AMERICAN BANKRUPTCY INSTITUTE

2019 Disruption, Consolidation and Innovation in the Health Care Industry

The Next Big Wave in Health Care Restructurings

Elizabeth A. Green, Moderator
BakerHostetler; Orlando, Fla.

Hon. Kevin J. Carey
U.S. Bankruptcy Court (D. Del.); Wilmington

Felicia G. Perlman
Skadden, Arps, Slate, Meagher & Flom LLP; Chicago

Louis E. Robichaux, IV
Ankura Consulting Group, LLC; Dallas

Matthew J. Ryan
Houlihan Lokey; Chicago

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Presented By:

Elizabeth A. Green
Baker & Hostetler LLP (Orlando, FL)

Hon. Kevin J. Carey
U.S.B.C. (D. Del.) (Wilmington, DE)

Felicia G. Perlman
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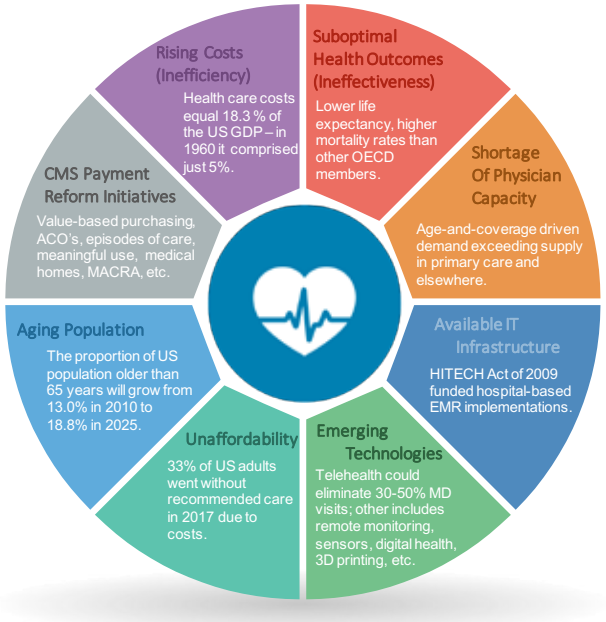
Ankura Consulting Group, LLC (Dallas, TX)

Matthew J. Ryan
Houlihan Lokey (Chicago, IL)

THE INCREASE IN HEALTHCARE COSTS FROM $3.5 TRILLION IN 2017 TO >$5.5 TRILLION IN 2025 - $2 TRILLION IN ONLY EIGHT YEARS – MAKE HEALTHCARE TRANSFORMATION INEVITABLE



Source: http://www.commonwealthfund.org/publications/in-the-literature/2016/nov/2016-international-health-policy-survey-of-adults; commentary added by Alvarez and Marsal

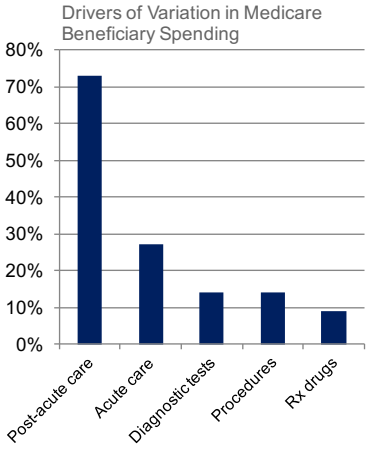
ERA OF HOSPITAL-CENTRICITY IS ENDING

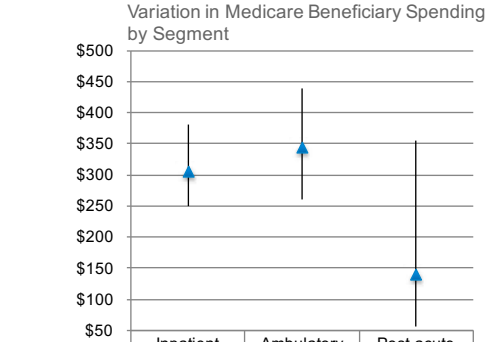
- **Inpatient volume drivers: More negative than positive**
  - Positive: Aging demographics, increased coverage – ACA Medicaid expansion and insurance mandate, economic recovery ("Great Recession") and expansion
  - Negative (all): Decline in cardiovascular admissions by 25.2% in 2005-2014 (e.g., earlier diagnosis, medical management, outpatient procedures), decline in rate of preventable admissions and readmissions, increased observation stays, increased Medicare Advantage penetration, surgical procedure volume shift to ambulatory centers, rising out-of-pocket costs (e.g., HDHP, employer cost shifting) and commercial cost subsidies (AHA statistics: Medicare - $0.88, Medicaid – 0.90)
  - Negative (rural only): Loss of local industry: population, employment, and insurance; Privately-insured seek care elsewhere due to negative perception of local care (rural)

- **Negative impact from alternative sites**
  - Growth of urgent care centers and retail clinics likely to incrementally affect ED and office visit volume
  - Ambulatory surgical volume in 2014: 9.9M, +18.2%; Inpatient surgical volume: 7.8M, -6.8%
  - Ambulatory surgical centers: 5,480 with 23% owned by hospitals. Recent consolidation: USPI/Tenet (450 centers), Envision/Amsurg (260), SCA/United-Optum (206).
  - Freestanding ASC Medicare payment is 53% of HOPD; CMS risk of site neutral payments

- **Positive impact from Medicaid expansion**
  - In 32 states, higher NPR and operating margins, particularly at safety net hospitals due to increased coverage and less uncompensated care
  - States receive FMAP of 90% for newly eligible Medicaid enrollees (vs 67% for enrollees based on pre-ACA criteria)

POST-ACUTE CARE ACCOUNTS FOR 73% OF THE VARIATION IN MEDICARE FFS BENEFICIARY SPENDING





	Inpatient	Ambulatory	Post-acute
25th percentile	$250	$260	$55
75th percentile	$380	$440	$355
▲Median	$305	$345	$140

The variation in PAC spending in PAC from the 25th to 75th percentile is 6.5x, far exceeding the variation in inpatient and ambulatory services

Source: Institute of Medicine. Variation in Healthcare Spending: Target Decision Making, Not Geography. June 2013. Note: The individual contributors sum to >100% because of covariance; MEDPAC

SKILLED NURSING FACILITIES BEING CHALLENGED BY CREATION OF HEALTH SYSTEM PREFERRED NETWORKS BASED ON QUALITY AND COST

Recent trends (since 2010)

- Number of SNFs relatively unchanged at 12,263
- Decline in Medicare FFS ($31B to $28B) and Medicaid spending ($50B to $46B), followed by slight resumption of growth
- Growth of Medicare Advantage penetration from 24-33% leading in more restrictive criteria for admissions, shorter stays and lower reimbursement of 11-37% compared to FFS
- Share of intensive rehab therapy (ultra > 12 hours/week, very high 8-12 hours/week) increased from 65% to 80%+ of Medicare FFS patients
- Decline in Medicare FFS (12.6%), non-Medicare margins (-2.0%) and net margins (1.4%)

Improving quality, though with significant variation in quality metrics

- Discharge to the community
- Potentially avoidable hospitalizations (during SNF stay, 30-days post SNF discharge)
- No improvement in mobility ADL (bed, transfer, ambulation)

Payment reform: ACO's, episode (bundled) payment models

Transitional care (high acuity) model for LTCH ineligible patients (<3 days ICU)?

Proposed change in reimbursement methodology from Resource Utilization Groups, Version 4 (RUG-IV) to a Resident Classification System, Version 1 (RCS-1)

- Under RCS-I, SNFs would receive higher reimbursement if they provided 15 or fewer days of Medicare coverage and only one form of therapy (not three). Medicare reimbursement would also be higher if 50-75% of a SNF's Medicare days were billed as non-rehabilitation.

Sources: MedPAC, Clifton Larson Allen SNF Facility Cost Comparison, 2015

HOSPITAL INPATIENT REHABILITATION FACILITIES FACE REIMBURSEMENT REDUCTION, WHEREAS LTACHS ARE BEING NEGATIVELY AFFECTED BY CHANGE IN COVERAGE CRITERIA

Inpatient rehabilitation facilities

- **Recent trends (since 2010)**
  - Medicare FFS margins have increased from 8.7% to 13.9%
  - Number of facilities, 1,182 relatively unchanged since 2002
  - Occupancy rate: 63%
- **Dichotomy between smaller hospital and larger free-standing facilities**
  - # Facilities: Hospitals 79% vs. Freestanding: 21%
  - # Discharges: 53% vs. 47%
  - Average discharges/annum: 215 vs. 722
  - Medicare FFS operating margins: 0.3% vs. 24.1%
- **CMS recognizes disparity in Medicare FFS operating margins: NFP margins of 1.5% vs. for-profit: 23.4%.**
- **HealthSouth, with 121 facilities, accounting for 21% of beds, 28% of patients served – acquired Encompass Home Health in Jan 2015**
- **FY18 reimbursement reduction of 5.0%**

Long-term acute care facilities

- **Recent trends**
  - Construction moratorium in 2007-12, combined with adverse market conditions has led to a nearly 10% decline in facilities to 391; decline in cases to 131k
  - Medicare FFS margin is 4.6%; with for-profit at 6.4% and NFP -6.0%
- **Kindred and Select Medical are the market leaders with 119 (primarily Acute Rehab Units within hospitals) and 103, respectively**
- **CMS recently changed the coverage criteria and reimbursement for Medicare FFS patients accounting for two-thirds of facility volume**
  - Beginning in FY16 and phased over 2 years, Medicare will pay LTACH rates only for patients with (a) a preceding ICU/CCU stay of 3+ days or (b) an MS-LTC-DRG for cases receiving at least 96 hours of mechanical ventilation services in the LTACH. *Only 23% of ICU patients have a LOS of 3+ days*;
  - All other Medicare patients will be paid at the site-neutral rate, which approximates 25% of the LTACH base rate.

HOME CARE REPRESENTS THE MOST ATTRACTIVE POST-ACUTE CARE SEGMENT

Recent trends (since 2010)

- Highly fragmented, with growth to 12,313 agencies
- Decline in Medicare FFS revenues from 19.6B to $18.4B
- Medicare FFS free-standing agency margins at 15.6% in 2015 despite rebasing; profitability varies widely by quintile of volume
- Hospital-based HHAs included in hospital inpatient metrics; margins for hospital-based HHAs -14.8%

Multiple drivers of longer-term growth

- Lower cost alternative to post-acute facility based care
- Medicaid Long-term Services and Support (LTSS) programs shifting away from SNFs to home care; MLTC growth
- "Aging at home" preferred by most consumers (compared to institutional care)
- Hospital at-home, as per Johns Hopkins?

Increasing focus on quality metrics

- Improvement in ambulation, ADLs, surgical wounds, pain, oral medication management, SOB
- Resource utilization: hospitalizations, ED visits +/- hospitalization
- FY16 Value-based reimbursement pilot in 9 states of 5-8% based on 25-30 quality indicators

Emerging (disruptive) technologies enable proactive and earlier communication with medical professionals, thereby facilitating timely intervention

- Remote monitoring
- Telehealth
- Fall prevention
- Sensors
- Artificial Intelligence

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HOSPICE REPRESENTS A COST EFFECTIVE ALTERNATIVE FOR END-OF-LIFE CARE

- **Recent trends (since 2010)**
  - Consolidating though still highly fragmented with 4,200 agencies; largest 100 hospice providers generate claims from 42.2% of hospice patients.
  - Medicare FFS margins of 8.2% (range: 7.4 -10.0%)
  - 46% of Medicare decedents use hospice; 75-79 (12.7%), 80-84 (17.0%) and >85 (47.4%)
- **Length of service often "too short or too long"**
  - 35% < 1 week, 14% 8-14 days; 20% > 90 days with half being live discharges
- **FY16 change in "routine care" reimbursement based on duration of service**
  - <60 days: $191; >60 days: $150
- **Increasing focus on quality metrics**
  - "Comfortable dying": Pain, shortness of breadth, nausea and constipation; and patient safety
  - Reporting of patient and family experience
- **Longer-term drivers of growth**
  - Cost-effective; 28% of Medicare spent on last six months of life
  - Aging demographics
  - Hospital preference to reduce ICU utilization and institutional mortality rate
  - Patient, caregiver and family preference and satisfaction
  - Growing acceptance of Advanced Directives and Palliative Care (through education initiatives)
  - Medicare Advantage plan termination with transfer into hospice

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HEALTHCARE DELIVERY WILL UNDERGO A TRANSFORMATION DURING THE NEXT 3-10 YEARS

Evolution of Healthcare Delivery Models	
Current Provider Model	Emerging Provider Model
Volume-driven	Value-driven
Facility and/or procedure cost	Total cost of care
Acute intervention	Proactive intervention and prevention
Disease/condition-centric	Patient-centric (co-morbidities, social determinants)
Process quality measures	Outcome quality measures
Facility-centric	Home-centric
Care fragmentation	Care integration
Uncoordinated care delivery	Coordinated care delivery
Silo'd	Across the continuum of care
Subjective (i.e., based on experience)	Objective (i.e., based on data insights)
Poor patient experience	Enhanced patient experience
Limited patient/caregiver engagement	Increased self-management
Performance: margin per service or procedure	Performance: Margin per covered or attributed life

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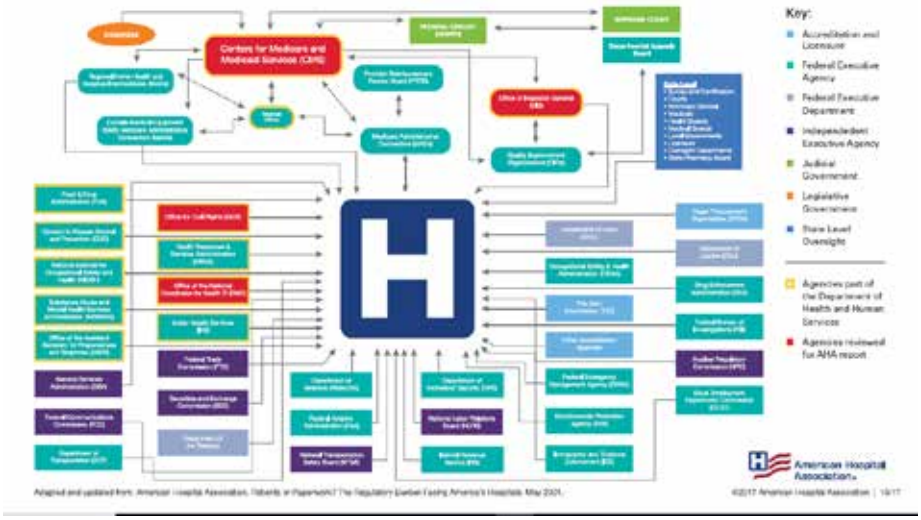
Federal Agencies with Regulatory or Oversight Authority Impacting Hospitals

Four federal agencies account for 629 regulatory requirements that health systems, hospitals and post-acute care providers must comply with, yet providers are subject to regulation and oversight from many other sources.



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OUTLINE OF US HEALTH AGENCIES (1 OF 2)
WITH FUNCTIONS RELATED TO INFECTION PREVENTION AND CONTROL

Department of Health and Human Services (HHS) -- Cabinet-Level Department which includes the following agencies:

A. Centers for Disease Control and Prevention (CDC)
1. National Institute for Occupational Safety and Health (NIOSH)
2. Coordinating Center for Infectious Diseases (CCID)
   a. National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID)
      i. Division of Healthcare Quality Promotion (DHQP)
3. Healthcare Infection Control Practices Advisory Committee(HICPAC)

B. Centers for Medicare and Medicaid Services (CMS)

C. National Institutes of Health (NIH)
1. The National Institute of Allergy and Infectious Diseases (NIAID)
2. National Library of Medicine (NLM)

D. Food and Drug Administration (FDA)
E. Health Resources and Services Administration (HRSA)
F. Agency for Healthcare Research and Quality (AHRQ)

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OUTLINE OF US HEALTH AGENCIES (1 OF 2)
WITH FUNCTIONS RELATED TO INFECTION PREVENTION AND CONTROL

II. Department of Labor (DOL) -- Cabinet-Level Department which includes:

A. Occupational Safety and Health Administration (OSHA)

III. U.S. Environmental Protection Agency (EPA) – Cabinet-Level agency

IV. Non-Governmental Agencies

A. Joint Commission
B. Institute of Medicine (IOM)

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AGENCY ACRONYMS

AHRQ:	Agency for Healthcare Research and Quality; part of HHS.
CCID:	Coordinating Center for Infectious Diseases; part of CDC.
CDC:	Centers for Disease Control and Prevention; part of HHS.
CMS:	Centers for Medicare and Medicaid Services; part of HHS.
DHQP:	Division of Healthcare Quality Promotion; part of NCPDCID under CDC
DOL:	US Department of Labor; Cabinet-level agency charged with protection of the American workforce.
FDA:	Food and Drug Administration; part of HHS.
HHS:	US Department of Health and Human Services; Cabinet-level primary health agency in the US.
HICPAC:	Healthcare Infection Control Practices Advisory Committee; part of CDC.
HRSA:	Health Resources and Services Administration; part of HHS.
IOM:	Institute of Medicine; non-governmental agency
NIH:	National Institutes of Health; part of HHS.
NIOSH:	National Institute for Occupational Safety and Health; part of CDC.
NLM:	National Library of Medicine; part of NIH.

DOES THE COURT HAVE JURISDICTION?

42 U.S.C. 405(h) as it applies to Medicare reads:

Finality of [Secretary's] decision

> **The findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decisions of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the [Secretary] or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter.**

This section is made applicable to the Medicare Act via operation of 42 U.S.C. 1395ii.

COURTS ARE SPLIT ON THIS ISSUE (1 OF 2)

In re Bayou Shores SNF, 828 F.3d 1297 (11th Cir. 2016):

> "Because we are persuaded that the 1984 amendments to § 405(h) were a codification and not a substantive change, we align ourselves with the Seventh, Eighth, and Third Circuits and hold that § 405(h) bars § 1334 jurisdiction over claims that 'arise under [the Medicare Act].'"

In re Town & Country Nursing Home Services, Inc., 963 F.2d 1146 (9th Cir. 1992):

> "The BAP rejected the Secretary's arguments and found 'the better reasoned position' to be that 'where there is an independent basis for bankruptcy court jurisdiction, exhaustion of administrative remedies pursuant to other jurisdictional statutes is not required.' … We agree."

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COURTS ARE SPLIT ON THIS ISSUE (2 OF 2)

***Family Rehabilitation Inc. v. Azar*, 886 F.3d 496 (5th Cir Mar. 27, 2018):**

> District Court found that it lacked subject matter jurisdiction over a request for TRO and injunction to prevent recoupment under Medicare. Fifth Circuit reversed, finding that District Court had jurisdiction under the collateral-claim exception to the channeling requirements of 42 U.S.C. § 405.

***Adams EMS, Inc. v. Azar,* 2018 WL 3377787 (S.D. Tex. July 11, 2018):**

> The Court granted Plaintiff's request for TRO against Secretary of the U.S. Department of HHS to require the Secretary to suspend the recoupment of an alleged Medicare overpayment based on "the alleged failure to provide the procedures for, and to timely adjudicate, an administrative appeal from the overpayment and recoupment findings."

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PROVIDER AGREEMENT: EXECUTORY CONTRACT OR NOT?

PAMC, Ltd. v. Sebelius, 747 F.3d 1214, 1221 (9th Cir. 2014) (internal citations omitted):

> "We have, on occasion, stated that providers and others have contracts with the government in this area, but our decisions have turned on the regulatory regime rather than on contract principles. ... [Here we hold that] '[u]pon joining the Medicare program, however, the hospitals received a statutory entitlement, not a contractual right.'"

In re Vitalsigns Homecare, Inc., 396 B.R. 232, 239 (Bankr. D. Mass. 2008):

> "majority of bankruptcy courts considering the Medicare-provider relationship conclude that the Medicare provider agreement, with its attendant benefits and burdens is an executory contract"

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UNIQUE FINANCIAL ASPECTS OF GOVERNMENT RECEIVABLES

- **Setoff is an equitable right of a creditor to deduct a debt it owes to the debtor from a claim it has against the debtor arising out of a separate transaction. Recoupment differs in that the opposing claims must arise from the same transaction.**

- **The Bankruptcy Code is not an independent source of law that authorizes setoff or recoupment; it recognizes and preserves setoff rights that exist under non-bankruptcy law. Section 553 of the Bankruptcy Code makes setoff available only when the obligations between debtor and creditor are (1) mutual, i.e., both obligations are held by the same parties, in the same right or capacity, and (2) both arise either prepetition or postpetition.**

- **Recoupment is the setting up of a demand arising from the same transaction or occurrence as the plaintiff's claim, to abate or reduce that claim; recoupment is recognized as an exception to the automatic stay.**

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ACQUISITION OF DISTRESSED HEALTH CARE BUSINESSES AND SUCCESSOR LIABILITY

- **Section 363(b) of the Bankruptcy Code provides a procedure for a debtor to obtain an order allowing the sale of assets free and clear of liens and most liabilities if one of the following conditions is satisfied: (1) Non-bankruptcy law permits the sale free and clear of interests (§363(f)(1)); (2) The party holding the interest in the property being sold consents (§363(f)(2)); (3) If the interest is a lien, the purchase price for the property is greater than the aggregate value of all liens on the property (meaning the debtor has equity in the property) (§363(f)(3)); (4) The validity of the interest is in bona fide dispute (§363(f)(4)) and The interest can be reduced to a claim for money (§363(f)(5)).**

- **The Second, Third, Fourth and Seventh Circuits, and many lower courts, have interpreted "any interest" expansively to include not only in rem interests in property, but also other obligations that may "arise from the property being sold."**

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SALE OF ASSETS IN BANKRUPTCY CONTINUED

- **If the Medicare Provider Agreement is an executory contract it must be transferred under section 365 of the Bankruptcy Code.**

- **The Government prefers this approach because Section 365 of the Bankruptcy Code requires the debtor to cure existing defaults and then effectively reinstates the contract as if bankruptcy had not intervened.**

- **However, if the Medicare Provider Agreement is a license to treat Medicare beneficiaries and subsequently bill Medicare, it can be sold under Section 363 of the Bankruptcy Code which can be used to limit successor liability:**

  - "The trustee, after notice and a hearing, may … sell property under subsection (b) or (c) of this section free and clear of any interest in such property of an entity other than the estate …"

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IMPACT OF HEALTHCARE BUSINESS BANKRUPTCY ON HEALTHCARE FRAUD CASES

- **The False Claims Act ("FCA") (31 U.S.C. §§ 3729–3733) applies to healthcare businesses and there is a widely held perception that the healthcare industry is full of "fraud, waste and abuse." Since the implementation in 1996 of the Health Care Fraud and Abuse Control Program, this program has "recovered" over $31 billion from the healthcare industry. As of the end of 2016 DOJ had over 1400 civil healthcare fraud matters pending.**

- **FCA cases are generally treated as exempt from the automatic stay as an exercise of a police or regulatory power. However, the Government is still required to file a proof of claim to obtain payment and section 502(c) of the Bankruptcy Code permits a bankruptcy court to estimate a claims for the purposes of allowance of the claim as to amount, voting on a plan, feasibility of a plan, and distributions under a plan. Thus, a debtor can seek a quick resolution of its liability, and do so in a favorable forum.**

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US GOVERNMENT HEALTH AGENCIES

US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention (CDC) (www.cdc.gov)

Based in Atlanta, Georgia, the CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. CDC seeks to accomplish its mission by working with partners throughout the nation and the world to

- monitor health,
- detect and investigate health problems,
- conduct research to enhance prevention,
- develop and advocate sound public health policies,
- implement prevention strategies,
- promote healthy behaviors,
- foster safe and healthful environments,
- provide leadership and training.

Those functions are the backbone of CDC's mission. Each of CDC's component organizations undertakes these activities in conducting its specific programs. The steps needed to accomplish this mission are also based on scientific excellence, requiring well-trained public health practitioners and leaders dedicated to high standards of quality and ethical practice.

Within CDC are five Coordinating Centers, the National Institute for Occupational Safety and Health, and Office of the Director

The National Institute for Occupational Safety and Health (NIOSH) ensures safety and health for all people in the workplace through research and prevention.

Of the Coordinating Centers, the one most closely related to APIC's work is the ***Coordinating Center for Infectious Diseases (CCID).*** Within CCID, the ***National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID)*** protects populations domestically and internationally through leadership, partnerships, epidemiologic and laboratory studies, and the use of quality systems, standards, and practices. NCPDCID collaborates with the Coordinating Center for Infectious Diseases (CCID), CDC, and the agency's national and global partners to conduct, coordinate, and support infectious disease surveillance, research, and prevention. Each of the center's six divisions complements this cross-cutting mission, working with internal and external partners to improve public health. APIC works most closely with the ***Division of Healthcare Quality Promotion (DHQP),*** to protect patients, protect healthcare personnel, and promote safety, quality, and value in the healthcare delivery system by providing national leadership for nine key areas.

- Healthcare outcomes,
- Outbreaks in healthcare settings,

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- Emerging antimicrobial-resistant infections,
- Efficacy of new interventions for patient safety,
- Clinical microbiology laboratory quality,
- Water quality in healthcare settings,
- Cost effectiveness of prevention interventions,
- Promotion of implementation and evaluation of prevention interventions, and
- Development of infection control guidelines and policies.

DHQP is organized into three main components: the Epidemiology and Laboratory Branch, the Prevention and Evaluation Branch, and the Healthcare Outcomes Branch.
The Epidemiology and Laboratory Branch (ELB) provides epidemiologic and laboratory assistance when investigating outbreaks of disease and other adverse events that occur in healthcare settings. ELB is a reference laboratory for U.S. hospitals and other healthcare facilities for the identification of staphylococci and their toxins, anaerobic bacteria, and enteric bacteria. ELB confirms and characterizes unusual antimicrobial resistance patterns and delineates the mechanism of resistance. ELB's environmental microbiology team is developing optimum methods to detect and decontaminate healthcare surfaces and water that may be contaminated with Category A and B bacterial agents in a bioterrorism event. The epidemiology section responds to outbreaks of new or emerging infectious diseases and other adverse outcomes associated with the delivery of healthcare. Examples of such responses include the first-ever description of rabies transmission associated with organ transplantation, investigation of nationwide outbreaks associated with contaminated medications and devices, investigation of a nationwide epidemic of Clostridium difficile-associated disease, and responding to the emergence of methicillin-resistant Staphylococcus aureus (MRSA) outside healthcare facilities, including increasing rates of MRSA skin and soft tissue disease.
The Prevention and Evaluation Branch (PEB) develops and promotes the implementation of evidence-based guidelines, recommendations, and other interventions to prevent healthcare-associated infections and antimicrobial resistance, related adverse events, and medical errors; evaluates the effectiveness of novel and proven interventions for prevention of healthcare-associated infections and antimicrobial resistance, related adverse events, and medical errors; and develops, disseminates, and evaluates training and other health communications tools designed to protect patients and healthcare personnel and to promote quality healthcare.
The Healthcare Outcomes Branch (HOB) conducts surveillance, research, and demonstration projects to measure the impact of healthcare-associated infections, adverse drug events, and other complications of healthcare. HOB staff work closely with healthcare practitioners and healthcare facilities and with partners in other federal agencies, accrediting bodies, and professional groups. A major initiative currently underway in HOB is the launch of the National Healthcare Safety Network (NHSN), a web-based system for monitoring healthcare-associated adverse events. More than 300 U. S. hospitals are enrolled; many more are expected to participate when NHSN is fully operational.

Also under the jurisdiction of CDC is the ***Healthcare Infection Control Practices Advisory Committee (HICPAC).*** HICPAC is a federal advisory committee made up of

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14 external infection control experts who provide advice and guidance to CDC and the Secretary of HHS regarding the practice of health care infection control, strategies for surveillance and prevention and control of health care associated infections in United States health care facilities. One of the primary functions of the committee is to issue recommendations for preventing and controlling health care associated infections in the form of guidelines, resolutions and informal communications. Other functions and activities include information exchange with CDC staff and formal and informal interactions with other CDC advisory committees such as the National Center for Infectious Diseases Board of Scientific Counselors, the Advisory Counsel on Elimination of Tuberculosis and the Advisory Committee on Immunization Practices.

The committee has liaison representatives from professional organizations and other federal agencies - including the Association for Professionals of Infection Control and Epidemiology Inc., the Society for Healthcare Epidemiology of America, the Association of Peri-Operative Registered Nurses, the Center for Medicaid and Medicare Services, the Food and Drug Administration; and such other non-voting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the Committee.

Centers for Medicare and Medicaid Services (CMS) (www.cms.hhs.gov)

CMS is the federal agency responsible for administering the Medicare, Medicaid, SCHIP (State Children's Health Insurance), HIPAA (Health Insurance Portability and Accountability Act), CLIA (Clinical Laboratory Improvement Amendments), and several other health-related programs.
Medicare is a federal government-funded health insurance program for:

- people age 65 or older,
- people under age 65 with certain disabilities, and
- people of all ages with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant).

Medicaid is a state administered health care coverage program for certain low-income individuals and families. Each state sets its own guidelines regarding eligibility and services.

CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that health care organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs. These minimum health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries CMS also ensures that the standards of accrediting organizations recognized by CMS (through a process called "deeming") meet or exceed the Medicare standards set forth in the CoPs / CfCs.

National Institutes of Health (NIH) (www.nih.gov)

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting medical research. Helping to lead the way toward important medical discoveries that improve

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people's health and save lives, NIH scientists investigate ways to prevent disease as well as the causes, treatments, and even cures for common and rare diseases. Composed of 27 Institutes and Centers, the NIH provides leadership and financial support to researchers in every state and throughout the world.

One of the NIH institutes, ***The National Institute of Allergy and Infectious Diseases (NIAID)*** conducts and supports research to study the causes of allergic, immunologic, and infectious diseases, and to develop better means of preventing, diagnosing, and treating these illnesses. Its many major areas of investigation include HIV/AIDS, Biodefense, Emerging and Re-emerging Infectious Diseases, Vaccine Development, and Antimicrobial Resistance.

The National Library of Medicine (NLM), the world's largest research library of the health sciences, serves scientists, health professionals, and the public.
The Library has a statutory mandate from Congress to apply its resources broadly to the advancement of medical and health-related sciences. It collects, organizes, and makes available biomedical information to investigators, educators, practitioners, and the public and carries out programs designed to strengthen existing and develop new medical library services in the United States. It conducts research in health communications, supports medical informatics, and provides information services and sophisticated tools in the areas of molecular biology and toxicology/environmental health. The Library creates Web-based services for the general public containing information from the NIH and other reliable sources.

Food and Drug Administration (FDA) (www.fda.gov)

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

Health Resources and Services Administration (HRSA) (www.hrsa.gov)

The Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services, is the primary Federal agency for improving access to health care services for people who are uninsured, isolated or medically vulnerable. Comprising six bureaus and 12 offices, HRSA provides leadership and financial support to health care providers in every state and U.S. territory. HRSA grantees provide health care to uninsured people, people living with HIV/AIDS, and pregnant women, mothers and children. They train health professionals and improve systems of care in rural communities. HRSA oversees organ, tissue and blood cell (bone marrow and cord blood) donation and vaccine injury compensation programs, and maintains

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databases that protect against health care malpractice and health care waste, fraud and abuse.

Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov)

AHRQ is the lead Federal agency on quality research. AHRQ, part of the U.S. Department of Health and Human Services, is charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services. AHRQ's broad programs of research bring practical, science-based information to medical practitioners and to consumers and other health care purchasers.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA) (www.osha.gov)

OSHA is an agency of the U.S. Department of Labor. Its role is to promote the safety and health of America's workforce, including healthcare workers, by setting and enforcing standards; providing training, outreach and education; establishing partnerships; and encouraging continual process improvement in workplace safety and health.

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA) (www.epa.gov)

The mission of the Environmental Protection Agency is to protect human health and the environment, working for a cleaner, healthier environment for the American people. EPA, an independent government agency, works to develop and enforce regulations that implement environmental laws enacted by Congress. EPA is responsible for researching and setting national standards for a variety of environmental programs, and delegates to states and tribes the responsibility for issuing permits and for monitoring and enforcing compliance. Where national standards are not met, EPA can issue sanctions and take other steps to assist the states and tribes in reaching the desired levels of environmental quality.

NON-GOVERNMENTAL AGENCIES

THE JOINT COMMISSION (Formerly the Joint Commission for the Accreditation of Healthcare Organizations [JCAHO]) (www.jointcommission.org)

The Joint Commission evaluates and accredits more than 15,000 health care organizations and programs in the United States. An independent, not-for-profit organization, The Joint Commission is the nation's predominant standards-setting and accrediting body in health care. Since 1951, it has maintained state-of-the-art standards that focus on improving the quality and safety of care provided by health care organizations. The Joint Commission's comprehensive process evaluates an organization's compliance with these standards and other accreditation or certification requirements. Joint Commission accreditation and certification is recognized nationwide

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as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. To earn and maintain The Joint Commission's Gold Seal of Approval™, an organization must undergo an on-site survey by a Joint Commission survey team at least every three years. (Laboratories must be surveyed every two years.)

The Joint Commission provides accreditation services for the following types of organizations:

- General, psychiatric, children's and rehabilitation hospitals
- Critical access hospitals
- Medical equipment services, hospice services and other home care organizations
- Nursing homes and other long term care facilities
- Behavioral health care organizations, addiction services
- Rehabilitation centers, group practices, office-based surgeries and other ambulatory care providers
- Independent or freestanding laboratories

The Joint Commission also awards Disease Specific Care Certification to health plans, disease management service companies, hospitals and other care delivery settings that provide disease management and chronic care services. It also has a Health Care Staffing Services Certification Program and is developing a certification program for transplant centers and health care services.

Joint Commission standards address the organization's level of performance in key functional areas, such as patient rights, patient treatment, and infection control. The standards focus not simply on an organization's ability to provide safe, high quality care, but on its actual performance as well. Standards set forth performance expectations for activities that affect the safety and quality of patient care. If an organization does the right things and does them well, there is a strong likelihood that its patients will experience good outcomes. The Joint Commission develops its standards in consultation with health care experts, providers, measurement experts, purchasers, and consumers.

INSTITUTE OF MEDICINE (IOM) (www.iom.edu)

The nation turns to the Institute of Medicine (IOM) of the National Academies for science-based advice on matters of biomedical science, medicine, and health. A nonprofit organization specifically created for this purpose as well as an honorific membership organization, the IOM was chartered in 1970 as a component of the National Academy of Sciences. The Institute provides a vital service by working outside the framework of government to ensure scientifically informed analysis and independent guidance. The IOM's mission is to serve as adviser to the nation to improve health. The Institute provides unbiased, evidence-based, and authoritative information and advice concerning health and science policy to policy-makers, professionals, leaders in every sector of society, and the public at large.