U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

September 4, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Examining Federal Efforts to Ensure Quality of Care and Resident Safety in Nursing Homes."

The Subcommittee on Oversight and Investigations will hold a hearing on Thursday, September 6, 2018, at 10:15 a.m. in 2322 Rayburn House Office Building, entitled "Examining Federal Efforts to Ensure Quality of Care and Resident Safety in Nursing Homes." The purpose of the hearing is to explore the roles of the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General at the U.S. Department of Health and Human Services (HHS OIG) relating to the management and safety of nursing home facilities.

I. WITNESSES

- Kate Goodrich, M.D., Director, Center for Clinical Standards and Quality, and Chief Medical Officer, CMS;
- Ruth Ann Dorrill, Regional Inspector General, HHS OIG; and
- John Dicken, Director, Health Care, Government Accountability Office (GAO).

II. BACKGROUND

The Committee on Energy and Commerce (the Committee) began conducting oversight of nursing homes after numerous media reports described instances of abuse, neglect, and substandard care occurring at SNFs and NFs across the country, including the Rehabilitation Center at Hollywood Hills where at least 12 residents died in the immediate aftermath of Hurricane Irma in September 2017.[1]

[1] *See, e.g.*, NH Staff, *Nursing home lawyers a no-show in records case*, NAPLES HERALD, May 22, 2018, http://naplesherald.com/2018/05/22/nursing-home-lawyers-a-no-show-in-records-case/; Blake Ellis and Melanie Hicken, *Sick, Dying and Raped in America's Nursing Homes*, CNN, Feb. 22, 2017, http://www.cnn.com/interactive/2017/02/health/nursing-home-sex-abuse-investigation/.

A. Management Failure at the Rehabilitation Center at Hollywood Hills

On October 20, 2017, the Committee sent a bipartisan letter requesting documents and information from Jack Michel, an owner of the Rehabilitation Center at Hollywood Hills (Rehabilitation Center) where at least 12 residents died in the immediate aftermath of Hurricane Irma in Florida.[2] The Committee raised concerns about the organization's failure to protect the health, safety, and welfare of residents at the facility.[3] According to the Florida Agency for Health Care Administration (AHCA), the Rehabilitation Center failed to follow adequate emergency management procedures after the facility's air conditioning system lost power during Hurricane Irma.[4] Despite increasingly excessive heat, staff at the facility did not take advantage of a fully functional hospital across the street and "overwhelmingly delayed calling 911" during a medical emergency.[5]

The facility also had contractual agreements with an assisted living facility and transportation company for emergency evacuation purposes yet did not activate these services.[6] CMS ultimately terminated the Rehabilitation Center from the Medicare and Medicaid programs following an on-site inspection where surveyors found that the facility failed to meet Medicare's basic health and safety requirements.[7] During a hearing before the Subcommittee on Oversight and Investigations in October 2017, CMS described the events at this nursing home as a "complete management failure."[8]

On November 17, 2017, Dr. Michel provided a response through his attorney to the Committee's inquiry, contending among other things, that the facility made patients as

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[2] Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to Dr. Jack Michel, Owner, Rehabilitation Center at Hollywood Hills, LLC (Oct. 20, 2017), *available at* https://energycommerce.house.gov/wp-content/uploads/2017/10/20171020HollywoodHills.pdf; *See also* NH Staff, *supra* note 1.

[3] Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to Dr. Jack Michel, Owner, Rehabilitation Center at Hollywood Hills, LLC (Oct. 20, 2017).

[4] Florida Agency for Health Care Administration, *Press Release: AHCA Suspends the License of the Rehabilitation Center of Hollywood Hills* (Sept. 20, 2017); Paul McMahon, et al., *Ninth nursing home patient dies; Gov. Scott details contact with state*, SUN SENTINEL, Sept. 19, 2018, http://www.sun-sentinel.com/news/hollywood-nursing-home-hurricane-deaths/fl-reg-nursing-home-ninth-death-20170919-story.html.

[5] AHCA Press Release, *ACHA Suspends the License of the Rehabilitation Center of Hollywood Hills*, (Sept. 20, 2017); U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), Survey of the Rehabilitation Center at Hollywood Hills, LLC, at 2 (Sept. 22, 2017); *State of Florida, Agency for Health Care Administration vs. Rehabilitation Center at Hollywood Hills, LLC*, Emergency Suspension Order (Sept. 20, 2017).

[6] U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), Survey of the Rehabilitation Center at Hollywood Hills, LLC (Sept. 22, 2017).

[7] U.S. Dep't of Health and Human Services, Centers for Medicare and Medicaid Services, *Notice to Public of Rehabilitation Center at Hollywood Hills, Termination Notice* (Oct. 11, 2017), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Termination-Notice-Florida-NH-Rehabilitation-Center-at-Hollywood-Hills-LLC.pdf.

[8] *Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season: Hearing Before the Subcomm. On Oversight & Investigations of the H. Comm. On Energy and Commerce*, 115th Cong., Preliminary Transcript, 108 (Oct. 24, 2017) *available at* https://docs.house.gov/meetings/IF/IF02/20171024/106530/HHRG-115-IF02-Transcript-20171024.pdf.

comfortable as possible during the loss of air conditioning.[9] According to the letter, "although AC power was lost on September 10, Hollywood Hills continued to otherwise have electrical power, and deployed eight 'spot coolers' (portable air conditioning units that had been purchased as part of hurricane preparedness) and numerous fans through the building in an effort to keep residents as comfortable as possible, given the loss of central air conditioning."[10] However, according to an engineer testifying in the ongoing litigation between the Rehabilitation Center and the State of Florida, Hollywood Hills failed to properly ventilate the portable coolers which resulted in increased temperatures in most of the facility, particularly the second floor where the majority of deaths occurred.[11] According to the expert, the coolers operated by the facility "made it worse."[12]

i. Past Allegations Involving Dr. Michel and Corporate Integrity Agreement

The Committee's investigation and public reports revealed that facilities affiliated with Dr. Michel have been the subject of federal government scrutiny for over a decade. In 2006, Larkin Community Hospital (Larkin), and others entered into a settlement agreement with the Department of Justice (DOJ) to resolve a civil case in which the government alleged Dr. Michel and his associates paid kickbacks and performed medically unnecessary treatments on elderly beneficiaries to generate Medicare and Medicaid payments.[13] According to DOJ's complaint, Dr. Michel initiated the scheme during a meeting with an associate of the then-owner of a nearby hospital, Larkin by proposing, "ask your boss if he would pay $1 million to make $5 million."[14] Thereafter, Dr. Michel and his associates allegedly entered into a scheme to engage in seven different types of kickback arrangements.[15]

Dr. Michel and the parties eventually settled with DOJ for $15.4 million without an admission of guilt.[16] With the settlement, Larkin and Dr. Michel entered into a five-year

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[9] Letter from Geoffrey D. Smith, Atty., Smith & Associates, to Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., (Nov. 17, 2017) (On file with the Committee).
[10] *Id.*
[11] Deposition of William Scott Crawford, PE, *State of FL for Healthcare Admin. Vs. Rehabilitation Center at Hollywood Hills*, Feb. 16, 2018, available at; *see also* Terry Spencer, *Expert: Coolers Made it Worse in Nursing Home Where 12 Died*, ASSOCIATED PRESS, Mar. 23, 2018, https://www.yahoo.com/news/expert-coolers-made-worse-nursing-home-where-12-185954138.html; Erika Pesantes, et. al, *Second Floor was Deadliest at Nursing Home with No Air Conditioning*, SUN SENTINEL, Oct. 6, 2017, http://www.sun-sentinel.com/news/hollywood-nursing-home-hurricane-deaths/fl-sb-nursing-home-sunrise-hollywood-20170927-story.html.
[12] *Id.*
[13] U.S. Dep't of Justice, Press Release, *Miami Hospital Pays $15.4 Million to Resolve Fraud Case for Kickbacks & Medically Unnecessary Treatments* (Nov. 30, 2006), *available at* https://www.justice.gov/archive/opa/pr/2006/November/06_civ_803.html.
[14] *United States v. Jack Jacob Michel, et al*., Complaint of the United States, No-04-21579-CIV-JORDAN/TORRES, at 31 (Filed Jun. 29, 2004) (S.D. Fla.).
[15] *Id*. at 30-36.
[16] U.S. Dep't of Justice, Press Release, *Miami Hospital Pays $15.4 Million to Resolve Fraud Case for Kickbacks & Medically Unnecessary Treatments* (Nov. 30, 2006) *available at* https://www.justice.gov/archive/opa/pr/2006/November/06_civ_803.html; *See also United States v. Philip Esformes*, Government's Motion for Pre-Trial Detention and Supporting Memorandum, Case No. 16-20549, at Attachment B, Page 6 (Filed Jul. 22, 2016) (S.D. Fla.) (Attachment B includes Settlement Agreement Binder from *United States v. Michel* ("Civil Action"), No-04-21579-CIV-JORDAN/TORRES (S.D. Fla.)).

Corporate Integrity Agreement (CIA) with HHS OIG in 2006.[17] Despite the CIA, media reports indicate that from approximately 2002 to 2016, at least one then-employee and physicians at Larkin were allegedly involved in the largest single criminal health care fraud case ever brought against individuals by DOJ.[18]

ii. Dr. Michel Continues to Own Multiple Health Care Related Facilities Participating in Federal Programs

Last year, state regulators in Florida raised concerns about patient safety at another facility owned by Dr. Michel.[19] In December 2016, the AHCA found 30 violations at Floridian Gardens Assisted Living Facility, including "sexual assault of patients, low staffing, and ignoring patients."[20] As a result, the facility was banned from accepting new patients for several months.[21] In September 2017, the AHCA took additional steps to close Floridian Gardens.[22] According to information obtained by the Committee from CMS, Dr. Michel currently has an ownership interest in at least 11 health care related facilities enrolled in Medicare despite the tragedy at the Rehabilitation Center and other previous instances of apparent wrongdoing.[23]

B. Emergency Preparedness at SNFs and NFs

Emergency preparedness is a critical issue for long-term care facilities, and CMS requires that Medicare- and Medicaid-certified nursing homes comply with certain federal requirements regarding emergency preparedness. HHS OIG has examined some of these requirements, issuing reports in 2006 and 2012 regarding emergency preparedness and response in nursing homes.[24] In these reports, HHS OIG found that there were gaps in nursing home preparedness and

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[17] U.S. Dep't of Health and Human Services, Office of Inspector General, Integrity Agreement Between the Office of Inspector General of the Dep't of Health and Human Services and Jack J. Michel, M.D. (Nov. 17, 2006); U.S. Dep't of Health and Human Services, Office of Inspector General, Integrity Agreement Between the Office of Inspector General of the Dep't of Health and Human Services and Larkin Community Hospital (Nov. 13, 2006).
[18] Jay Weaver, *Bribes to low-paid state worker key to $1 billion Miami Medicare fraud case, prosecutors say*, MIAMI HERALD, Jul. 29, 2017, http://www.miamiherald.com/news/local/article164232522.html; *See also* U.S. Dep't of Justice, Press Release, *Three Individuals Charged in $1 Billion Medicare Fraud and Money Laundering Scheme* (Jul. 22, 2016), *available at* https://www.justice.gov/opa/pr/three-individuals-charged-1-billion-medicare-fraud-and-money-laundering-scheme.
[19] Melanie Payne & Arek Sarkissian, *Nursing Home Deaths: Owner's Other Facility Faced State Ban on New Patients*, USA TODAY NETWORK FLORIDA, Sept. 15, 2017, https://www.usatoday.com/story/news/nation-now/2017/09/15/nursing-home-deaths-owners-other-facility-faced-state-ban-new-patients/672340001/.
[20] *Id.*
[21] *Id.*
[22] *See* Florida Agency for Health Care Administration, *Press Release: AHCA Takes Additional Action to Close Larkin-Owned ALF* (Sept. 28, 2017), https://www.ahca.myflorida.com/Executive/Communications/Press_Releases/pdf/Larkin-OwnedALFPR.pdf.
[23] E-mail from Staff, Centers for Medicare and Medicaid Services to Staff, H. Comm. on Energy & Commerce (May 11, 2018. 5:12 pm) (On file with the Committee).
[24] U.S. Dep't of Health and Human Services, Office of the Inspector General, *Nursing Home Emergency Preparedness and Response During Recent Hurricanes*, OEI-06-06-00020 (Aug. 2006) *available at* https://oig.hhs.gov/oei/reports/oei-06-06-00020.pdf; U.S. Dep't of Health and Human Services, Office of Inspector General, *Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007-2010*, OEI-06-09-00270 (Apr. 2012) *available at* https://oig.hhs.gov/oei/reports/oei-06-09-00270.pdf.

response and made recommendations to CMS to update and revise certain federal requirements regarding emergency preparedness.[25]

Over the past decade, CMS has adopted new policies and procedures to improve emergency preparedness in nursing homes and other health care facilities. For example, in 2007, CMS issued three emergency preparedness checklists for health care facilities (including nursing homes), State Long Term Care (LTC) Ombudsman programs, and State Survey Agencies.[26] More recently, in September 2016, CMS finalized a new emergency preparedness rule for Medicare and Medicaid participating providers and suppliers that imposed new requirements on 17 different provides/suppliers, including long-term care facilities.[27] The rule, among other things, outlined four core elements of the Emergency Preparedness Program for all provider types (*i.e.*, Risk Assessment and Planning, Policies and Procedures, Communication Plan, and Training and Testing).[28] At the Subcommittee's October 2017 hearing entitled "Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season," CMS was asked about its emergency preparedness requirements and testified that the surveyors would begin surveying for the new rule starting in November 2017 and that the rule required, among other things, generators, emergency preparedness plans, and training on a continual basis.[29]

C. CMS Oversight of National Nursing Homes

On April 2, 2018, the Committee wrote to CMS Administrator Seema Verma, requesting documents and information relating to CMS' oversight of SNFs and NFs participating in the Medicare and Medicaid programs.[30] Media reports cited in the letter described instances of nursing home residents being abused and neglected and, in some instances, the nursing homes subsequently failing to detect and investigate adequately the abuse and neglect.[31] Analysis conducted by one news outlet found that between 2013 and 2016, the federal government cited more than 1,000 nursing homes for either mishandling cases related to, or failing to protect residents against, rape, sexual abuse, or sexual assault, with nearly 100 facilities incurring multiple citations.[32] The Centers for Disease Control (CDC) National Center for Health

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[25] *Id.*
[26] U.S. Dep't of Health and Human Services, Office of Inspector General, *Gaps Continue to Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007-2010*, OEI-06-09-00270, at 5 (Apr. 2012).
[27] Centers for Medicare and Medicaid Services, *Emergency Preparedness Rule*, CMS.GOV (last updated Jul. 9, 2018), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html.
[28] *Id.*
[29] The compliance deadline for the new rule was November 15, 2017. *Id.*; *Examining HHS's Public Health Preparedness for and Response to the 2017 Hurricane Season: Hearing Before the Subcomm. On Oversight & Investigations of the H. Comm. On Energy and Commerce*, 115th Cong., Preliminary Transcript, 108 (Oct. 24, 2017) *available at* https://docs.house.gov/meetings/IF/IF02/20171024/106530/HHRG-115-IF02-Transcript-20171024.pdf.
[30] Letter from Hon. Greg Walden, Chairman, H. Comm. on Energy & Commerce, et al., to Hon. Seema Verma, Administrator, Centers for Medicare & Medicaid Services (Nov. 17, 2017) *available at* https://energycommerce.house.gov/wp-content/uploads/2018/04/20180402CMS.pdf.
[31] Ellis and Hicken, *supra* note 1.
[32] *Id.*

Statistics found that, as of 2014, there were 15,600 nursing home facilities in the United States; 69.8 percent of U.S. nursing home facilities have for-profit ownership.[33]

For over a decade, HHS OIG has identified improving care for vulnerable populations, including the care provided to individuals receiving nursing home care, as a top management challenge for HHS and has continuously expressed concerns about residents being at risk of abuse and neglect.[34] According to HHS OIG's 2017 report on top management challenges:

> Nursing facilities continue to experience problems ensuring quality of care and safety for people residing in them. OIG identified instances of substandard care causing preventable adverse events, finding an estimated 22 percent of Medicare beneficiaries had experienced an adverse event during their nursing stay.[35]

The report further states that "OIG continues to raise concerns about nursing home residents being at risk of abuse and neglect. In some instances, nursing home care is so substandard that providers may have liability under the False Claims Act."[36]

In addition, GAO has developed a substantial body of work wherein CMS' efforts to ensure that nursing home residents are free from abuse and receive the proper standard of care have been called into question.[37]

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[33] Centers for Disease Control and Prevention, *Nursing Home Care* (last updated May 3, 2017) *available at* https://www.cdc.gov/nchs/fastats/nursing-home-care.htm.

[34] U.S. Dep't of Health and Human Services, Office of Inspector General, *Top Management and Performance Challenges Facing HHS 2017, #4 Improving Care for Vulnerable Populations* (last accessed Aug. 29, 2018), https://oig.hhs.gov/reports-and-publications/top-challenges/2017/2017-tmc.pdf; U.S. Dep't of Health and Human Services, Office of Inspector General, *Top Management and Performance Challenges Facing HHS 2016, #7 Ensuring Quality of Care and Safety for Vulnerable Populations* (last accessed Aug. 29, 2018), https://oig.hhs.gov/reports-and-publications/top-challenges/2016/TMC_2016_508.pdf; U.S. Dep't of Health and Human Services, Office of Inspector General, *OIG's FY 2015 Top Management and Performance Challenges Facing the Department of Health and Human Services, Management Challenge 6: Ensuring Quality in Nursing Home, Hospice, and Home- and Community-Based Care* (last accessed Aug. 29, 2018), https://oig.hhs.gov/reports-and-publications/top-challenges/2015/2015-tmc.pdf.

[35] 2017 Management Challenges, *supra* note 34.

[36] *Id*.

[37] *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-16-33, Nursing Home Quality: CMS Should Continue to Improve Data and Oversight (2015) *available at* https://www.gao.gov/assets/680/673480.pdf. *See also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-280, Nursing Homes: More Reliable Data and Consistent Guidance Would Improve CMS Oversight of State Complaint Investigations (2011) *available at* https://www.gao.gov/assets/320/317514.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-197, Poorly Performing Nursing Homes: Special Focus Facilities Are Often Improving, but CMS's Program Could be Strengthened (2010) *available at* https://www.gao.gov/assets/310/302117.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-70, Nursing Homes: Addressing the Factors Underlying Understatement of Serious Care Problems Requires Sustained CMS and State Commitment (2009) *available at* https://www.gao.gov/assets/300/298953.pdf; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-517, Nursing Homes: Federal Monitoring Surveys Demonstrate Continued Understatement of Serious Care Problems and CMS Oversight Weaknesses (2008) *available at* https://www.gao.gov/assets/280/275154.pdf; and U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-07-241, Nursing Homes: Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes for Repeatedly Harming Residents (2007) *available at* https://www.gao.gov/assets/260/258016.pdf.

i. Oversight of Nursing Homes: Surveys, Deficiencies, and Corrective Action Plans

HHS utilizes state health agencies or other state agencies to determine if nursing homes meet the minimum federal requirements for participation in the Medicare and Medicaid programs (hereinafter "Conditions of Participation" or "CoPs").[38] Accordingly, through an agreement with HHS, the state agency is required to "conduct standard surveys to determine whether nursing homes are in compliance with Federal participation requirements."[39] A standard survey is defined as "a periodic nursing home inspection," using procedures specified in CMS' *State Operations Manual* (hereinafter "Manual"), "that focuses on a sample of residents selected by the state agency to gather information about the quality of resident care furnished to Medicare or Medicaid beneficiaries in a nursing home."[40] A survey must take place at each facility "at least once every 15 months."[41] However, each state must maintain a statewide average of conducting surveys once every 12 months.[42] Nursing homes that do not achieve substantial compliance within six months will be terminated from participating in Medicare and Medicaid.[43]

The state is also required to review "complaint allegations" with the option to "conduct a standard survey or an abbreviated standard (complaint survey) to investigate noncompliance with the CoPs.[44] "A nursing home's noncompliance with a Federal participation requirement is defined as a deficiency."[45] The state agency determines the deficiency rating utilizing severity and scope components.[46] Each deficiency is assigned a letter rating of A to L, with L being the most serious and A the least.[47]

Severity is the degree of or potential for resident harm and has four levels, beginning with the most severe: (1) immediate jeopardy to resident health or safety, (2) actual harm that is not immediate jeopardy, (3) no actual harm with potential for more than minimal harm but not immediate jeopardy, and (4) no actual harm with potential for minimal harm. Scope is the number of residents affected or pervasiveness of the deficiency in the nursing home and has three levels: (1) isolated, (2) pattern, (3) widespread. The Manual provides information on the severity and scope of levels used to determine the deficiency rating.[48]

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[38] *See* U.S. Dep't of Health and Human Services, *Office of Inspector General, Kansas Did Not Always Verify Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid* (A-07-17-03218), Sept. 2017, *available at* https://oig.hhs.gov/oas/reports/region7/71703218.pdf.
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] 42 U.S.C. § 1395i–3(g)(2)(A)(iii)(I) and 42 U.S.C. § 1396r (g)(2)(A)(iii)(I).
[43] CMS Nursing Home Enforcement, *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationEnforcement/Nursing-Home-Enforcement.html. *See also* 42 U.S.C. § 1395i-3(h)(2)(C) and 42 U.S.C. § 1396r(h)(3)(D).
[44] HHS OIG Report, *supra* note 38.
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*

Table 1: Severity and Scope Levels for Deficiency Ratings[49]

SEVERITY	SCOPE		
	Isolated	Pattern	Widespread
Immediate jeopardy to resident health or safety	J	K	L
Actual harm that is not immediate jeopardy	G	H	I
No actual harm with potential for more than minimal harm but not immediate jeopardy	D	E	F
No actual harm with potential for minimal harm	A	B	C

Nursing homes are required to submit corrective actions plans to either the appropriate state agency or CMS, detailing how the nursing home corrected the deficiency or plans to correct the deficiency.[50] After receiving the plan, the state or CMS certifies whether the facility is in substantial compliance with the CoPs.[51] Substantial compliance occurs when "there is substantial compliance by verifying correction of the identified deficiencies through obtaining evidence of correction or conducting an onsite review."[52]

According to information provided to the Committee by CMS, the number of complaint surveys with deficiencies cited at the immediate jeopardy level has increased each of the last four years. In 2013, there were 1,250 complaints at the immediate jeopardy level compared to 1,801 in 2017, the most recent data available—an increase of more than 44 percent.[53]

ii. Delays Reviewing Complaint Allegations

While staffing shortages continue to be an issue for a variety of reasons in the nursing home industry and at state agencies, some nursing home residents appear to be placed in unsafe situations because of a lack of oversight by state agencies and CMS.[54] A September 2017 Data Brief issued by the HHS OIG found that in 2015, 764 immediate jeopardy nursing home complaints were not investigated by state agencies within two working days, as required by CMS, and 473 complaints were not investigated within 15 days.[55] Immediate jeopardy is described by CMS as being instances where "the facility's noncompliance with more or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment,

[49] U.S. Dep't of Health and Human Services, Office of Inspector General, *Florida Did Not Always Verify Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid*, A-04-17-0852 (Apr. 2018) *available at* https://oig.hhs.gov/oas/reports/region4/41708052.pdf.
[50] HHS OIG Report, *supra* note 38.
[51] *Id.*
[52] *Id.*
[53] Centers for Medicare and Medicaid Services, *supra* note 23. Federal law requires states to maintain procedures and adequate staff to investigate complaints of violations of federal requirements by SNFs and NFs. *See* 42 U.S.C. § 1395i-3(g)(4)(A) and 42 U.S.C. § 1396r(g)(4)(A).
[54] *See* John Caniglia & Jo Ellen Corrigan, *Ohio Nursing Home Inspectors Fail to Meet Federal Deadlines Amid Serious Understaffing: A Critical Choice*, THE PLAIN DEALER, Apr 23, 2017, *available at https://www.cleveland.com/metro/index.ssf/2017/04/ohio_nursing_home_inspectors_f.html.*
[55] U.S. Dep't of Health and Human Services, Office of Inspector General, *A Few States Fell Short in Timely Investigation of the Most Serious Nursing Home Complaints: 2011-2015* (OEI-01-16-00330) (Sept. 2017) *available at* https://oig.hhs.gov/oei/reports/oei-01-16-00330.pdf.

or death to a resident."[56] HHS OIG also found that 4,743 high priority nursing home complaints were not investigated in 2015 within the required 10 working day period.[57]

However, it should also be noted that failing to properly address and administer complaint investigations has been a long-standing problem for state agencies and CMS. For example, a report issued by the U.S. General Accounting Office[58] in 1999 found that "[s]erious complaints alleging that nursing home residents are being harmed can remain uninvestigated for weeks or months. Such delays can prolong situations in which residents may be subject to abuse, neglect resulting in serious care problems like malnutrition and dehydration, preventable accidents, and medication errors."[59] According to the report, CMS (then known as the Health Care Financing Administration (HCFA))[60] had only established minimal standards for complaint investigations and did not perform adequate oversight to ensure resident complaints were being investigated in a timely manner.[61] HHS OIG also made similar findings in a 2006 report, once again noting inadequacies in CMS' oversight.[62]

iii. Correction of Deficiencies Not Always Verified

HHS OIG has also issued several reports examining whether states always verified correction of deficiencies identified during surveys of nursing homes participating in Medicare and Medicaid.[63] While in some instances HHS OIG found that states properly verified correction of deficiencies identified during surveys of nursing homes,[64] HHS OIG generally found that states did not always verify correction of deficiencies identified during surveys of nursing homes participating in Medicare and Medicaid.[65] For example, in September 2017, HHS OIG released a report finding that Kansas did not always verify whether nursing homes corrected

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[56] *Id.*
[57] *Id.*
[58] The U.S. General Accounting Office was renamed the U.S. Government Accountability Office (GAO) in July 2004. *See* GAO Human Capital Reform Act of 2004, Pub. L. 108-271, 118 Stat. 811 (2004).
[59] U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-99-80, Nursing Homes: Complaint Investigation Process Often Inadequate to Protect Residents (1999) *available at* https://www.gao.gov/assets/230/227108.pdf.
[60] CNN, *Medicare agency renamed as prelude to reforms*, CNN, June 14, 2001, http://www.cnn.com/2001/HEALTH/06/14/hcfa.changes/.
[61] U.S. GEN. ACCOUNTING OFFICE, *supra* note 59.
[62] U.S. Dep't of Health and Human Services, Office of Inspector General, *Nursing Home Complaint Investigations* (OEI-01-04-00340) (July 2006) *available at* https://oig.hhs.gov/oei/reports/oei-01-04-00340.pdf.
[63] According to a May 2018 report issued by HHS OIG, OIG had released 15 reports related to this topic. *See, e.g.*, U.S. Dep't of Health and Human Services, Office of Inspector General, *Nebraska Did Not Always Verify Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid*, A-07-17-03224 (May 2018) *available at* https://oig.hhs.gov/oas/reports/region7/71703224.pdf.
[64] *See, e.g.*, U.S. Dep't of Health and Human Services, Office of Inspector General, *Missouri Properly Verified Correction of Deficiencies Identified During Surveys of Nursing Homes*, A-07-16-03217 (Mar. 17, 2017) *available at* https://oig.hhs.gov/oas/reports/region7/71603217.pdf; U.S. Dep't of Health and Human Services, Office of Inspector General, *Oregon Properly Verified Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid*, A-09-16-02007 (Mar. 14, 2016) *available at* https://oig.hhs.gov/oas/reports/region9/91602007.pdf.
[65] HHS OIG Report, *supra* note 63 at Appendix B.

deficiencies.[66] The report found that, out of 100 sampled deficiencies identified during CY 2014 surveys, Kansas failed to adequately verify that the deficiencies were corrected 52 percent of the time.[67] HHS OIG also found that the state failed to conduct required standard surveys within the required 15-month timeframe for 35 of 79 nursing homes in CY 2014.[68] According to a recent media report, Kansas "may conduct less than 40% of required nursing home surveys" during 2018.[69]

iv. Inconsistency of Penalties

According to information reviewed by the Committee, there appears to be variation in penalties among states and regions relating to how civil monetary penalties (CMPs) are assessed. In some cases, there is little to no correlation between the severity of deficiency and the resulting civil monetary penalty. Even within the same state, some facilities can incur significant civil monetary penalties despite not having any serious deficiencies while other facilities may have been cited for several deficiencies yet incur little to no penalties. For example, at least one nursing home did not incur any financial penalty even after being cited for not protecting residents after a case of sexual abuse was sustained.[70] There also appears to be a variation relating to intra-facility penalties. For instance, some facilities are cited for having serious deficiencies, sometimes in successive surveys, yet incur little to no monetary penalties. Alternatively, these facilities may incur significant civil monetary penalties for deficiencies that are relatively low on CMS' severity scale.

v. 1150B Authority Delegation

According to an August 2017 Early Alert, HHS OIG identified 134 Medicare beneficiaries who were treated in 2015 and 2016 for injuries that may have been caused by abuse or neglect when the individual was receiving care at a SNF.[71] HHS OIG raised concerns that CMS has inadequate procedures to ensure that incidents of potential abuse or neglect at SNFs are identified and reported in accordance with applicable requirements.[72] Under Section 1150B of the Social Security Act, covered individuals in federally funded SNFs and NFs are required to immediately report any reasonable suspicion of a crime committed against a resident of that facility.[73] The law imposes various penalties, including CMPs of up to $300,000 and possible

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[66] U.S. Dep't of Health and Human Services, Office of Inspector General, *Kansas Did Not Always Verify Correction of Deficiencies Identified During Surveys of Nursing Homes Participating in Medicare and Medicaid*, A-07-17-03218 (Sept. 2017) *available at* https://oig.hhs.gov/oas/reports/region7/71703218.pdf.
[67] *Id.*
[68] *Id.*
[69] Kimberly Marselas, MCKNIGHT'S LONG-TERM CARE NEWS, Apr. 26, 2018, https://www.mcknights.com/news/agency-may-conduct-less-than-40-of-required-nursing-home-surveys-in-kansas-this-year/article/761192/.
[70] Ellis and Hicken, *supra* note 1.
[71] U.S. Dep't of Health and Human Services, Office of Inspector General, *Early Alert: The Centers for Medicare & Medicaid Services Has Inadequate Procedures to Ensure That Incidents of Potential Abuse or Neglect at Skilled Nursing Facilities Are Identified and Reported in Accordance with Applicable Requirements* (A-01-17-00504) (Aug. 24, 2017) *available at* https://oig.hhs.gov/oas/reports/region1/11700504.pdf.
[72] *Id.*
[73] 42 U.S.C. § 1320b-25(b).

exclusion from participation in federal health care programs, for failure to report possible crimes against SNF and NF residents.[74]

According to HHS OIG, CMS has not, however, taken any enforcement actions using section 1150B of the Social Security Act or used the penalties it contains despite its effective date of March 23, 2011.[75] CMS officials told HHS OIG that CMS has not taken any enforcement actions under 1150B "because the HHS Office of the Secretary has not delegated the enforcement of section 1150B to CMS[,]" and that it had "not identified any instances in which a covered individual failed to report an incident of potential abuse or neglect of a Medicare beneficiary."[76] CMS further indicated that it had commenced working with the HHS Office of the Secretary in June 2017 to obtain the delegated enforcement authority.[77] CMS is continuing to work on the delegation authority.

vi. CMS' Administration of the Special Focus Facility (SFF) Program

As part of the Nursing Home Oversight and Improvement Program, the HCFA[78] created a Special Focus Facility (SFF) initiative in 1998.[79] The SFF program is designed to address nursing homes that have more problems than other nursing homes, more serious problems than most other nursing homes, and a pattern of serious problems that has persisted over a long period of time.[80] A facility is placed in the SFF program if the State Survey Agency selects the facility from a list of program candidates that is created by CMS.[81] As a SFF, the nursing home is subject to twice as many in-person visits by survey teams as other nursing homes and may face progressive enforcement actions.[82] CMS expects that within about 18-24 months the nursing home will: (1) improve and graduate from the SFF program; (2) be terminated from the Medicare and Medicaid programs; or (3) be provided with an extension of time to continue participating in the SFF program because the nursing home has made "very promising progress."[83]

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[74] 42 U.S.C. § 1320b-25(c).
[75] HHS OIG, *supra* note 71.
[76] *Id*.
[77] *Id*.
[78] The HCFA was renamed the Centers for Medicare & Medicaid Services (CMS) in June 2001. *See* CNN, *supra* note 60.
[79] *See* Statement of Alice Bonner, PhD, RN, Director of the Division of Nursing Homes, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services Before the United States Senate Special Committee on Aging (July 2, 2012), *available at* https://www.aging.senate.gov/imo/media/doc/hr248ab.pdf.
[80] Centers for Medicare and Medicaid Services (CMS), *Special Focus Facility ("SFF") Initiative* (last updated Aug. 16, 2018), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/NHs.html.
[81] *See* Centers for Medicare and Medicaid Services, *Center for Clinical Standards and Quality/Survey & Certification Group, Fiscal Year (FY) 2017 Special Focus Facility (SFF) Program Update* (Mar. 2, 2017), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-20.pdf.
[82] Centers for Medicare and Medicaid Services (CMS), *Special Focus Facility ("SFF") Initiative* (last updated Aug. 16, 2018), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/NHs.html.
[83] *Id*.

Since the program's creation, CMS has made improvements to the program to, among other things, increase the number of nursing homes participating in the program, strengthen enforcement, enhance transparency, and rate all nursing homes using a Five-Star Quality Rating System.[84] As of August 16, 2018, there were a total of 85 facilities in the SFF program, including 20 newly added facilities to the SFF program, 33 facilities in the SFF program that had not improved, 32 facilities in the SFF program that had shown improvement, and 25 facilities that had recently graduated from the SFF program.[85] According to CMS' August 16, 2018 update regarding facilities in the SFF program, the amount of time that the current facilities in the SFF program have been in the program ranges from 0 months to 47 months.[86] Some of these facilities have been in the program longer than CMS' expected 24 months, as the list shows that two facilities have been in the SFF program for more than 24 months and have not improved and 4 facilities have been in the SFF for more than 24 months and have shown improvement.[87]

It is important to note that the SFF program does not supersede the statutory requirement that a nursing home be terminated from the Medicare and/or Medicaid program if it does not achieve substantial compliance with federal requirements within six months of the date of the first findings of noncompliance.[88]

D. Updated SNF and NF Conditions of Participation

Congress enacted the Federal Nursing Home Reform Act (hereinafter "Act" or "Nursing Home Reform Act") as part of the Omnibus Budget Reconciliation Act of 1987.[89] The enactment of the Nursing Home Reform Act followed the publication of a comprehensive study conducted by the Institute of Medicine's Committee on Nursing Home Regulation which found that, at the time, quality of care in many of the nation's nursing homes was lacking.[90] The Committee on Nursing Home Regulation therefore recommended "[a] major reorientation of the regulatory system is needed to make it focus on the care being provided to residents and the effects of the care on their well-being."[91]

The Act required SNFs and NFs to provide, among other things, "services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care[,]"[92] and established minimum personnel requirements

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[84] Centers for Medicare and Medicaid Services (CMS), *Special Focus Facility ("SFF") Initiative* (last updated Aug. 16, 2018), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/NHs.html.
[85] *Id.*
[86] *Id.*
[87] *Id.*
[88] *See* CMS, *supra* note 81. *See also* 42 U.S.C. § 1395i-3(h)(2)(C) and 42 U.S.C. § 1396r(h)(3)(D).
[89] Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 (1987).
[90] INST. OF MED., COMM. ON NURSING HOME REGULATION, IMPROVING THE QUALITY OF CARE IN NURSING HOMES 22 (1986). *See also* U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-99-46, Nursing Homes: Additional Steps Needed to Strengthen Enforcement of Federal Quality Standards 5 (1999) *available at* https://www.gao.gov/assets/230/227015.pdf.
[91] INST. OF MED., *supra* note 90 at 22.
[92] 42 U.S.C. § 1395i-3(b)(2) and 42 U.S.C. § 1396r(b)(2) (Under the Act, NFs must also provide residents activities in accordance with the written plan of care).

for resident nursing care.[93] The Act also included a resident "bill of rights" requiring NFs and SNFs to promote and protect the rights of residents to, among other things, be free from restraints, including chemical restraints, imposed for discipline or convenience and the rights of residents to be active participants in the planning of their medical care.[94] In furtherance of the Act's intent and policy objectives, the HCFA[95] issued implementing regulations in 1989 and 1991, establishing the Conditions of Participation (CoPs) for SNFs and NFs participating in the Medicare and Medicaid programs.[96] However, enforcement of some implementing regulations did not become effective until July 1995, attributable, in part, to the large volume of comments HCFA received during the rulemaking process.[97]

On July 16, 2015, CMS issued a proposed rule to update comprehensively the CoPs for NFs and SNFs participating in the Medicare and Medicaid programs. CMS issued its final rule on October 4, 2016.[98] The final rule divided the updated CoPs into three phases—with Phase 1 requirements to be implemented by November 28, 2016 and Phase 2 and Phase 3 requirements to be implemented by November 28, 2017 and November 28, 2019, respectively.[99] CMS estimated that the total projected cost of the final rule would be $831 million in the first year of implementation, and $736 million per year in subsequent years.[100]

In a June 30, 2017 memorandum, CMS announced that it was imposing a 12-month moratorium on the use of civil money penalties, denial of payment, and/or termination from the Medicare and Medicaid programs, for facilities determined to be out-of-compliance with certain Phase 2 regulations, though noting that the regulations would still take effect on November 28, 2017.[101] CMS maintained that it would use the year-long period to "educate facilities about certain new Phase 2 quality standards by requiring a directed plan of correction or additional in-service training."[102] On November 24, 2017, CMS announced it was extending the moratorium on the enforcement of certain Phase 2 requirements for a period of 18-months, in lieu of the previously announced 12-months, "[t]o address concerns regarding the scope and timing of the revised requirements[.]"[103]

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[93] 42 U.S.C. §§ 1395i-3(b)(4)-(5) and 42 U.S.C. §§ 1396r(b) (4)-(5).
[94] 42 U.S.C. § 1395i-3(c) and 42 U.S.C. § 1396r(c).
[95] The HCFA was renamed the Centers for Medicare & Medicaid Services (CMS) in June 2001. *See* CNN, *supra* note 60.
[96] 54 Fed. Reg. 5,316 (Feb. 2, 1989) and 56 Fed. Reg. 48,826 (Sept. 26, 1991).
[97] U.S. Gen. Accounting Office, *supra* note 90.
[98] 81 Fed. Reg. 68,688 (Oct. 4, 2016).
[99] *Id.*
[100] *Id.*
[101] Memorandum from Dir., Survey and Certification Group, Centers for Medicare and Medicaid Services to State Survey Agency Directors (June 30, 2017) *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-36.pdf.
[102] *Id.*
[103] Memorandum from Dir., Survey and Certification Group, Centers for Medicare and Medicaid Services to State Survey Agency Directors (Nov. 24, 2017) *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-04.pdf. In its memo, CMS noted that it was not extending the moratorium on regulations that address reporting requirements for the reasonable suspicion of a crime due to the concerns about significant resident abuse going unreported.

III. ISSUES

The following issues may be examined at the hearing:

- Federal efforts to verify that SNFs and NFs participating in the Medicare and Medicaid programs are meeting the mandatory CoPs, which are intended to ensure that beneficiaries receive the appropriate levels of care and are free from abuse or neglect;

- The role of State Survey Agencies in overseeing SNFs and NFs, and CMS' oversight thereof;

- The consistency and proportionality of enforcement remedies imposed on SNFs and NFs that have been determined to be out of compliance with one or more CoPs;

- Evaluation of SNFs and NFs that have a commonality of ownership;

- CMS' Administration of the Special Focus Facility program;

- Implementation of the emergency preparedness rule and the adequacy of emergency preparedness in SNFs and NFs across the country; and

- HHS OIG's and GAO's work evaluating abuse, neglect, and substandard care occurring at SNFs and NFs.

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Lamar Echols, Christopher Santini, or Natalie Turner of the Committee staff at (202) 225-2927.