonetheless oversee and are responsible for any aspect of the SNF's operations, including management/oversight of matters such as maintenance. (Number (2), however, does not mean every SNF employee who is responsible for any action in the SNF's organization (e.g., nurse, administrative assistant) need be reported. There must be some degree of broader oversight and decision-making authority involved.)
- (viii) <u>Management Services</u> Includes parties that furnish to the SNF the services described in (vii) above under contract or other arrangement with the SNF (e.g., management company).
- (ix) Operational Control Includes persons/entities that oversee and have responsibility for any aspect of the SNF's daily activities or transactions (e.g., person in charge of the SNF's (1) medical records, (2) patient activities, or (3) dietary/food operations). The person need not serve in a supervisory role to have operational control.
- (x) "Part" of the Facility Includes any physical or operational portion of the facility (e.g., a separate wing of the facility; social worker unit; nursing unit).
- (xi) <u>Policies or Procedures</u> Includes persons/entities responsible for developing or furnishing guidelines regarding the execution of any aspect of the SNF's operations (e.g., consultant hired to prepare emergency/evacuation plans, patient treatment procedures, patient transfer procedures, etc.)

Note that legal services furnished by attorneys do not typically fall within any of the above categories. However, if an attorney provides services or exercises control that are/is not legal in nature but otherwise come(s) within one of the categories above, the SNF must disclose him/her in that role(s) (e.g., an attorney furnishes administrative services that are outside of his/her legal practice and unrelated to any attorney-client relationship).

V. SNF ATTACHMENT DATA ELEMENTS & SNF REPORTING RESPONSIBILITIES

The SNF must complete the applicable sections of the Attachment – which is divided into two parts: Organizations and Individuals -- for <u>all</u> parties that must be reported. For instance, suppose the SNF must disclose 10 individuals and 7 organizations on the Attachment. The Organizations section of the Attachment must be completed 7 times, once for each organization; the Individuals section must be completed 10 times, once for each person.

Sections (V)(A) and (B) outline the data elements in the Organizations and Individuals sections of the Attachment.

A. Organizations

1. Section A – Identifying Data

The Section A data duplicates that in Section 5 of the Form CMS-855A. CMS reiterates that the entity reported in Section A could be one that has long been required to be reported under section 1124(a) (e.g., 5 percent owner, managing organization) or an entity that section 1124(c) now mandates be reported (e.g., an ADP, a lessor).

2. Section B – Type of Organization

The Section B data, too, mirrors that in Section 5 of the Form CMS-855A. Note that SNFs, like Section 5 entities, will now need to answer the following question: "Is this organization the ultimate parent company in a multi-organizational group of entities?" The SNF must check "Yes" or "No" for each entity listed in Section A.

3. Section C – Chain Home Offices Only

Section C only applies if the SNF itself is part of a chain. It does not apply to entities listed in Section A of the Attachment. To illustrate, assume a SNF is a chain member and reports 8 entities in Section A of the Organizations section. The SNF need only furnish Section C data once (that is, for its own status as a chain provider) and can leave Section C blank for 7 of the 8 organizations reported in Section A.

4. Section D – Questions 1-5 (Direct Ownership of SNF)

These questions ask the SNF whether the entity listed in Section A (hereafter occasionally referenced as Section A Entity (SAE)) has a direct ownership interest in the SNF. The SNF need only respond to the question that pertains to the $\underline{\text{SNF's}}$ business type (rather than the SAE's business type). As an example, if the SNF is a corporation and the SAE is a limited partnership, it need only answer Question 1 and can disregard Questions 2-5 (i.e., it need not check "No" to Questions 2-5). If the SNF is a limited partnership, it must answer Question 4 but not Questions 1, 2, 3, and 5.

Question 5 would include, for example, SNFs that are government agencies and sole proprietorships.

For SAEs for which the SNF checks "Yes," the SNF must report the effective date and exact percentage of ownership.

The total reported combined direct ownership for all reported SAEs cannot be more than 100 percent.

5. Section D – Questions 6 and 7 (Indirect Ownership of SNF)

The SNF need only respond to the question that pertains to the SNF's business type. It need not indicate "No" for the other question.

For SAEs for which the SNF checks "Yes," the SNF must report the effective date and exact percentage of ownership.

6. Section D – Question 8 (Mortgage and Security Interest)

This is not a new Form CMS-855A data element for SNFs. SNFs have long been required to provide this information on the Form CMS-855A.

If the SNF checks "Yes," it must furnish the effective date and percentage of the interest. It must also disclose whether it is a mortgage or a security interest.

7. Section D – Question 9 (Trustees)

If the SNF checks "Yes," it must furnish the effective date of the trusteeship.

8. Section D – Question 10 (Control and Parts of SNF)

Question 10 applies regardless of the SNF's business type. If the SNF checks "Yes", it must address the "Operational," "Managerial," and "Financial" data elements. If it answers "Yes" to any of these three, it must:

- (i) List the effective date of the SAE's control (i.e., when it began)
- (ii) List the type(s) of control, such as the type(s) of managing control.
- (iii) List the parts of the SNF over which the SAE exercises control (e.g., billing department). If the SAE exercises control over the SNF's entire organization, the SNF can state "All parts" (or something similar) in the applicable box.

If an SAE exercises multiple types of control and/or different parts of the SNF are involved, the SNF must differentiate between them when responding to (i), (ii), and (iii). For instance, if operational and financial control are involved, the SNF must identify <u>and clearly distinguish</u> the types and parts in the same box (i.e., describe the forms of financial control, which parts they pertain to, the types of managerial control, etc.)

Note that the SNF need not furnish a lengthy, minutely detailed outline of every sub-category of control the SAE exercises or of every individual sector/part of the organization. The SNF need only provide sufficient data such that CMS can ascertain the SAE's forms of control and the SNF parts involved.

9. Section D – Question 11 (Services Furnished)

Question 11 applies regardless of the SNF's business type. If the SNF checks "Yes", it must address the seven the succeeding types of services. If it answers "Yes" to any of them, it must identify the effective date (i.e., the date on which these services began) and explain the type of service the SAE furnishes. If an SAE provides multiple types of services, the SNF must differentiate between them when furnishing the required description in Question 11.

10. <u>Section D – Question 12 (Lease/Sublease)</u> – If the SNF indicates that the SAE leases or subleases property to the SNF, the latter must describe the lease arrangement (e.g., whether it is a lease or a sublease; what real property is being leased to the SNF and how much; how much control the SNF has over the property; etc.) and the lease's length (e.g., when it began).

11. Section D – Question 13 (Real Property Ownership)

(A) Parameters of Question

- Indirect Ownership Question 13 includes 5 percent or greater <u>indirect</u> ownership of the property in question. For instance, suppose Company W owns 80 percent of the total value of the SNF's real property. Company X owns 50 percent of Company W. This means that Company X indirectly owns 40 percent (80 x 0.5) of the SNF's real property and must be reported. If Company Y owns 40 percent of Company X, it indirectly owns 16 percent (40 x 0.4) of the SNF's real property and must be disclosed. If, however, Company Z owns 20 percent of Company Y, it would not have to reported as a real property owner because its indirect ownership is only 3.2 percent (16 x 0.2).
- Total Value This means the total value of <u>all</u> real property the SNF owns or leases. Said property can include satellite locations (e.g., sites other than the main locations), offices, office buildings, other non-medical sites, etc. It is the owned/leased property itself, rather than the activities conducted thereon (e.g., medical, administrative), that is determinative. If the SNF owns <u>and</u> leases property, the 5 percent threshold applies to the <u>combined total value of both</u>. That is, there is not a separate 5 percent floor for owned property and another one for leased property. However, if the SNF owns or leases space within a larger building or complex, only the owned or leased space not the entire building or complex --applies when calculating the total property value.
- (B) Requirements of Completion The SNF must address Question 13 regardless of the SNF's business type. If the SNF checks "Yes", it must provide the effective date and exact percentage of ownership as well as state whether it is of real property the SNF owns or of real property the SNF leases or subleases. (Only a brief response is required for the latter question. A detailed explanation is unnecessary.)

12. Section D - Questions 14-18 (Ownership/Management of ADP)

The SNF must disclose whether the reported SAE has any of the Question 14-18 ownership/trustee interests in any ADP of the SNF. As explained previously, all organizations that meet the definition of an ADP must be reported as an SAE. An ADP will effectively be identified as such if the SNF answered "Yes" to Question 9, 10, 11, 12, and/or 13 when completing the Organizations section of the Attachment for that SAE. Consider the following:

EXAMPLE: Companies A, B, C. D, E, F, and G are reported as SAEs in the SNF Attachment. When completing the Attachment for each of these seven SAEs, the SNF checked "Yes" to Question 10 for Companies A and B and "Yes" to Question 11 for Company C. The SNF did not check "Yes" for Questions 9, 10, 11, 12, and 13 for Companies D, E, F, and G. Strictly for purposes of completing the Attachment, this means that Companies A, B, and C are considered ADPs. In completing the Attachment for each SAE, therefore, the SNF must identify whether the SAE has one of the Question 14-18 interests in Company/ADP A, B, or C. So, for example, the SNF would have to report whether:

- Company B has one of the Question 14-18 interests in Company A or C.
- Company E has one of the Question 14-18 interests in Company A, B, or C.

Questions 14-18 would not apply to whether any of the 7 SAEs has a Question 14-18 interest in Company D, E, F, or G, for the latter four were not reported as ADPs.

To reiterate, Questions 14-18: (a) only apply to interests <u>in an ADP</u>, not in the SNF itself; but (b) nonetheless must be completed for all SAEs irrespective of whether they themselves are ADPs.

Note that Questions 14-18 reflect the above-cited definition of "organizational structure" in section 1124(c)(5)(D) of the Act and underscore that the SNF must disclose the ADP's organizational structure within these questions. As an illustration, section 1124(c)(5)(D)(i) of the organizational structure definition requires, in part, that an ADP's 5 percent or greater owners be reported if the ADP is a corporation. Question 14 accordingly asks whether, if the ADP is a corporation, the SAE is a 5 percent or greater owner thereof.

If the SNF lists multiple ADPs that are of different business types, the SNF may need to answer multiple questions in 14-18 – one for each business type. For example, assume the SNF reports the following SAEs:

- Company W, which is not an ADP.
- Company X, which is a corporation and qualifies as an ADP.
- Company Y, which is an LLC and qualifies as an ADP.
- Company Z, which is a general partnership and qualifies as an ADP.

X, Y, and Z are the only ADPs listed.

In this scenario:

- Company W The SNF must complete Questions 14, 15, and 16 for Company W. This
 is because the SNF reported at least one ADP that is a corporation (Question 14), an LLC
 (Question 15), and general partnership (Question 16). Questions 17 and 18 need not be
 completed because no ADP was listed that is a limited partnership or trustee,
 respectively.
- Company X The SNF must complete Questions 15 (because it listed an ADP that is an LLC) and 16 (because it listed an ADP that is a general partnership) for Company X. (Note that an ADP can have a reportable ownership/trustee interest in another listed ADP.)

Companies Y and Z would be similarly addressed.

In addition:

• As applicable, the SNF must also report all required information within the question for any "Yes" answer (e.g., percentage of ownership). This includes identifying the ADP of

- which the SAE is an owner/trustee. The name of the ADP listed within the question here must match the name of said ADP as the SNF reported it in Section A.
- As noted, Questions 14-18 only reference ADPs that are corporations, LLCs, general partnerships, limited partnerships, and trustees. If the SNF does not report any ADPs in Section A that fall within one of these five categories, Questions 14-18 do not apply. For instance, if the SNF lists only two ADPs in Section A and both are government agencies, Questions 14-18 need not be completed. It must be emphasized, however, that any entity that qualifies as an ADP must be reported in Section A regardless of its business type. SNFs should not assume that because Questions 14-18 are limited to the above-referenced five business types that only those five ADP types must be reported in Section A.

13. Section D – Question 19

If the SNF answered "Yes" to Question 14, 15, 16, 17, or 18, it must complete Question 19. For purposes of Question 19 **ONLY**, the term "interest" means any of the interests (ownership, trustee, LLC managerial) listed in the "organizational structure" definition in section 1124(c)(5)(D) of the Social Security Act. (See section II(B)(2)(iii) above for this definition.)

Question 19 asks whether the ADP owner/trustee/LLC manager (as indicated in Question 14, 15, 16, 17, or 18) has any interest in the SNF itself OR in <u>another</u> ADP of the SNF. If the SNF answers "Yes," it must list the legal business name (LBN) of the entity (i.e., the SNF itself or <u>another</u> ADP of the SNF) in which the ADP owner/trustee/LLC manager has an interest.

14. Section E - Adverse Legal Actions – The SNF must complete Section E for each SAE.

B. Individuals

The SNF must complete the Individuals section for each person who must be reported.

1. Section A – Individual Identifying Information - The Section A data duplicates that in Section 6 of the Form CMS-855A. The individual reported in Section A (hereafter occasionally a Section A Individual (SAI)) could be one that has long been required to be reported under section 1124(a) (e.g., 5 percent owner, managing employee) or an individual that section 1124(c) now mandates be reported.

2. Section B – Questions 1-7 (Ownership of SNF)

See sections (V)(A)(4) and (5) above for information. The guidance in those two sections generally applies to Questions 1-7 of the Individuals section of the Attachment.

3. Section B – Question 8 (Corporate Officer or Director)

Consistent with longstanding requirements under section 1124(a), SNFs that are corporations must disclose their officers and directors (as those terms are defined in § 424.502). Each officer and director must be separately reported in Section A of the Individuals section of the Attachment and all applicable data furnished for that person.

As explained in the § 424.502 "director" definition, the term includes any member of the corporation's governing body irrespective of the precise title of either the board or the member (e.g., members of the board of trustees of a non-profit organization).

4. Section B – Question 9 (Governing Body Member for Non-Corporations)

If the SNF is <u>not</u> a corporation, it must: (1) disclose all the members of its governing body as SAIs and complete the Individuals section of the Attachment for each; and (2) answer "Yes" to Question 9 for each member and furnish the required Question 9 data. Such persons may include, but are not limited to: (1) LLC members; (2) partners in a general partnership; and (3) general partners in a limited partnership, etc. The only exception to this requirement is if a governmental or tribal organization will be legally and financially responsible for Medicare payments the SNF receives (as explained in Section 6 of the Form CMS-855A). In this case, the governing body members of the governing/tribal organization (e.g., members of state health commission, city council members) need not be reported as governing body members in Section A or in Question 9. However, they may need to be disclosed as SAIs in Section A in another capacity, such as a person who exercises operational control over or who is a managing employee of the SNF.

5. <u>Section B – Questions 10 through 15 (Mortgage/Security, Trustees, Control, Services, Leases, Property)</u>

See sections (V)(A)(6) through (11) above for information. The guidance in those sections generally applies to Questions 10-15 of the Individuals section of the Attachment.

If an SAE listed in the Organizations section of the Attachment exercises control over or furnishes services to the SNF, persons within that organization who exercise/furnish said control or services must also be disclosed as SAIs in the Individuals section. This is akin to current policy regarding managing organizations that must be disclosed consistent with section 1124(a) of the Act; persons within an organization who meet the managing employee definition in § 424.502 must reported even if the entity is already being disclosed as a managing organization.

(QUESTION 16 – THE APPLICABLE CHECKBOX IN QUESTION 16 SHOULD BE CHECKED IF THE LISTED SAI IS THE SNF'S MEDICAL DIRECTOR OR ADMINISTRATOR. NOTE THAT THE SNF'S MEDICAL DIRECTOR AND ADMINISTRATOR FALL WITHIN THE DEFINITION OF "MANAGING EMPLOYEE" IN § 424.502 AND MUST BE REPORTED IN SECTION A OF THE SNF ATTACHMENT.)

6. Section B – Questions 17 through 21 (Ownership/Management of ADP)

See section (V)(A)(12) above for information. The guidance in that section generally applies to Questions 17-21 of the Individuals section of the Attachment.

7. Section B – Question 22 (ADP Officer/Director/Member)

The SNF must indicate if the SAI in question is a corporate officer, corporate director, or LLC manager of any ADP of the SNF. If the person is, the SNF must report the effective date, the

person's title, type of position (e.g., corporate officer), and the ADP of which the SAI is an officer, director, or LLC manager.

8. Section D – Question 23 (ADP Interest in Another Entity)

If the SNF answered "Yes" to Question 17, 18, 19, 20, 21, or 22, it must complete Question 23. For purposes of Question 23 **ONLY**, the term "interest" means any of the interests (ownership, trustee, LLC managerial, officer, director) listed in the "organizational structure" definition in section 1124(c)(5)(D) of the Social Security Act. (See section II(B)(2)(iii) above for this definition.)

Question 23 asks whether the ADP owner/trustee/LLC manager/officer/director (as indicated in Question 17, 18, 19, 20, 21, or 22) has any interest in the SNF itself OR in <u>another</u> ADP of the SNF. If the SNF answers "Yes," it must list the LBN of the entity (i.e., the SNF itself or <u>another</u> ADP of the SNF) in which the ADP owner/trustee/LLC manager/officer/director has an interest.

9. <u>Section C - Adverse Legal Actions</u> – The SNF must complete Section C for each SAI.

VI. ADDITIONAL INFORMATION

A. Identifiers

The SNF is required to report the social security numbers of only the following parties on the Attachment:

- o 5 percent or greater direct or indirect owners of the SNF
- o General or limited partners of the SNF (regardless of the percentage)
- Managing employees of the SNF (as the term "managing employee" is defined in 42 CFR § 424.502)
- Corporate officers
- Corporate directors
- o Persons with a 5 percent or greater mortgage or security interest in the SNF

B. Supporting Documentation

At this time, SNFs need only submit the applicable supporting documentation otherwise required under Section 17 of the Form CMS-855A.

Section 17 of the Form CMS-855A requires copies of all bills of sale or sales agreements for all reportable ownership changes. Yet this pertains only to <u>SNF</u> ownership changes, not to ADP ownership changes. The latter must still be disclosed pursuant to 42 CFR § 424.516(g), but the associated documentation is unnecessary.

C. Organizational Charts

Consistent with longstanding policy and in light of section 1124(c), SNFs are required to submit the following charts with their initial, revalidation, reactivation, and 42 CFR § 489.18 CHOW applications:

- A chart identifying all the entities listed in Section A of the Organizations section of the Attachment that shows their relationships with the SNF and each other. (This chart will thus include the SNF's organizational ADPs.)
- A chart identifying the organizational structures of all its owners, <u>including owners not listed in the SNF Attachment</u> (e.g., less than 5% direct or indirect owners of corporations).
- A chart outlining the organizational structures of each ADP of the facility. This must include a written description of the relationship of each ADP to the facility and to all the SNF's other ADPs.

At least one of these three charts must also identify the SNF's ultimate parent company and the entities situated between the SNF and the parent in the organizational arrangement.

D. Changes of Information

The SNF must report the following changes described in the SNF Attachment within 30 days of the change:

- o 5 percent or greater direct or indirect owners of the SNF
- o General or limited partners of the SNF (regardless of the percentage)
- Managing organizations or employees of the SNF (as the term "managing employee" is defined in 42 CFR § 424.502). This includes Question 16 of the Individuals section regarding medical directors and administrators.
- o Corporate officers of the SNF
- o Corporate directors of the SNF
- o Persons with a 5 percent or greater mortgage or security interest in the SNF
- o Trustee interests in the SNF
- o Any types of control or services as described in Questions 10 and 11 of the Organizations section and Questions 12 and 13 of the Individuals section.
- o Information on organizations and individuals that lease or sublease real property to the SNF (i.e., Question 12 of the Organizations section and Question 14 of the Individuals section).
- Ownership of total value of SNF's real property or the property on/in which the SNF operates (i.e., Question 13 of the Organizations section and Question 15 of the Individuals section).

All other changes to data on the SNF Attachment must be reported within 90 days of the change.