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DO AMERICANS HAVE A RIGHT TO BE PROTECTED FROM WRONGFUL DEATH?

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"Be patient and calm; no one can catch a fish with anger"-

-Herbert Hoover

I. Health and Life

One could be lost in the debate of what is a right in the United States. The terms constitutional, unalienable, liberty rights, negative constitution, entitlement, natural rights, and so forth, could be stretched to mean something different to everyone. If one asks a room full of people: "do Americans have a right to healthcare in the U.S. just like citizens of other countries have a right to universal healthcare in their countries?", the room will explode into debate, with some pulling to protect their best financial interests and others advocating for patients, further dividing the mix between administrators and clinicians. This is to be expected when a country's healthcare system continues to transition into a business model based on corporate and marketing theories and principles.

Some claim the right to "life" outlined in the Constitution does not equate to a constitutional right to healthcare in the U.S.¹ However, without health, there is no life, and no other guaranteed right matters. Perhaps, we are asking the wrong question. The question we should be asking is: do Americans have a right to be protected from wrongful death?

II. Healthcare costs in the U.S. and recommendations in 2007 and 2017 by the Congressional Budget Office to reduce healthcare costs

There are various U.S. and international organizations tracking issues, such as healthcare spending in the U.S., how U.S. healthcare spending compares to healthcare spending in other relatively wealthy democracies and what is projected in the future for the U.S. economy. A 2007 study by the Congressional Budget Office (CBO) concluded that without changes to federal law, total spending on healthcare would rise from 16% of gross domestic product (GDP) in 2007 to 25% in 2025, 37% in 2050 and 49% in 2082.² Despite this relatively high level of spending on healthcare, the U.S. does not appear to achieve substantially better health benchmarks when compared to other developed countries.³ Evidence exists that more expensive care does not always mean higher-quality care.⁴

The CBO's message in this study was a call for changes to the laws as these projections for future healthcare spending indicate unsustainability.⁵ This projected spending has the U.S. federal budget on a path to debt accumulation that will cause substantial harm to the economy.⁶ Medicare and Medicaid are projected to bankrupt the U.S. government in less than a decade.⁷ Most of the projected spending, other than debt interest payments, will be in the form of spending on Medicare, Medicaid and Social Security.⁸ Some have predicted that if entitlements are not reformed, future

⁵ Id.

¹ Article: State Constitutionalism and the Right to Healthcare, 12 U. Pa. J. Const. L. 1325

² https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/11-13-lt-health.pdf

³The Commonwealth Fund, Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Healthcare. By Eric C Schneider, Dana O. Sarnak, David Squires, Arnav Shah, and Michelle M. Doty, available at http://www.commonwealthfund.org/interactives/2017/july/mirror-mirror

⁴ https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/11-13-lt-health.pdf

⁶ Congressional Record 155, no. 107 (July 16, 2009): S7606–S7619, available at https://www.congress.gov/crec/2009/07/16/CREC-2009-07-16.pdf

⁷ Khan F. Article: Towards Achieving Lasting Healthcare Reform: Rethinking the American Social Contract. Annals of Health Law, 2010: 19

⁸ Congressional Record 155, no. 107 (July 16, 2009): S7606–S7619, available at https://www.congress.gov/crec/2009/07/16/CREC-2009-07-16.pdf

generations will have to pay punitive tax rates that will end liberty as we have known it, thereby hindering our prosperity.⁹ "We have seen countries like Greece, that once felt their government was "too big to fail," experience disruptive austerity and sudden drops in living standards." ¹⁰

Consistently increasing spending that outpaces revenues creates a budget deficit that:

- reduces national savings
- forces the federal government to borrow at higher interest rates
- hinders domestic investment that, in turn, depresses income growth
- forces higher taxes as a possible alternative to create revenue to pay for the federal debt, which, in turn, forces further slowdown of economic development ¹¹

The effects of rising healthcare costs are not limited to public programs; unbridled healthcare cost increases can also limit the growth of cash earnings for workers with employee-based coverage, and make individual private coverage prohibitively expensive.¹²

In 2007, analysts proposed focusing on cutting wasteful spending, such as reducing payments to the Medicare Advantage Programs, administered by private for-profit health insurance companies, as a fundamental change rather than simply reallocating spending among different sectors of the economy.¹³ Medicare Advantage Programs are estimated to have a 12% higher cost than the cost of enrolling beneficiaries in the traditional fee-for-service component of Medicare where providers are paid directly.¹⁴ In 2017, three years after the implementation of the Affordable Care Act (ACA), the CBO addressed the federal debt again. On the first of each month, the federal government pays \$24 billion to administer Medicare Advantage and Medicare Part D plans.¹⁵ (EXHIBIT 1)

In 2017, the CBO, once again, called for reform in federal laws to address the rising federal budget deficit because the nation's spending growth continued to outpace growth in revenues.¹⁶ Analysts also agreed that the most important factor driving the long-term growth of healthcare costs was the emergence, adoption and widespread diffusion of new medical technologies and services that increase demand.¹⁷ Aging of the population is another factor in increased healthcare costs. However, without reforming the current financing structure of healthcare in the U.S., any attempts to reform the U.S. healthcare system in general will continue to be ineffective.

The Centers for Medicare and Medicaid Services (CMS) and the Office of the Actuary National Health Statistics 2016 report on National Health Expenditure shows the U.S. spent \$3.3 trillion

https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53336-debtlimit.pdf

⁹ Saving The American Dream: The Heritage Plan to Fix The Debt, Cut Spending, and Restore Prosperity, May 10, 2011, State News Service

¹⁰ Id.

¹¹ Id.

 ¹² Healthcare Spending CQ Congressional Testimony, Peter Orszag, Director Congressional Budget Office, January 31, 2008
 ¹³ Congressional Budget Office, The Long Term Outlook for Healthcare Spending, November 2007, available at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/11-13-lt-health.pdf

¹⁴ Id

¹⁵ Congressional Budget Office, Federal Debt and the Statutory Limit, November 2017, available at

¹⁶ Id.

¹⁷ Healthcare Spending CQ Congressional Testimony, Peter Orszag, Director Congressional Budget Office, January 31, 2008

(\$10,348 per person) for 2016.¹⁸ The share of GDP devoted to health was 17.9% in 2016—up from a 17.7% share in 2015.¹⁹ The years 2015 and 2016 reflect the implementation of the ACA. This is a major increase from the year 2000 when the GDP devoted to healthcare was 13.3%, or \$4,855 per person,²⁰ and access to health insurance was affordable for both employers and employees.²¹ The major healthcare programs', primarily Medicare, spending continues rising as a share of U.S. GDP.²² The CBO projects that federal debt held by the public would amount to 74% of GDP over the next several years—more than twice what it was at the end of 2007 and more than in any previous year since 1950.²³ The U.S. national debt was 5.7 trillion in the year 2000, 21.5 trillion by 2018²⁴ and is projected to continue increasing.

Despite the CBO's recommendations and projections, CMS predicted that healthcare spending would increase at an accelerated pace beginning in 2018, mainly because of higher spending on Medicaid and Medicare, and projected faster growth in medical prices compare to recent historical lows.²⁵ In 2016, the U.S. already spent twice as much on healthcare (\$10,348 per person) than the average spent by other comparable wealthy nations similar in size (\$5,169 per person), and 31% higher than Switzerland, the next highest per capita spender (\$7,919 per person).²⁶ The federal government borrows 40 cents of every dollar it spends.²⁷ Further, the U.S. population continues to grow, from approximately 308 million in the 2010²⁸ to roughly 321 million in 2017.²⁹

While the U.S. has similar public healthcare spending as other comparable nations, by 2017, U.S. private sector spending on healthcare was triple that of other countries' private sector healthcare spending.³⁰ U.S. private sector healthcare spending is 8.8% of GDP, compared to 2.7% on average in other similar countries.³¹ These numbers affirm the CBO's 2008 warning that employee-base coverage and individual private coverage will become prohibitively expensive.³²

III. Healthcare in the 1980s and 1990s: America's traditional Model of Care

¹⁸ Office of the Actuary National Health Statistics Group, National Healthcare Spending in 2016, available at https://www.cms.gov

¹⁹ Id.

²⁰ Id.

 ²¹ Sara R. Collins, Munira Z. Gunja, and Michelle M. Doty, How Well Does Insurance Coverage Protect Consumers from Health Care Costs? Findings from the Commonwealth Fund Biennial Health Insurance survey, 2016, October 18, 2017
 ²² Healthcare Spending Today and in the Future: Impact on Federal Deficit and Debt, March 30, 2017, available at www.cbo.gov/publication/52480

²³ Congressional Budget Office, Updated Budget Projections: 2015-2025 (CBO, March 2015)

²⁴ <u>https://treasurydirect.gov/govt/reports/pd/histdebt/histdebt_histo5.htm</u>

²⁵ The Centers for Medicare and Medicaid Services, Press release: 2016-2025 Projections of National Health Expenditures Data Released Feb 15, 2017, available at <u>https://www.cms.gov/newsroom/press-release/2016-2025-projection-national-health-expenditures-data-release</u>

²⁶ Bradley Sawyer and Cynthia Cox, How does health spending in the U.S. compares to other countries, Feb 13, 2018, available at https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start

²⁷ Saving The American Dream: The Heritage Plan to Fix The Debt, Cut Spending, and Restore Prosperity, May 10, 2011, State News Service

²⁸ United States Census Bureau, Census 2010, available at <u>https://factfinder.census.gov/faces/nav/jsf/pages/community_facts.</u>
<u>xhtml?src=bkmk</u>

²⁹ Id.

³⁰ Bradley Sawyer and Cynthia Cox, How does health spending in the U.S. compares to other countries, Feb 13, 2018, available at https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/#item-start ³¹ Id.

³¹ Id

³² Healthcare Spending CQ Congressional Testimony, Peter Orszag, Director Congressional Budget Office, January 31, 2008

A Health Care Finance Review in the early 1990s described the U.S. as having no single nationwide system with health services provided by a loosely structured delivery system organized at the local level with little coordination between private and public programs.³³ This not only undermined the clinical team that delivered those services, but it also compromises "the core American principles of free enterprise and individual rights, as well as moral commitment to protect the less fortunate, themes expressed throughout the U.S. Constitution and separate states' constitutions."³⁴

The Health Care Finance Review acknowledged that "nevertheless, persons without health insurance were not entirely without healthcare; although they received fewer and less coordinated services than those with insurance, many of the "uninsured" received health services through public clinics and hospitals, state and local health programs or private providers who finance the care through charity and by many shifting costs to other payers."³⁵ This review did not mention the clinicians who provided services past their shift to care for patients without any compensation, but rather to meet a social commitment to the community and patients in any setting.

Reports or statements describing the U.S. healthcare structure before the ACA are very different from how a clinician would describe it. The traditional American Model of Care was patient-centered³⁶ and based on patients' healthcare needs and diagnoses. The objectives of illness-prevention activities were to reduce the risk of illness, promote good health habits and maintain the individual's optimal function.³⁷ Services were provided by licensed professionals, guided by their respective disciplines' authoritative body of knowledge.³⁸ Patients' outcomes measured the effectiveness of care rendered or guided the implementation of changes to the individual patients' plan of care when problems remained unresolved.³⁹

Professional standards of care (SOC) and standards of practice (SOP) defined the legal due care expected from doctors and nurses.⁴⁰ Education and licensing defined each discipline's **s**cope of practice.⁴¹ Physicians were primarily responsible for the diagnosis of illnesses and the medical or surgical treatment of that illness.⁴² In this context a "model" is a framework used to describe a profession and theories are based on the ideas described in the model.⁴³ Models provide a body

 ³³ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ³⁴ Article: State Constitutionalism and the Right to Health Care, 12 U. Pa. J. Const. L. 1325

³⁵ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992 ³⁶ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone,

^{1993,} J.B. Lippincott Company

³⁷ Id.

³⁸ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, J.B. Lippincott Company

³⁹ Applications of the Nursing Process and Nursing Diagnosis: An Interactive Text, Marilyn E. Donges, Mary Frances Moorhouse, 1992 by F.A. Davis Company

⁴⁰ Campbell v. Hosp. Serv. Dist. No. 1, 862 So. 2d 338, 2003 La. App. LEXIS 3340, 37,876 (La.App. 2 Cir. 12/10/03)

⁴¹ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, J.B. Lippincott Company

⁴² Id.

⁴³ Health Assessment in Nursing, Second edition, Patricia Gonce Morton, 1993, F.A. Davis Company

of knowledge that can be applied to the profession's practice to allow practitioners to explain their profession.⁴⁴ Medical models tend to emphasize the cure of diseases.⁴⁵

Nurses complemented the prescribed medical treatment for a specific illness or condition by developing a nursing care plan that incorporated the "nursing diagnosis and treatments to address human responses to actual and potential illness/health problems."^{46,47,48} To avoid confusion and objections "to nursing diagnosis because the word "diagnosis" has a medical connotation, many nurses preferred the terms need or problem."⁴⁹ An understanding of basic human needs and the individualized definition of wellness and illness prepared the nurse to integrate the human dimension into the care given in order to promote wellness, prevent illness, restore health and facilitate coping with altered function or death.⁵⁰ Nursing models tend to emphasize the human response to illness.⁵¹

In the 1980s, initiatives stressed the importance of defining the role and practice of community health nursing and public health nursing with a vision to care for individuals within the framework of a healthy community.⁵² Clients (patients) in the home were under the care of a physician who certified a medical plan of treatment, to be reviewed at least every 60 days, or as needed, given changes in a patient's condition.⁵³ Nursing was evolving from a technical service to a patient-centered process and a profession with its own body of knowledge. Furthermore, nursing was gaining recognition as a profession based on the criteria a profession must have: a strong scientific base, strong service orientation, recognized authority by a professional group, a code of ethics and a professional organization that sets standards, engages in ongoing research and institutes professional autonomy.⁵⁴

Nursing education was, and still is, fragmented. Education preparation for nursing practice involves several different types of programs:⁵⁵ Licensed Practical Nurse (LPN) and Licensed Vocational Nurse (LVN) are one-year programs; Associate Degree Registered Nurse (RN) is a two- year program; Diploma in Nursing RN is a three-year program; Baccalaureate in Nursing (RN-BSN) is a four-year program. A master's degree in nursing prepares the nurse for managerial roles, education and for clinical specialist roles. A Nurse Practitioner is a master's degree RN with privileges to prescribe medication, a role that was traditionally reserved for physicians. A doctoral degree in nursing prepares nurses for advanced academic work and research.

⁴⁴ *Id*. P. 20

⁴⁵ *Id.* P. 26

⁴⁶ Applications of the Nursing Process and Nursing Diagnosis: An Interactive Text, Marilyn E. Donges, Mary Frances Moorhouse, 1992, F.A. Davis Company

⁴⁷ Health Assessment in Nursing, Second edition, Patricia Gonce Morton, 1993, F.A. Davis Company

⁴⁸ *Id.* NANDA taxonomy of Nursing Diagnosis

⁴⁹ Health Assessment in Nursing, Second edition, Patricia Gonce Morton, 1993, F.A. Davis Company P.24

⁵⁰ *Id.* P. 2

⁵¹ American Nurses Association (ANA) (1980)

⁵² Community Health Nursing Theory and Practice, Claudia M. Smith, Frances A. Maurer, 1995, by W.B. Saunders Company P. 4-7

⁵³ Id. P. 784

⁵⁴ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, J.B. Lippincott Company P. 8

⁵⁵ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, by J.B. Lippincott Company P. 12

There was, and still is at present, a disconnection in diffusing the profession of nursing's body of knowledge from theory to actual clinical practice. There are still many nurses that do not know that NANDA stands for North American Nursing Diagnosis Association or cannot even provide a short description of "nursing diagnosis." The nursing profession would have benefitted from standardizing the educational preparation of all clinical nurses prior to adding advanced clinical degrees with expanded roles. Worth noting is the difference between public and private hospital in the 1990s - public hospitals held nurses accountable for completing a printed nursing care plan to complement the nurse's note in SOAP/SOAPIER format,⁵⁶ while private hospitals had nurses just complete a note. Today, nurses are buried in the EMR and some collecting "core measures" data.^{57,58}

Medical diagnoses specify illnesses or conditions, such as diabetes, heart failure, hepatitis, cancer and pneumonia.⁵⁹ Medically necessary care was mostly covered by public and private health insurance. Non-medically necessary care, like cosmetics and fertility, were mostly affordable because providers had to compete to attract patients or individuals had to plan for it and pursue treatment that they could afford, however, their lives did not depend on the treatments or services. Ideally, proper "medical necessity" decision-making approves medically appropriate care for payment and denies payment for inappropriate care.^{60,61} Separating medically necessary care to cover all citizens from non-medically necessary care is essential to maximize resources and maintain an equitable and sustainable healthcare system.^{62,63} Otherwise, the U.S. is at risk of funding non-medically necessary care for some patients while others go without life-saving treatments.

The U.S. also had a payment structure to cover the medically-necessary healthcare needs of the population: traditional Medicare for the elderly, retirees and some of the disabled funded by the government from taxes collected from employee wages throughout their work-life;^{64,65} traditional Medicaid for some of the poor jointly funded by states and the federal government;⁶⁶ affordable employee-employer sponsored plans for workers and their families, mainly through for-profit health insurance companies,⁶⁷ and charity care for others not covered.⁶⁸ CMS were established to

http://www.nationalacademies.org/hmd/~/media/8D03963CAEB24450947C1AEC0CAECD85.ashx

⁶⁴ <u>CMS.gov, Medicare Program - General Information</u>

⁵⁶ Applications of the Nursing Process and Nursing Diagnosis: An Interactive Text, Marilyn E. Donges, Mary Frances Moorhouse, 1992 by F.A. Davis Company P. 115-119

 ⁵⁷ <u>https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Core-Measures.html</u>
 ⁵⁸ Core Measures: The Nurse's Role, Three (3.0) Contact Hours, Bette Case di Leonardi, Course Expires: 12/10/2016 First

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⁵⁹ Applications of the Nursing Process and Nursing Diagnosis: An Interactive Text, Marilyn E. Donges, Mary Frances Moorhouse, 1992 by F.A. Davis Company P.36

⁶⁰ Article: Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring, Targeted Enforcement, and Regulatory Reform, 120 Penn St. L. Rev. 109

⁶¹ Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential Health Benefits January 14, 2011 @

 ⁶² Article: Unhealthy Determinations: Controlling "Medical Necessity", 22 Va. J. Soc. Pol'y & L. 435
 ⁶³ Id.

⁶⁵ 26 USCS § 3402

 ⁶⁶ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ⁶⁷ Sara R. Collins, Munira Z. Gunja, Michelle M. Doty, How Well Does Insurance Coverage Protect Consumers from Health Care Costs? Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2016, October 18, 2017

⁶⁸ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992

administer Medicare and the federal portion of Medicaid.⁶⁹ Care for the elderly retirees and the poor was coordinated by CMS through local Department of Health and Human Services.

When employers partially compensate employees, in the form of health benefits, they are subject neither to personal income tax nor Social Security tax; if such wages were taxed as income, then Federal revenues would have increased by an estimated \$56 billion in 1990.⁷⁰ Workers replenished the Medicare fund from taxes collected from employee wages.⁷¹ This part of the population was usually healthier, able to coordinate their care (and their family's care) with or without assistance; moreover, this portion of the population followed up with their care with primary care or community physicians.

Hospitals were mostly held to their not-for-profit status by virtue of operating for their primary purpose: to serve the community.⁷² The specialized nature of hospital facilities limited the value of such facilities outside the context of an operating hospital.⁷³ The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) "evaluated healthcare organizations and inspired them to excel in providing safe and effective care of the highest quality and value".⁷⁴ JCAHO made on-site visits to hospitals and set national accreditation standards for hospitals and organizations. Facility administrators' primary role was to administrate the facilities.

Small businesses, like home care agencies, offered services to the government and the private sector. Competitive for-profit and non-for-profit healthcare providers, organizations and facilities delivered the bulk of healthcare services, including to government program beneficiaries, through contractual arrangements.⁷⁵ It was easier to hold individual providers and smaller facilities accountable. Patient confidentiality was maintained and shared on a minimum-to-know basis for clinical purposes to coordinate services and care for the individual patient. The complexity and contradictions of the Health Insurance Portability and Accountability Act (HIPAA) was just evolving,⁷⁶ and the Electronic Medical Record (EMR)⁷⁷ was not available yet.

Professional practice of individual disciplines (medicine, nursing, social work, physical therapy, and so forth) was, and still is, rooted in a strong scientific basis with respective professional boards to maintain each disciplines' standards of care and practice, while holding its members accountable for competent practice.⁷⁸ In healthcare, special duties arise from the contractual aspects of the physician (clinician)-patient relationship.^{79,80} Standards of care and practice are the measuring

74 http://www.jointcommission.org/

⁶⁹ National Archives, Centers for Medicare & Medicaid Services, Office of the Federal Register, available at https://www.federalregister.gov/agencies/centers-for-medicare-medicaid-services

⁷⁰ Id.

⁷¹ 26 USCS § 3402

 ⁷² Valuation of Hospitals and Medical Centers, James J. Unland, Published by the Health Management Research Institute, 1989
 Chapter 5

⁷³ Id.

⁷⁵ Id.

⁷⁶ HIPAA and Confidentiality: Practice May Change, But Principles Endure, Course CE 513, Margaret Ecker, MS, RN, PNP, available at https://lms.nurse.com/Asps/CourseContent.aspx?uniqueid=28616190&topicid=863&page=2&lsAnthology=1

⁷⁷ H.R.1- 111 Congress (2009-2010), American Recovery and Reinvestment Tax Act of 2009, HITECH Act

 ⁷⁸ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, by J.B. Lippincott Company

⁷⁹ The Law of Healthcare Administration, J. Stuart Showalter, Seventh Edition P. 104

⁸⁰ Johnston v. St. Francis Med. Ctr., 799 So. 2d 671, 2001 La. App. LEXIS 2423, 35,236 (La. App. 2 Cir. 10/31/01);

tools for determining if a healthcare practitioner was negligent in the delivery of care.⁸¹ Malpractice is the term generally used to describe negligence of professional personnel.⁸²

In the 1980s and 1990s, there was no need to specify that the clinical team meant the clinicians that delivered direct clinical care and established a legal duty of care to the patient. Administrators tended to their administrative duties, not influencing the provision of direct patient care; therefore, it was not a necessity for administrators to document in patients' records. The healthcare team took care of patients with a fiscal responsibility for providing timely medically necessary care for a patient's well-being and safety, and to maximize resources. Administrators had a fiscal responsibility to maintain the institution's viability.

It should be common sense that any system that prevents a physician (clinician) to treat a patient for his/her condition (diagnosis) based on authoritative clinical knowledge (treatments), because it is not profitable for the healthcare insurance industry or a vast source of revenue for the hospital corporation industry, is simply an outrage! The U.S. had laws to protect the safety of patients, increase access to care and discourage the commercialization and exploitation of the medical profession.⁸³

The financial world, on the other hand, was not as fragmented, and saw the opportunity to see patient utilization of services as a financial tool such that it creates models for "hospital and medical centers to acquire real economic value primarily by virtue of their ability to generate net cash flow (sometimes called 'free cash flow'), regardless of whether they were operated as for-profit or not-for-profit organizations."⁸⁴ In order to gain insight into a hospital's business fundamentals and their effect upon cash flow, five key areas of business performance need to be examined:⁸⁵

- market position;
- regulatory position (including federal, state and local legislative bodies; agencies of the federal government; state and federal licensing agencies; municipal and county health departments, as well as zoning commissions; third-party payers, such as insurance companies, public health departments, Medicare and Medicaid);
- operations;
- physical facilities; and
- financial position.

Patient utilization, market position and market share were to be evaluated keeping in mind their influence upon cash flow.⁸⁶ During the 1980s, the hospital industry went through a "reorganization craze" which caused single entity, straightforward community hospitals to become multiple-entity,

⁸¹ id

⁸² Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, by J.B. Lippincott Company

⁸³ The Law of Healthcare Administration, J. Stuart Showalter, Seventh edition

⁸⁴ Valuation of Hospitals and Medical Centers, James J. Unland, Published by the Health Management Research Institute, 1989 Chapter 5

⁸⁵ Id.

⁸⁶ Id.

multi-tiered "health corporations," and it became truly amazing how complicated the right attorney could make even the smallest community hospital organization - and get paid (a lot) for it!⁸⁷

The Health Care Finance Review, at the beginning of this session, that reported in the 1980s and 1990s "persons without health insurance were not entirely without healthcare" was in "ignorance" or lacking "full awareness" of how the structure and coordination of services in the U.S. healthcare system was meant to work.⁸⁸ Notwithstanding, the report continued to find "flaws" with the healthcare system, stating: "the financing and delivery system of the 80s and 90s had little incentive to contain cost as long as a third-party payer would honor any bill submitted; and the third-party insurer-payer had little incentive to pressure providers to control cost if the insured (or his representative, typically an employer) was willing to pay an ever-increasing health insurance premium.".⁸⁹

The movement to "sell" healthcare as a business and run it as an enterprise to generate "cash flow" went slowly into motion with business practices that, in this author's view, are not applicable to healthcare as they are unethical and even criminal. Economists claim that "basic economic principles related to the unsustainability of U.S. healthcare costs have made the transformation of moving healthcare from a volume-based model, in place since the 1960s, to a value-based business model inevitable."⁹⁰ This author will argue that the undermining of America's core principles and values, compromising the traditional American Model of Care and the unleashed insatiable greed of for-profit (or revenue-generating) enterprises are the marketing tools to sell the story of the "inevitable transformation" sound real.

In healthcare, utilization is intended to be a cost control measure as well as a monitoring tool. Over-utilization could signal patients' deteriorating health. Over-utilization can also represent misuse of unnecessary services that suggests possible fraud, abuse, improper billing and even unethical/predatory "marketing". Unlike businesses, where "over-utilization" or increased sales means profit, revenue and is the desired outcome of marketing, over-utilization or unnecessary utilization of services is not a desired outcome in healthcare. Affordable primary care, preventive care and early chronic disease management are paramount to maintaining individuals at their healthiest functional levels and preventing most of the expensive treatments needed with advanced and deteriorating conditions.⁹¹

Market share increases can allow a company to achieve greater scale with its operations and improve profitability.⁹² Market share also elevates executive salaries, and that is added to the costs that patients must pay for services. A company that is growing its market share will be raising its revenues faster than its competitors.⁹³ Hospital administrators in the 1980s and 1990s should have

⁸⁷ Id.

⁸⁸ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992 ⁸⁹ *Id.*

⁹⁰ A Primer on Hospital Accounting and Financing for Directors and Other Healthcare Providers, Felix Kaufman, PHD, CPA, Fifth edition

⁹¹ The Uninsured: A Primer, The Kaiser Commission on Medicaid and the Uninsured, November 2016, available at http://files.kff.org/attachment/Report-The-Uninsured-A%20Primer-Key-Facts-about-Health-Insurance-and-the-Unisured-in-America-in-the-Era-of-Health-Reform

⁹² Market Share, Will Kenton, July 26, 2018, Investopenia, available at https://www.investopedia.com/terms/m/marketshare.asp

⁹³ Id.

known, based on basic accounting, marketing and business principles, that the business concept of market share applied to healthcare is the antithesis of the utilization review and utilization-management processes designed to "prevent unnecessary services and control cost in healthcare."⁹⁴

In the context of market share in healthcare, one health system expanding beyond what is needed to serve the community will drive "negative competition", forcing other health systems to "compete" and stay visible in the community. Certain communities and states will have an excess of duplicate services, and others will be left underserviced or provided substandard services. The business model and marketing activities described by the Marketing Accountability Standards Board⁹⁵ to generate cash flow do not work in healthcare because a person cannot be forced to buy a product they cannot afford, and providing excess services not needed to patients with coverage for the purpose of billing is fraudulent.

IV. Protecting the medically-necessary care review can save patients' lives and prevent unnecessary healthcare expenditure

According to the American Medical Association (AMA), "medical necessities" are healthcare services or products that a prudent physician would provide to a patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:

- in accordance with generally accepted standards of medical practice;
- clinically appropriate in terms of type, frequency, extent, site and duration; and
- not primarily for the economic benefit of the health plans and purchasers or for the convenience of the patient, treating physician or other healthcare provider.⁹⁶

Effective in 2014, the ACA requires all qualified health benefits plans, including those in exchanges and within individual and small group markets outside of exchanges, with the exception of grandfathered individual and employer-sponsored plans, to offer at least an essential health benefits package with the following general categories of services: ambulatory services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, including behavioral health treatment, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive care, wellness care, chronic disease management and pediatric services, including oral and vision care.⁹⁷

Benefit and coverage mandates attempt to ensure that health insurance companies provide plans that cover essential health services. However, mandates are hotly contested by the health insurance industry based on arguments of impinging upon the right to free contracts and debates that mandates raise premiums for all consumers, thereby contributing to rates of uninsurance.⁹⁸ The

 ⁹⁴ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ⁹⁵ Statement of Marketing Accountability Standards No. 1, Marketing Metric Audit Protocol, February, 2009

 ⁹⁶ Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential Health Benefits January 14, 2011, available at http://www.nationalacademies.org/hmd/~/media/8003963CAEB24450947C1AEC0CAECD85.ashx

⁹⁷ Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential Health Benefits January 14, 2011, available at <u>http://www.nationalacademies.org/hmd/~/media/</u> <u>8D03963CAEB24450947C1AEC0CAECD85.ashx</u>

⁹⁸ Article: Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring Targeted Enforcement and Regulatory Reform. 120 Penn St. L. Rev 109

Institute of Medicine (IOM) found evidence that suggests while some mandates contribute to rising premiums, others reduce premiums; but there are concerns that certain mandates are not "evidenced-based" and do not always reflect best practices.⁹⁹

Proponents of mandates point out that mandates could help correct market failures and reduce costs if they are medically appropriate because consumers foregoing appropriate care that is not covered, by insurance, could get sicker and require more expensive care.¹⁰⁰ This evidence is not new. Even in the 1980s, a RAND retrospective study of medical procedures found that 15-30% of those medical procedures were inappropriate, unnecessary or both, inferring that the medical evidence did not justify the medical intervention.¹⁰¹ If the estimate for clearly inappropriate procedures alone were applied to all medical spending, this would amount to unnecessary expenditures of between \$99 billion to \$198 billion in 1990.¹⁰²

The "prudent physician" standard of medical necessity ensures that physicians are able to use their expertise and exercise discretion, consistent with good medical care, in determining the medical necessity for care to be provided to each individual patient.¹⁰³ Physicians (clinicians) have a legal "duty of care" to patients; meaning a doctor (clinician) owes to the patient a degree of skill, care and diligence as possessed by or expected of a reasonably competent physician (clinician) under the same or similar circumstances.¹⁰⁴ The courts have held that "a physician treating a patient is not held to a standard of absolute precision; rather, his/her conduct and judgment are evaluated in terms of reasonableness under the circumstances existing when his/her professional judgment was exercised, and not on the basis of hindsight or in light of subsequent events." ¹⁰⁵ The same is true for other licensed clinicians.

Determining medical necessity of treatments and procedures is a necessary component of any healthcare system that is committed to providing high-quality healthcare at a sustainable cost; however, reliance on medical necessity to determine healthcare coverage is only as productive as the larger health care system within which medical necessity determinations occur.¹⁰⁶ Definitions of both "medical" and "necessity" are flexible and interpretations are varied; as a consequence, the value of medical necessity determinations depends on the character of a nation's healthcare delivery and payment structure, and on the identity of those rendering medical necessity determinations.¹⁰⁷ An evaluation of the process underlying medical necessity decision-making could provide some indication of plans' willingness to exercise sound discretion.¹⁰⁸

V. CMS coordinated* and fragmented programs: Vulnerability for waste, fraud, abuse and unjust enrichment

¹⁰⁶ Article: Unhealthy Determinations: Controlling "Medical Necessity," 22 Va. J. Soc. Pol'y & L. 435
 ¹⁰⁷ Id.

⁹⁹ Id.

¹⁰⁰ Id.

¹⁰¹ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992 ¹⁰² *Id.*

¹⁰³ Id.

¹⁰⁴ Core Curriculum for Legal Nurse Consulting, Vickie L. Milazzo, RN, MSN, JD, Twelfth edition, Medical Legal Consulting Institute, Inc., 1985-2005

¹⁰⁵ Campbell v. Hosp. Serv. Dist. No. 1, 862 So. 2d 338, 2003 La. App. LEXIS 3340, 37,876 (La.App. 2 Cir. 12/10/03);

¹⁰⁸ Article: Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring, Targeted Enforcement, and Regulatory Reform, 120 Penn St. L. Rev. 109

*This author has refrained from using the term "publicly" funded programs, as Medicare is not publicly funded, but services for Medicare members are coordinated by CMS through traditional Medicare or Medicare Advantage Programs. (Section VI - Managed Care and Exhibit 1)

An entitlement program in the U.S. means all eligible for enrollment in the program are legally entitled to receive benefits, and the government cannot refuse to provide beneficiaries all medically necessary and covered services owing to lack of funds.¹⁰⁹ Entitlement programs do not have a cap on spending; therefore, funds have to be available to meet rising healthcare costs and unexpected needs.¹¹⁰ This is a critical consideration as Medicare and Medicaid are projected to bankrupt the U.S. government in less than a decade.¹¹¹

CMS¹¹² was created to administer oversight of the Medicare program and the federal portion of the Medicaid program to: ensure program beneficiaries are aware of the services for which they are eligible and that those services are accessible and of high quality, to develop health and safety standards for providers of healthcare services authorized by Medicare and Medicaid legislation and to administer the State Children's Health Insurance Program (SCHIP), the HIPPA regulation and several other health-related programs.

- Traditional Medicare is the federally funded health insurance program for retirees 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).¹¹³ Medicare is funded by the government from a tax collected from employee wages.¹¹⁴
- Traditional Medicaid is the health insurance program for certain groups of the poor. It is jointly financed by the federal and state governments.¹¹⁵

In addition to entitlement programs, The Children's Health Insurance Plan (CHIP) is a block grant program that is a sum of money allocated from the federal government to states over a certain period of time.¹¹⁶ If program's costs exceed available funds, additional money will not be made available.¹¹⁷ There are numerous other important health insurance and direct service programs funded by federal, state and local governments to provide assistance to certain populations. Some examples are: the Ryan White Care Act for HIV/AIDS patients, the Women, Infants and Children (WIC) assistance program to provide supplemental nutrition and education to poor women and their children and the Indian Health Service for American Indians and Alaska Natives.¹¹⁸ There

¹⁰⁹ Joel B. Teitelbaum and Sarah E. Wilensky (2017) Essentials of Health Policy and Law, Burlington, MA, Jones & Bartlett Learning

¹¹⁰ Id.

¹¹¹ Khan F. Article: Towards Achieving Lasting Healthcare Reform: Rethinking the American Social Contract. Annals of Health Law, 2010: 19

¹¹² National Archives, Centers for Medicare & Medicaid Services, Office of the Federal Register, available at <u>https://www.federalregister.gov/agencies/centers-for-medicaid-services</u>

¹¹³ CMS.gov, Medicare Program - General information

^{114 26} USCS § 3402

 ¹¹⁵ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ¹¹⁶ Joel B. Teitelbaum and Sarah E. Wilensky (2017) Essentials of Health Policy and Law, Burlington, MA, Jones & Bartlett Learning, Chapter 11

¹¹⁷ *Id.* ¹¹⁸ Id

are also waiver programs such as the New York State Medicaid Traumatic Brain Injury Waiver program.¹¹⁹

The State Children's Health Insurance program (SCHIP) of 1997, and later reauthorized in 2009 under the Children's Health Insurance Program Reauthorization Act, is funded by the federal government through block grants.¹²⁰ In order for states to be eligible for payment under Medicaid, each state must submit a Title XXI plan for approval by the Secretary of the Department of Health and Human Services (DHHS) that details how the state intends to use the funds and fulfill other requirements under the law and regulations at 42 CFR Part 457.¹²¹

- 1. **Separate CHIP:** A program under which a state receives federal funding to provide child health assistance to uninsured, low-income children that meets the requirements of section 2103 of the Social Security Act.
- 2. **Medicaid expansion CHIP:** A program under which a state receives federal funding to expand Medicaid eligibility to targeted low-income children that meet the requirements of section 2103 of the Social Security Act.
- 3. **Combination CHIP:** A program under which a state receives federal funding to implement both a Medicaid expansion and separate CHIP.

Despite all these programs, millions of Americans, including children, are left uninsured or underinsured, families are bankrupted and the nation's healthcare spending continues to grow unsustainably.

VI. Managed care, the utilization review and utilization management review: An expensive and failed attempt to reform the U.S. healthcare system that often leads to diagnostic errors, may cause patients harm and even lead to death

The managed care movement in the 1980s was initiated to "control healthcare costs."¹²² CMS began hiring private for-profit insurance companies to progressively become administrators for some of the government and publicly funded programs. Healthcare insurance plans managed and administered by for-profit health insurance companies are also known as Advantage Plans. The federal government did not regulate insurance companies.¹²³ It is unclear to this author at which point CMS empowered the administrators of Advantage Plans to conduct utilization reviews (UR) and utilization-management (UM) reviews by applying "evidenced-based" guidelines to override medical judgment and deny medically necessary care deemed non-medically necessary by the insurers (who are manly for-profit). Based on a simple common sense definition, for-profit health insurance administration is the antithesis of social services administration. As mentioned earlier,

¹¹⁹ NYS Department of Health, available at <u>https://www.health.ny.gov/health_care/medicaid/program/longterm/tbi.htm</u> ¹²⁰ Joel B. Teitelbaum and Sarah E. Wilensky (2017) Essentials of Health Policy and Law, Burlington, MA, Jones & Bartlett Learning

¹²¹ CMS.gov/chip/state-program-information/index.html

¹²² The Law of Healthcare Administration, J. Stuart Showalter, Seventh edition

¹²³ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992

on the first of each month, the federal government pays \$24 billion to administer Medicare Advantage and Medicare Part D plans.¹²⁴ (**EXHIBIT 1**)

A physician caring for a patient has a legal duty of care to the patient, and the interference from insurance claims reviewers to deny care deemed medically necessary by a physician is disruptive to the physician-patient relationship.^{125,126} Patients should reasonably expect that their treating physicians (clinicians) exercise sound judgment surrounding the services, treatments and medications they are provided, and that clinical decisions are based on authoritative clinical knowledge, tested and improved through the years. Diagnostic errors may cause harm to patients by preventing or delaying appropriate treatment, providing unnecessary or harmful treatment or resulting in psychological and financial repercussions.¹²⁷

Physicians have expressed their frustration at the lack of transparency in the American healthcare system of who and how decisions are made for medically necessary services in the U.S.¹²⁸ Some healthcare providers have argued over the consistent discrepancy in clinician's and insurer's perspectives on medical necessity, which bestows insurers with a degree of comfort issuing denials based on established "insurance practices" even though such decisions outrage physicians.¹²⁹ However, how many of these physicians have requested to review the "evidence-based" guidelines used by the insurers to conduct reviews? Do insurers claim proprietary rights to the information? Do they cite a regulation or rule from an authority that doctors (clinicians), as non-legal experts, will not dare question? Who is responsible for forcing clinicians to argue the medical necessity of a service or treatment based on a non-clinical perspective?

Moreover, these arguments lack acknowledgement of a fundamental legal distinction - for-profit insurance companies do not owe the same legal **"duty of care"** to patients that treating physicians and clinicians do. Corporate directors have a "duty of care" to protect the corporation.¹³⁰ Very little was found by this author in the literature addressing a conflict of interest in the context of for-profit health insurance companies deciding whether to pay or deny medically necessary care and, by doing so, making a profit. A conflict of interest is defined as: "A situation in which regard for one duty leads to disregard of another."¹³¹ Insurers' overly burdensome "benefit utilization-management" practices are unethical, inefficient and, in some instances, illegal.¹³² Further, they result in poor quality of care and take healthcare decisions away from practitioners and patients.¹³³

A letter to DHHS/CMS requesting guidance on how to obtain information related to Medicare and Medicaid transitioning into managed care was never answered. (EXHIBIT 2) A letter to the

¹³¹ Barron's Law Dictionary, Steven H. Gifis, Fifth edition

¹²⁴ Congressional Budget Office, Federal Debt and the Statutory Limit, November 2017, available at https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53336-debtlimit.pdf

¹²⁵ Johnston v. St. Francis Med. Ctr., 799 So. 2d 671, 2001 La. App. LEXIS 2423, 35,236 (La. App. 2 Cir. 10/31/01)

¹²⁶ Worthy, McClughen, & Kulkarni, Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care

¹²⁷ Improving Diagnosis in Health Care, Quality Chasm Series, Sept 2015, Institute of Medicine

 $^{^{128}}$ Article: Unhealthy Determinations: Controlling "Medical Necessity," 22 Va. J. Soc. Pol'y & L. 435 129 Id.

¹³⁰ Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors, The Office of the U.S. Department of Health and Human Services and The American Health Lawyer Association

¹³² Worthy, McClughen, & Kulkarni, Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care

¹³³ Id.

Office of the Inspector General (OIG) requesting information on who prosecutes or investigates private/for-profit/commercial insurance companies for allegations related to fraud and abuse went unanswered. (**EXHIBIT 3**) A letter to the Equal Employment Opportunity Commission (EEOC) requesting information that describes trends in healthcare providers reporting harassment, abuse and retaliation went unanswered. (**EXHIBIT 4**)

VII. For-profit health insurance before and after the ACA: Administrative waste that interferes with access to timely and medically necessary care

A fundamental difference in the U.S. healthcare system compared to the healthcare systems of other industrialized nations that provide universal healthcare for all of its citizens is that the payer(s) and administrator(s) of those foreign health insurance plans, whether public or private, are not-for-profit.¹³⁴ In the early 1990s, the Swiss government concluded that its nation's dramatic rise in healthcare costs and aggressive insurers' policies to deny coverage constituted a national crisis.¹³⁵ Switzerland's healthcare system is very similar to the U.S. as it is primarily based on private insurers and providers.¹³⁶ In the 1980s and 1990s, as continues today, the U.S. lacks set prices for healthcare services; in contrast to the U.S., other countries control health costs through central budgets and all-payer rate setting.¹³⁷ Yet, even with price transparency in the U.S. in this author's view, healthcare cannot run in the context of a business to generate profit and revenue.

The 2010 healthcare reform law, known as the ACA¹³⁸ did little to reduce the fragmentation of healthcare; as a matter of fact, it yielded a system that is even more complex.¹³⁹ The ACA's expanded health insurance markets were also built on the state-regulated, market-driven health insurance systems that predated the ACA.¹⁴⁰ Private health insurance market behaviors historically caused concern on areas such as: contractual exclusions of certain categories of care from coverage, UR and medical-necessity judgments, restricted provider networks and discrimination in plan design and administration.¹⁴¹ The ACA did not reform the failures of the for-profit health insurance system in the U.S., but rather overhauled a health insurance industry that historically interfered with access to timely medically necessary care and burdened the system with wasteful administrative costs.

The ACA went further and attempted to bind every American to buy into the U.S. for-profit health insurance industry with all its inherent failures. The constitutionality of the ACA continues to be challenged.¹⁴² Whatever the merits of the final 2010 healthcare reform bill in terms of improving the access, cost and quality of American healthcare, this effort will necessarily be deficient and

¹³⁴ T.R. Reid, The Healing of America: A Global Quest for Better, Cheaper, and Fairer Health Care, The Penguin Press, 2010 ¹³⁵ *Id.*

¹³⁶ Id.

 ¹³⁷ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ¹³⁸ The Patient Protection and Affordable Care Act, PUBLIC LAW 111–148—MAR. 23, 2010

 ¹³⁹ T.R. Reid, The Healing of America: A Global Quest for Better, Cheaper, and Fairer Health Care, The Penguin Press, 2010
 ¹⁴⁰ Article: Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring Targeted
 Enforcement and Regulatory Reform. 120 Penn St. L. Rev 109
 ¹⁴¹ Id.

¹⁴² The New York Times, Texas Judge Rules Affordable Care Act Unconstitutional, But Supporters Vow To Appeal, December 14, 2018

require significant reformulation as it was formed outside of a political context in which basic healthcare is an intrinsic part of the American social contract.¹⁴³ To achieve lasting, rational and comprehensive healthcare reform, there must be political consensus in the U.S. whereby healthcare is regarded as a basic, fundamental right.¹⁴⁴

As stated earlier, in 2007, prior to the passage of the ACA, CBO analysts proposed focusing on cutting wasteful spending. In 2017, the CBO, once again, called for reform in federal laws to address the rising federal budget deficit.¹⁴⁵ Yet, without reforming the current payment and financing structure of healthcare in the U.S., any attempts to "reform" the U.S. healthcare system will continue to be ineffective, as stated previously, and the CBO's recommendations will continue to be ignored.

U.S. studies from the early 1990s suggested that the difference in controlling administrative costs alone in the U.S.' healthcare system could have helped finance health coverage for the uninsured.¹⁴⁶ A comprehensive study in 2015 by Professor Gerald Friedman,¹⁴⁷ chair of the Economic Department at the University of Massachusetts at Amherst, shows that in New York, with a single-payer system that cuts administrative waste, the savings amount to \$71 billion a year: \$26.5 billion by eliminating private for-profit health insurance administrative costs; \$20.7 billion by reducing healthcare provider administration of health insurance claims; \$2 billion by eliminating employer administration of health benefits; \$5.4 billion by reducing fraudulent billing; and \$16.3 billion by capturing savings from insurance overpriced drugs and medical devices.

The \$24 billion the federal government pays every first of the month to administer Medicare Advantage and Medicare Part D plans¹⁴⁸ does not account for the money that physicians and facilities also spend on internal and external appeals processes, for example, cases in which insurers deny coverage of services because they determine that the services requested are not "medically necessary" in light of the insured's individual circumstances.¹⁴⁹ All these costs are passed on to taxpayers in the form of higher taxes or more expensive insurance premiums and cost-sharing.

In the Nation's Health Dollar report for Calendar Year 2016, ¹⁵⁰ CMS only allocated 8% of the year's health spending to government administration and net costs of health insurance. Hospital care spending and costs associated with physician and clinical services appeared to have consumed 32% and 20% of the year's budget, respectively. It is hard to believe that administrative cost only consumed 8% of CMS' 2016 budget as the U.S. ranks 10th among 11 other comparable nations in

¹⁴⁸ Congressional Budget Office, Federal Debt and the Statutory Limit, November 2017, available at https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53336-debtlimit.pdf

¹⁴³ Khan F. Article: Towards Achieving Lasting Healthcare Reform: Rethinking the American Social Contract. Annals of Health Law, 2010: 19

¹⁴⁴ Id.

¹⁴⁵ Id.

 ¹⁴⁶ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ¹⁴⁷ Economic Analysis of the New York Health Act, Gerald Friedman, PhD, April 2015, available at http://www.infoshare.org/main/Economic_Analysis_New_York_Health_Act_-GFriedman_-April_2015.pdf

¹⁴⁹ Article: Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring, Targeted Enforcement, and Regulatory Reform, 120 Penn St. L. Rev. 109

¹⁵⁰ The Nation's Health Dollar, Calendar Year 2016: Where it went, Center for Medicare & Medicaid Services, Office of the Actuary National Health Statistics Group.

healthcare administrative efficiency.¹⁵¹ These national health dollars need to be explained further to show how much physicians and hospitals waste in the administrative costs of arguing the medical necessity of the care rendered, as well as how much is spent to run all the fragmented programs that provide federal and state funding to special populations.

Another failed attempt to control healthcare costs implemented by the federal government and reimbursement regulators was to set fees through the Medicare Diagnosis-Related Groups (DRG) system and through the prospective payment system.^{152,153} The insurance plan paid only the amount of money assigned to the specific diagnosis: if the cost for hospitalization was greater than that assigned, the hospital absorbed the additional cost; if the cost was less than that assigned, the hospital made a profit.¹⁵⁴ The old "step-down" cost-based reimbursement had given way to fee-setting among federal and state regulators and many private insurers through managed care contracts.¹⁵⁵ The DRG approach did not work either. Moreover, DRG "price standardization" only applied to Medicare and Medicaid plans, leaving commercial insurance plans (employee-employer sponsored plans and those from the private sector) unprotected to be charged higher prices than Medicare and Medicaid members for the same diagnosis and treatment. (EXHIBIT 5: Examples of DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 for analytical purpose)¹⁵⁶

VII. UR for the for-profit insurance payer (EXHIBITS 6, 7 and 8)

Private for-profit health insurance companies acting as managed care organizations (MCOs) review medical claims submitted by providers to determine if the services rendered were medically necessary, or not. These MCOs' staff are allowed to issue denial for payments of claims if they determine the services were not medically necessary. (EXHIBIT 6) MCOs reviewing cases for medical necessity use their choice of standard clinical care guidelines, such as the Milliman care guidelines (MCG).¹⁵⁷ (EXHIBITS 7 and 8) CMS traditionally conducts medical necessity reviews according to InterQual Guidelines.

Nurses and doctors working for insurance companies should be qualified and free of conflict of interest to apply the "evidence-based" guidelines' criteria to render accurate medical necessity review decisions with sound prudent clinical judgment. Who do medical or nursing reviewers working for private for-profit insurance companies owe a "duty of care" to when applying Milliman Care Guidelines?

¹⁵¹ The Commonwealth Fund, Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Healthcare. By Eric C Schneider, Dana O. Sarnak, David Squires, Arnav Shah, and Michelle M. Doty, available at http://www.commonwealthfund.org/interactives/2017/july/mirror-mirror

¹⁵² Id. Chapter 9, P 226

¹⁵³ A Primer on Hospital Accounting and Financing for Directors and Other Healthcare Providers, Felix Kaufman, PhD, CPA, Fifth edition

¹⁵⁴ Fundamentals of Nursing: The Art and Science of Nursing Care, Second edition, Carol Taylor, Carol Lillis, Priscilla LeMone, 1993, by J.B. Lippincott Company, P 43

¹⁵⁵ Valuation of Hospitals and Medical Centers, James J. Unland, Published by the Health Management Research Institute, 1989: Finance Health Care Business: Chapter 9, P 226

¹⁵⁶ DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014, available at <u>https://www.cms.gov/Research-</u> <u>Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient2014.html</u>

¹⁵⁷ Milliman Care Guidelines, Part of the Hearst Network, ORG M-505 Atrial Fibrillation 22nd Edition

It is also unclear to this author who monitors MCOs' compliance adhering to MCG or InterQual recommendations. The Employee Retirement Income Security Act of 1974 (ERISA) 502 (a) (1) (B) does not permit consequential damages that would compensate enrollees for injuries resulting from denied benefits.¹⁵⁸ While ERISA protects MCOs from tort liability for denying coverage for treatments recommended by a treating physician, the law was not meant to protect MCOs from fraudulent denial of services and benefits, particularly when the denial is contrary to the recommendations even outlined in the clinical care guidelines, of which the MCOs claim to follow when conducting medical reviews. The elements of an ERISA estoppel claim are:¹⁵⁹

- (1) A knowing misrepresentation by the defendant;
- (2) Made in writing;
- (3) With reasonable reliance on that misrepresentation by plaintiffs; and
- (4) To the plaintiff's detriment

JCAHO managed care accreditation program, established in 1989, was discontinued in 1990 and replaced with the network accreditation program in 1994.¹⁶⁰ It is unclear to this author if at some point JCAHO was the authority to set accreditation standards for MCOs conducting medical necessity reviews and was later replaced by the Utilization Review Accreditation Commission (URAC). A letter from the author to JCAHO also went unanswered. (**EXHIBIT 9**)

URAC was established in 1990 as a third-party healthcare quality administrator.¹⁶¹ URAC is an independent, non-profit accreditation entity responsible for accrediting insurance companies to conduct URs for medical necessity of claims submitted by providers to the insurance company.¹⁶²

A letter to URAC requesting the following information was not answered: (EXHIBIT 10)

- Under which government authority does URAC operate?;
- Does URAC report to a government agency?; and
- Are there any laws, statutes or regulations pertaining to the establishment of URAC?

The URAC website has a section entitled "Case Management Accreditation", where it describes the Standards and Measures applied by URAC to accredit organizations for case management and UR. Under the section for measurements on quality of care (or any other session on the website), there is no criteria listed to measure the organization seeking accreditation on accuracy and effectiveness applying clinical care guidelines when conducting URs/medical necessity reviews. The MCG and InterQual guidelines are those employed by insurance companies and organizations that conduct medical necessity reviews to override medical judgment and deny services.

¹⁵⁸ Article: ERISA and Liability for Provision of Medical Information, 84 N.C.L. Rev. 471

¹⁵⁹ Vallone v. CNA Fin. Corp., 128 F. Supp. 2d 1131, U.S. Federal, US District Court for the Northern District of Illinois, Dec 28, 2000

¹⁶⁰ Core ,Curriculum for Legal Nurse Consulting, Vickie L. Milazzo, RN, MSN, JD, Twelfth edition, Medical Legal Consulting Institute, Inc., 1985-2005.

¹⁶¹ About URAC, available at <u>https://www.urac.org/about-urac</u>

¹⁶² Id.

VIII. The uninsured, underinsured and poor before and after the ACA

A 2009 Harvard study found that nearly 45,000 annual deaths are associated with lack of health insurance, with a 40% greater risk of death among uninsured, working-age Americans, even after taking into account socioeconomics, health behaviors and baseline health.¹⁶³ One of the main goals of the ACA was to expand insurance coverage and increase access to care.¹⁶⁴ Under the ACA, as of 2014, Medicaid coverage has been expanded to nearly all adults with incomes at or below 138% of the federal poverty level (FPL) in states that adopted the expansion,¹⁶⁵ and tax credits are available for people with incomes up to 400% of the FPL who purchase coverage through a health insurance marketplace.¹⁶⁶

As of the ACA's first open-enrollment period in the fall of 2013, the number of uninsured Americans has fallen from 41 million to 27 million.¹⁶⁷ Prior to the implementation of the ACA insurance expansions, approximately 47% of uninsured people reported that they were unable to access care because of cost; gaining coverage cut that figure by half to 20.9%.¹⁶⁸ Still, by 2015, 28 million non-elderly people remained uninsured, with nearly half (46%) saying that the main reason was because coverage is too expensive.¹⁶⁹ For many uninsured people, the costs of health insurance and medical care are weighed against equally essential needs, like housing, food and transportation to work; many uninsured adults report difficulty paying basic monthly expenses, such as rent, food, and utilities.¹⁷⁰

The ACA was presumably built upon the foundation of employee-employer-based coverage and to fill in historic gaps in insurance availability and affordability with the Medicaid expansion and tax credits.¹⁷¹ Yet, 28 million non-elderly people still lacked coverage in 2015 and there are many more Americans that are underinsured. It is estimated that 41 million U.S. adults aged 19 to 64 with insurance all year remained underinsured, and that is up significantly from 31 million people in 2014.¹⁷² Studies have found that the underinsured population is predominantly composed of people in employer plans: 56% of underinsured adults had coverage through employer plans.¹⁷³ In addition, people with coverage throughout the individual market, including the ACA marketplaces, and Medicare beneficiaries who are disabled adults under the age of 65, are disproportionately represented among the underinsured.¹⁷⁴

¹⁶³ The Harvard Gazette, Harvard Medical Study Links Lack of Insurance to 45,000 US Deaths a Year, September, 18, 2009 ¹⁶⁴ https://www.commonwealthfund.org/publications/issue-briefs/2017/may/effect-affordable-care-act-health-care-access ¹⁶⁵ The uninsured: A primer, The Kaiser Commission on Medicaid and the uninsured, November 2016,

http://files.kff.org/attachment/Report-The-Uninsured-A%20Primer-Key-Facts-about-Health-Insurance-and-the-Unisured-in-America-in-the-Era-of-Health-Reform

¹⁶⁶ Id.

¹⁶⁷ https://www.commonwealthfund.org/publications/issue-briefs/2017/may/effect-affordable-care-act-health-care-access ¹⁶⁸ *Id.*

¹⁶⁹ The Uninsured: A Primer, The Kaiser Commission on Medicaid and the Uninsured, November 2016,

http://files.kff.org/attachment/Report-The-Uninsured-A%20Primer-Key-Facts-about-Health-Insurance-and-the-Unisured-in-America-in-the-Era-of-Health-Reform

¹⁷⁰ Id.

¹⁷¹ Id.

¹⁷² Sara R. Collins, Munira Z. Gunja, and Michelle M. Doty, How Well Does Insurance Coverage Protect consumers from Health Care Cost? Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2016, October 18, 2017

¹⁷⁴ Id.

Underinsured is defined as a person insured all year but having experienced one of the following: out-of-pocket costs, excluding premiums, equivalent 10% or more of income; out-of-pocket costs, excluding premiums, was equivalent to 5% or more of income if low-income (<200% of poverty, \$23,760 for an individual and \$48,600 for a family of four); or, deductibles equivalent to 5% or more of income.¹⁷⁵ In adults with health insurance coverage, 43% report having problems affording their deductibles, premiums or cost-sharing.¹⁷⁶ Among the insured with medical bill problems, 63% used up most or all their savings, and 42% took on an extra job or worked more hours.¹⁷⁷

In some states, wages at 200% FPL do not even provide a comfortable living. To meet healthcare expenses, many patients report cutting back on essentials, like food, clothing and basic household items; ultimately, some delay or skip getting the healthcare they need.¹⁷⁸ Consumers foregoing appropriate care that is not covered by insurance could get sicker and require more expensive care in the future.¹⁷⁹ The consequences to forego needed healthcare can be severe, particularly when preventable conditions or chronic diseases go undetected.¹⁸⁰

In 2016, the average annual premiums for employer-sponsored health insurance were \$6,435 for single coverage and \$18,142 for family coverage, while workers' wages only increased 2.5% and inflation increased 1.1% over the period.¹⁸¹ Premiums for family coverage have increased 20% since 2011 and 58% since 2006.¹⁸² Covered workers are often faced with additional annual deductibles, copayments, coinsurance, additional cost-sharing for hospital admissions and outpatient surgery.¹⁸³ In the event of catastrophic illness, these patients will additionally face hospital costs that could expose them and their families to bankruptcy.

The average cost of a three-day hospital stay is roughly \$30,000 and comprehensive cancer care can cost hundreds of thousands of dollars; once a patient spending for covered services reaches the plan's deductible, the plan covers a portion of the medical expenses.¹⁸⁴ Marketplace plans cover between 60% and 90% of covered expenses.¹⁸⁵ The other 40% to 10% is the patient's responsibility: 40% or 10% of a bill that is "hundreds of thousands of dollars" has the potential to

¹⁷⁵ Id.

¹⁷⁶ Data Note: Americans' Challenges with Health Care Costs, Bianca DiJulio, Ashley Kirzinger, Bryan Wu and Mollyann Brodie, March 02, 2017

¹⁷⁷ The Kaiser Family Foundation, New Kaiser/New York Times Survey Finds One in Five Working-Age American With Health Insurance Report Problems Paying Medical Bills, released Jan 5, 2016, available at <u>https://www.kff.org/health-costs/press-</u> release/new-kaisernew-york-times-survey-finds-one-in-five-working-age-americans-with-health-insurance-report-problemspaying-medical-bills

¹⁷⁸ Id.

¹⁷⁹ Id.

¹⁸⁰ The Uninsured: A Primer, The Kaiser Commission on Medicaid and the Uninsured, November 2016, available at <u>http://files.kff.org/attachment/Report-The-Uninsured-A%20Primer-Key-Facts-about-Health-Insurance-and-the-Unisured-in-America-in-the-Era-of-Health-Reform</u>

 ¹⁸¹ 2016 Employer Health Benefits Survey, Kaiser Family Foundation, September, 14, 2016
 ¹⁸² Id.

¹⁸³ Id

¹⁸⁴ Protection from High Medical Costs, available at <u>https://www.healthcare.gov/why-coverage-is-important/protection-from-high-medical-costs</u>

¹⁸⁵ Id.

bankrupt¹⁸⁶ a patient who has already paid thousands of dollars in premiums, deductibles, co-pays and co-insurance.

For people covered by employee-employer-based insurance - which includes more than half of Americans under age 65, or more than 150 million people - plans were historically far more comprehensive and cost-protective than individual market coverage.¹⁸⁷ By the year 2014, private health insurance premiums were estimated to have increased 191%, and workers' contributions rose 212%, and this is while workers' earnings growth slowed in terms of rising from 38% in 2009 to 54% in 2014.¹⁸⁸ It is obvious that the ACA finance and payment structure leaves patients with no option but to forgo medical care, leading to the patient's demise or absorb unsustainable debt that results in bankruptcy and threatens the well-being of working American families.

Prior to the passage of the ACA, attempts at healthcare reform should have recognized that maintaining employer-sponsored health insurance, which accounts for the largest sector of the population, with continued access to comprehensive and cost-effective coverage, was in the best interest of employees, their families and the nation en masse. If a person with an insurance plan cannot afford healthcare services and treatments, it is the equivalent of not possessing health insurance and he/she should be counted as uninsured.

In this context, the ACA added coverage to roughly 13 million, leaving 28 million still uninsured, by "underinsuring" many Americans that traditionally had affordable healthcare through employee-employer benefits (once more, 150 million people). The Center for Disease Control (CDC)'s primary goal in its national initiative, "Healthy People 2020 Framework", to attain high-quality, longer lives free of preventable disease, disability, injury and premature death for all Americans,¹⁸⁹ largely depends on Americans having access to comprehensive and cost-effective coverage. In this author's view, it is important to further determine which part of the population or which employee-employer plans were "grandfathered"¹⁹⁰ after the ACA and if those populations represent any particular industry or sector of the economy.

In the U.S. healthcare system, patients are not aware of charges until they have made use of the services. The effect of contracts between hospital systems and insurers can be difficult to see directly because negotiations are secret, and the contract details, including pricing, typically are not disclosed, even to insurers' clients.¹⁹¹ Roughly 40% of people who receive health benefits

¹⁸⁶ David Himmelstein et al., "Market Watch: Illness and Injury As Contributors to Bankruptcy," Health Affairs Web Exclusive, February 2, 2005, pp. W5-62

¹⁸⁷ Sara R. Collins, Munira Z. Gunja, and Michelle M. Doty, How Well Does Insurance Coverage Protect Consumers from Health Care Costs? Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2016, October 18, 2017

¹⁸⁸ The Commonwealth Fund, Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Healthcare. By Eric C Schneider, Dana O. Sarnak, David Squires, Arnav Shah, and Michelle M. Doty, available at http://www.commonwealthfund.org/interactives/2017/july/mirror-mirror

¹⁸⁹ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2020 Framework, available at <u>https://www.healthypeople.gov/sites/default/files/HP2020Framework.pdf</u>

¹⁹⁰ Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential Health Benefits, January 14, 2011, available at <u>http://www.nationalacademies.org/hmd/~/media/</u> <u>8D03963CAEB24450947C1AEC0CAECD85.ashx</u>

¹⁹¹ The Wall Street Journal: Behind Your Rising Health-Care Bills: Secret Hospital Deals that Squelch Competition, Anna Wilde Mathews, Sept. 18, 2018

through work are now enrolled in a high-deductible health plan (HDHP) according to a 2017 report from the National Center for Health Statistics.^{192,193}

With the growth of HDHPs, patients' own resources now represent a growing percentage of the revenue stream for hospitals, physicians' offices and other medical service providers.¹⁹⁴ If the patient cannot afford to pay hospitals' and providers' bills, the insurance does not pay the providers until the patient meets their annual deductibles, which often, patients cannot afford. In this author's view, HDHPs are in violation of the "founding principles" upon which the ACA was presumably premised as it leaves almost half of employees without access to affordable healthcare. The ACA generally requires employers with 50 or more full-time employees to offer a group health plan or group health insurance coverage that provides minimum essential coverage.¹⁹⁵ However, coverage has to be affordable or patients will not be able to seek care or use needed services.

The CBO assumed in 2008, under current law, that the federal government would make regulatory changes aimed at slowing the growth of spending on federal health programs and that Medicare beneficiaries' demand for healthcare services would decline as Medicare premiums and cost-sharing amounts consumed a growing share of their income.¹⁹⁶ This tactic also prevents the elderly from seeking the care they require after paying through their working lives' taxes collected from employee wages and allocated to the Medicare fund; the elderly must now also pay private for-profit insurance companies for Medicare Advantage Programs to "administer" their plan.

Americans today are paying higher premiums, face additional annual deductibles, copayments, coinsurance, additional cost-sharing for hospital admissions and outpatient surgery, foregoing care as even with "healthcare insurance", they cannot afford costs, threatened by bankruptcy at the point when they do need care in the future after years of paying for premiums: why is health insurance needed at all? Where is the money the U.S pays in healthcare costs today going? From this author's perspective the ACA was crafted based on unethical business practices that lead to misappropriation of American's funds and false enrichment of private for-profit insurers and executives in the "healthcare industry" while socializing the risk. From 1975 to 2005, the share of national health expenditure that was financed privately fell slightly, from 59% to 55%, while the share that was financed publicly rose correspondingly, from 41% to 45%.¹⁹⁷

¹⁹² Know what you owe: Lifting the veil of secrecy in health care pricing can boost the consumer experience, Srini Attili, Principal, Deloitte Consulting, July 19, 2018

¹⁹³ Health Insurance Coverage: Early Release of Coverage From The National Health Interview Survey, January- September 2017, Michael E. Martinez, M.P.H., M.H.S.A., Emily P. Zammitti, M.P.H., and Robin A. Cohen, Ph.D. Division of Health Interview Statistics, National Center for Health Statistics

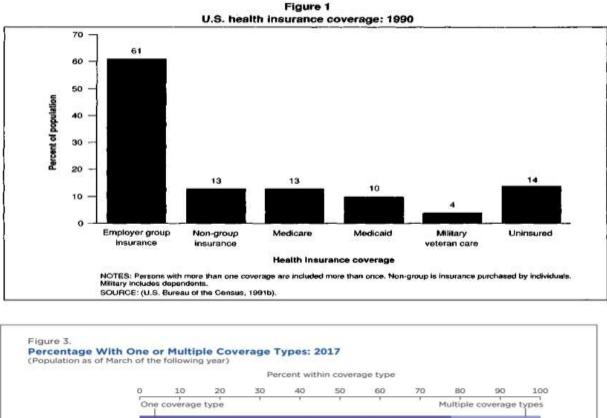
¹⁹⁴ Know what you owe: Lifting the veil of secrecy in health care pricing can boost the consumer experience, Srini Attili, Principal, Deloitte Consulting, July 19, 2018

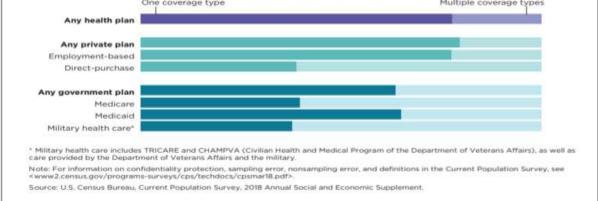
¹⁹⁵ 26 U.S.C.S. § 5000A(f)(2); 26 U.S.C.S. §§ 4980H(a), (c)(2)

¹⁹⁶ Health Care Spending CQ Congressional Testimony, Peter Orszag, Director Congressional Budget Office, January 31, 2008

¹⁹⁷ https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/11-13-lt-health.pdf

Figures 1 and 3 purporting to depict more Americans are covered by health insurance today are a mere optical illusion^{198,199} as, in actual fact, there are more Americans today that are unable to afford care even when they are "covered" by a health insurance plan.





Prior to the ACA, the poor had protections under the law that will not be available to the working class with the passage of the ACA, owing to the federal poverty guidelines and income restrictions, as well as escalating healthcare prices. The Emergency Treatment and Active Labor Act

 ¹⁹⁸ Special report: A Layman's Guide to the U.S. health Care System, Nancy De Lew, George Greenberg, and Kraig Kinchen, 1992
 ¹⁹⁹ Health Insurance Coverage in the United States: 2017, U.S. Census Bureau, available at https://www.census.gov/content/dam/Census/library/publications/2018/demo/p60-264.pdf

(EMTALA)²⁰⁰ guaranteed access to an emergency medical evaluation regardless of ability to pay. The act requires hospitals that receive Medicare funding and that provide emergency services to evaluate any person that arrives at their emergency room and requests treatment. If the evaluation confirms that the patient has an emergency medical condition, including active labor, the hospitals are required to provide stabilizing treatment regardless of a patient's ability to pay.²⁰¹

Charity care programs helped uninsured patients who could not afford to pay their medical bills or did not qualify for government aid.²⁰² Furthermore, state funds were traditionally established to compensate hospitals for indigent care. For example, since 1983, the New York State Hospital Bad Debt and Charity Care Pool (BDCC) and Hospital Indigent Care Pool (the Pool) are funds to underwrite a portion of uncompensated care costs to hospitals.²⁰³ In 2008 alone, New York State distributed \$847 million in Medicaid funds to public and voluntary hospitals through multiple sub-Pools and allocation formulas.²⁰⁴ (**EXHIBIT 11**)

The Supreme Court has dealt with some of the ACA's contradicting provisions: "The reality that states were given no real choice but to expand Medicaid was not an accident. Congress assumed states would have no choice, and the ACA depends on states having no choice, because its Mandate requires low-income individuals to obtain insurance many of them can afford only through the Medicaid Expansion."²⁰⁵ This thwarts lower population states' efforts, like Mississippi, to meet the needs of its residents through special programs coordinated by small businesses, like the Jackson Medical Mall Foundation,²⁰⁶ the Mississippi Center for Justice, ²⁰⁷ and Mississippi Department of Health and Human Services. They assist families with housing, job seeking, job opportunities and healthcare for the underserved."²⁰⁸ In Mississippi, the health crisis has led to an existential crisis for the Medicaid industry, with battle lines drawn over saving money and finding profit. Up and down the Delta's red-dirt roads, insurers and hospitals are fighting over billions of dollars that Medicaid has yielded for managed care plans since 2011, even as lawmakers say they cannot afford to cover any more of the state's poor.²⁰⁹

IX. The ACA & CMS' new value-based care: paving the way to 2082 and spending 49% of U.S. GDP in healthcare

In 2016, suicide became the second-leading cause of death for those aged between 10 through 34 and the fourth-leading cause for those aged 35 through 54. From 1999 through 2017, the ageadjusted suicide rate increased 33%. Life expectancy for the U.S. population in 2016 was 78.6, a

²⁰⁰ 42 U.C.S. § 1395dd

²⁰¹ https://www.US .gov/paying-for-medical

²⁰² https://www.US .gov/paying-for-medical

²⁰³ A Report on the Hospital Indigent Care Pool, January 2008, available at

https://www.health.ny.gov/facilities/hospital/indigent care/2008_indigent_care_report.htm#exec_summary²⁰⁴ *Id.*

²⁰⁵ *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 132 S. Ct. 2566, 183 L. Ed. 2d 450, 2012 U.S. LEXIS 4876, 80 U.S.L.W. 4579, 2012-2 U.S. Tax Cas. (CCH) P50, 423, 109 A.F.T.R.2d (RIA) 2012-2563, 80 A.L.R. Fed. 2d 501, 53 Employee Benefits Cas. (BNA) 1513, 23 Fla. L. Weekly Fed. S 480, 2012 WL 2427810

²⁰⁶ Jackson Medical Mall Foundation

²⁰⁷ Mississippi Center for Justice.

²⁰⁸ Jackson Medical Mall Foundation: Celebrating 20 Years of Excellence, Primus Wheeler Jr., Executive Director

²⁰⁹ Medicaid blues: Hospitals, insurers wage political battle over managed-care dollars, Susannah Luthi, September 22, 2018

decrease of 0.1 year for 2015.²¹⁰ As of December 21, 2018, there were 334 mass shootings in the US.²¹¹ In 2017, there were 70,237 drug overdose deaths.²¹² Further, in 2017, the age-adjusted rate of drug overdose deaths in the U.S. was 9.6% higher than that rate in 2016.²¹³ The U.S. has the seventh highest cancer rate in the world - we are definitely higher than where we should be.²¹⁴ A new study shows that the U.S. spends far more than Europe on cancer care but has a higher mortality rate for lung cancer, the leading killer.²¹⁵ If figures for all four leading cancers (lung, breast, colorectal and prostate cancer) in the U.S. are added together, the U.S. had 729,000 excess deaths from 1982 to 2010 while spending roughly \$1.6 *trillion* more than Europeans,²¹⁶ even though, according to the World Health Organization, Europeans have higher smoking rates.^{217,218}

Physicians are leaving their private practices because of rising costs and lower insurance reimbursement, and, for some, escaping the burden of dealing with insurers and paying for electronic health records is the greatest independence.²¹⁹ Health systems offer them full-time employment in exchange for their practice's book of business.²²⁰ A study published in the *Journal of Health Economics* found that physicians' prices increased on average by 14.1% after they became part of hospital systems.²²¹ This arrangement is beneficial for large health corporations as they pursue increased market share, and they become free to contract with the insurer directly, making the effect of contracts difficult to scrutinize because negotiations are secret.²²² 2016 marked the first year in which less than half of practicing physicians owned their own practice— 47.1%, and this was about 6% lower than in 2012.²²³

Physicians driven out of their practices leave the community without even the lowest level of care traditionally available to patients. Private physician practices provide personalized care to patients, and they are the most cost-effective in terms of offering preventive care and chronic disease management as they are able to design and implement interventions to address individual patient needs. Physicians in their own practice are autonomous to implement clinical decisions based on clinical best practices and authoritative medical knowledge, independent of a facility's business plans and business target metrics.

A survey of physicians by the AMA found that 42% of respondents were burned out, and 15% admitted to experiencing either clinical or colloquial forms of depression.²²⁴ More than half of

https://www.webmd.com/cancer/news/20110123/us-has-7th-highest-cancer-rate-in-the-world?print=true

²¹⁰ Mortality in The United States, 2016, Sherry L. Murphy, B.S., Jiaquan Xu, M.D., Kenneth D. Kochanek, M.A., and Elizabeth Arias, Ph.D.

²¹¹ https://www.gunviolencearchive.org/

²¹² https://www.cdc.gov/nchs/products/databriefs/db329.htm

²¹³ Id.

 $^{^{\}rm 214}$ U.S. Has $7^{\rm th}$ Highest Cancer Rate in the World, Denise Mann, Jan 24, 2011, at

²¹⁵ Cancer Spending Higher in U.S. Than in Europe—and So Is Cancer Mortality, John Horgan, June 8, 2015 at

https://blogs.scientificamerican.com/cross-check/cancer-spending-higher-in-u-s-than-in-europe-and-so-is-cancer-mortality/ ²¹⁶ *Id.*

²¹⁷ Id.

²¹⁸ http://gamapserver.who.int/gho/interactive_charts/tobacco/use/atlas.html

²¹⁹ Dr. Dilemma: Independence or Health System? Reich-Hale, David, Newsday, June 25, 2017

²²⁰ Id.

²²¹ Behind Your Rising Health-Care Bills: Secret Hospital Deals That Squelch Competition, Anna Wilde Mathews, Sept. 18, 2018 ²²² Id.

²²³ AMA Economic and Health Policy Research, May 2017

²²⁴ Physician burnout: It's not you, it's your medical specialty, Aug. 3, 2018, Sara Berg, Senior Staff Writer. AMA Wire

physicians chose "too many bureaucratic tasks" as the leading cause of burnout.²²⁵ Others complained of spending too many hours at work, lack of respect, increased computerization of their practice and insufficient compensation as the top causes of burnout.²²⁶ In 2005, paperwork consumed one-third of physicians time;²²⁷ a recently published investigation in the *Annals of Internal Medicine* found that for every hour physicians were seeing patients, they were now spending nearly two additional hours on paperwork.²²⁸

Four reasons have been cited for the increased requirements in paperwork:²²⁹ First, there are now so many people involved in a doctor's practice beyond the doctor himself or herself (administration, lawyers, insurance companies, etc.); second, doctors are not designing much of the paperwork and whoever is designing and requiring the paperwork has little clue on how to perform the work of a physician; third, hospitals and clinics are not investing in clerical help; and fourth, the system is not changing to accommodate doctors.

A study on the effect of nurse understaffing and burnout on poor patient outcomes concluded that in hospitals with high patient-to-nurse ratios, surgical patients experience higher risk-adjusted 30day mortality and failure-to-rescue rates, and nurses are more likely to experience burnout and job dissatisfaction.²³⁰ The Agency for Healthcare Research and Quality (AHRQ) defines burnout as a syndrome characterized by emotional exhaustion that causes depersonalization and decreased personal accomplishment at work.²³¹ Burned out clinicians become detached, which is presumed to result in poor interactions with patients and, therefore, poses a threat to patient safety.²³²

Overlooking the working conditions of the healthcare workforce has been compared to the "phantom limb pain" of the Institute for Healthcare Improvement (IHI)'s Triple Aim to improve patient care quality, decreasing total cost of care and improving the experience of care for patients.²³³ The well-being of the healthcare workforce is essential for acting on and implementing the necessary changes for achieving the Triple Aim.^{234,235} The IHI's triple Aim initiative seeks to:²³⁶ focus on individuals and family, redesign primary care services and structures, engage in population health management and perform cost-control and system integration and execution.

²²⁵ Id.

²²⁶ Id.

²²⁷ How Much Paperwork Is Too Much? James H. Sanders Jr., MD, Fam Pract Manag. 2005 Jan;12(1):12, available at https://www.aafp.org/fpm/2005/0100/p12.html

²²⁸ Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties, Christine Sinsky, MD; Lacey Colligan, MD; Ling Li, PhD; Mirela Prgomet, PhD; Sam Reynolds, MBA; Lindsey Goeders, MBA; Johanna Westbrook, PhD; Michael Tutty, PhD; George Blike, MD, *Ann Intern Med.* 2016;165(11):753-760.

²²⁹ Doctors Wasting Over Two-Thirds of Their Time Doing Paperwork, Forbes, Sep 7, 2016, available at <u>https://www.forbes.com/sites/brucelee/2016/09/07/doctors-wasting-over-two-thirds-of-their-time-doing-paperwork/#3ae7c8215d7b</u>

²³⁰ Aiken LH, Clarke SP, Sloane DM, Sochalski J, Silber JH. Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction. *JAMA*. 2002; 288(16):1987–1993. doi:10.1001/jama.288.16.1987

²³¹ https://psnet.ahrq.gov/perspectives/perspective/190/burnout-among-health-professionals-and-its-effect-on-patient-safety ²³² *Id.*

²³³ Spinelli WM. The phantom limb of the triple aim. Mayo. Clin. Proc. 2013;88:1356–7. PubMed

²³⁴ Linzer, M., Poplau, S., Grossman, E. et al., J. Gen. Intern. Med. (2015) 30: 1105. https://doi.org/10.1007/s11606-015-3235-4

²³⁵ Institute for Healthcare Improvement, The Triple Aim, Healthcare Executives, 64-66 (Jan./Feb. 2009)

²³⁶ The Law of Healthcare Administration, J. Stuart Showalter, Seventh edition P.254

The Triple Aim is a clinical approach to the nations' health; the ACA and CMS' value-based care starting in 2012 has led to a mere reallocation of wealth.

"Patient safety" as a new discipline ²³⁷ is an invention of value-based care and a symptom of physician and nurses being spread too thin in the commercialization of medicine. Patient safety represents the foundation of the professions of medicine and nursing and it is embedded in the professions' authoritative knowledge, standards of care, standards of practice, codes of ethics and in the implementation of their work. The IOM's report, "To Err is Human", was intended to increase awareness around more clinicians being needed to take care of patients and avoid preventable errors. Instead, after the ACA and CMS's value-based care model, healthcare is more fragmented and unaffordable. Care will continue to become depersonalized as the staff becomes more disengaged from an increasingly fragmented and complex system.

X. Conclusion: Reforming the U.S. healthcare system

Americans have a right to timely medically necessary care and protection from wrongful death. The U.S. has a traditional model of care that works if payment for care is not administered in a for-profit manner or to generate revenue. Medically necessary healthcare services or products are for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms.²³⁸ "Comparative effectiveness" research as proposed by the CBO,²³⁹ free of conflict of interest and not for the benefit of profit or revenue, could aid in identifying surgeries, procedures and technologies that have limited utility and are not cost-effective.²⁴⁰ Nonetheless, the medical necessity standard can already help determine surgeries, procedures and technologies that are non-medically necessary or not superior to standard-traditional medical care. Separating medically necessary care from non-medically necessary care is not rationing, but rather a just and fair distribution of resources that protects patients from preventable disease, disability, injury and premature death.²⁴¹

There is no sense to continue "innovating" more expensive "treatments" for advanced diseases when patients do not have access to the basic early preventive care and early disease management of chronic conditions that halts the progression and "seemingly" inevitable need of such "innovation". Even in the context of capitalism and consumer-driven markets, "consumers" cannot possibly be the party "demanding" more complex and expensive treatments if they were deprived of the basic treatments and care that will prevent such a "demand".

The UR and UM processes need to be free of conflict of interest, as well. URs and UMs must be efficient and cost-effective with clear, standardized, medically authoritative knowledge and clinical guidelines that are easy to understand and administered through already existing resources

 ²³⁷ What Exactly is Patient Safety? Linda Emanuel, MD, PhD; Don Berwick, MD, MPP; James Conway, MS; John Combes, MD; Martin Hatlie, JD; Lucian Leape, MD; James Reason, PhD; Paul Schyve, MD; Charles Vincent, MPhil, PhD; Merrilyn Walton, PhD
 ²³⁸ Statement of the American Medical Association to the Institute of Medicine's Committee on Determination of Essential
 Health Benefits January 14, 2011, available at http://www.nationalacademies.org/hmd/~/media/8D03963CAEB24450947C1AEC0CAECD85.ashx

²³⁹ https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/11-13-lt-health.pdf

 ²⁴⁰ Breaking the Fever: A new Construct for Regulating Overtreatment, 48 U.C. Davis L. Rev. 1261
 ²⁴¹ U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2020
 Framework, available at https://www.healthypeople.gov/sites/default/files/HP2020Framework.pdf

in the U.S. Department of Health and Human Services. These processes cannot be applied to challenge medical (clinical) knowledge and deny services to generate profit and revenue. URs' and UM's clinical value are in ensuring quality of care, identify misuse of services and establish which providers have a pattern of wasteful use of resources along with determining patterns of deviations from medical and clinical standards of care and practice.

While the traditional American model of care had room for improvement, as no system is entirely perfect, replacing it with a business model of care with known, traditionally "troublesome stakeholders" was a foreseeable mistake that will create a more fragmented and expensive system, and therefore leave many more patients, individuals and families at risk of injury and death.

The health insurance industry should be held accountable under the laws in this country ^{242,243,244,245} for causing the misdiagnosis, delayed treatment and even death of patients; their bad faith interference with prudent medical judgment also affects the data collected for prevention, treatment and cures of future generations. Knowingly denying insured patients medically necessary care that can lead to death becomes the direct cause of patients' injuries and demise. A Medicare patient with an asthma exacerbation requires the same treatment and stabilization as a patient who has a commercial health insurance plan. Should the patient with a commercial plan be allowed to battle an asthma attack with home inhalers to avoid unaffordable hospital bills until he/she progresses to status asthmaticus and faces death?

Unscrupulous hospital administrators should be made responsible for the damages they have caused communities and individuals with accounting, marketing and business principles that they should have known cannot be applied to healthcare as affordability to healthcare and services trumps profit and revenue. In healthcare, utilization is intended to be a cost-control measure as well as a monitoring tool to improve patients' outcomes and regulate unnecessary costs. Primary care providers, essential for the exercise of prudent clinical judgment for the prevention of illness and management of chronic conditions, are indispensable in the community.

While the preamble to the Constitution of The United States is a precatory and non-binding provision,²⁴⁶ it establishes the faith of the common men and women in this country and their government: in uncertain times, we will always find our way back to order, to enjoy life, liberty and the pursuit of happiness; and secure the blessings of liberty to ourselves and our posterity.

²⁴² Compliance Management: A How-to Guide for Executives, Lawyers, and Other Compliance Professionals, Nitish Singh, PhD, and Thomas J. Bussen, 2015

 ²⁴³ Fraud and Abuse Investigation Handbook for the Healthcare Industry, Robert A. Griffith and Paul W. Shaw, First Edition, 2014
 ²⁴⁴ Sutowski v. Eli Lilly & Co., 82 Ohio St. 3d 347, 696 N.E.2d 187, 1998 Ohio LEXIS 1833, 1998-Ohio-388, CCH Prod. Liab. Rep.
 P15, 296

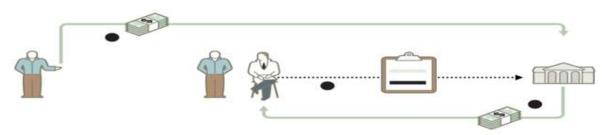
²⁴⁵ The Law of Healthcare Administration, J. Stuart Showalter, Seventh edition

²⁴⁶ Article: State Constitutionalism and the Right to Health Care, 12 U. Pa. J. Const. L. 1325

Exhibit 1

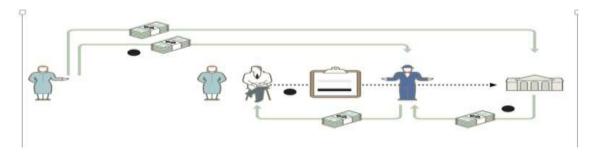
Traditional Medicare^{247 248}

- 1. Members pay a monthly premium to the Centers for Medicare and Medicaid Services (CMS) whether or not they visit a doctor. CMS also receives funding from U.S. taxpayers.
- 2. If members see a doctor, the doctor sends a copy of their medical report to CMS in order to be paid.
- 3. CMS pays the doctor. Traditional Medicare compensates doctors according to the procedures they perform lab tests, scans, operations, etc.



Medicare Advantage: ²⁴⁹ On the first of each month, the federal government pays \$24 billion to administer Medicare Advantage and Medicare Part D plans.²⁵⁰

- 1. Members also pay a monthly premium to CMS, and often a separate premium to a private insurance company.
- 2. If members see a doctor, the doctor sends a copy of the medical report to the private insurer, who then pays the doctor.
- 3. CMS pays the private insurer a base rate for each member. If the private insurer tells CMS that the member requires treatment for certain conditions, CMS pays the insurer more.



²⁴⁷ The New York Times, UnitedHealth Overbilled Medicare by Billions, U.S. Says in Suit, May 19, 2017

²⁴⁸ United States ex rel. Poehling v. United Health Grp., Inc., 2018 U.S. Dist. LEXIS 37418

 ²⁴⁹ The New York Times, UnitedHealth Overbilled Medicare by Billions, U.S. Says in Suit, May 19, 2017
 ²⁵⁰ Congressional Budget Office, Federal Debt and the Statutory Limit, November 2017, available at https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53336-debtlimit.pdf

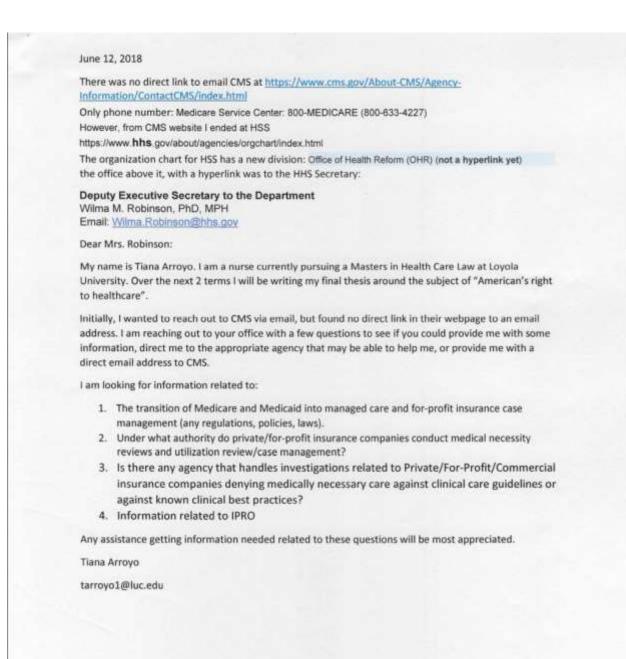
Arroyo, Tiana From: Arroyo, Tiana Sent: Tuesday, June 12, 2018 10:21 PM karen.giles@hhs.gov To: Subject: FW: Questions Follow Up Flag: Follow up Flag Status: Flagged Dear Mrs. Giles: I am forwarding this general questions email to you, as per the instructions on Mrs. Robinson's away message. Kindly let me know if you may be able to assist. Thank you for your help, Tiana Arroyo From: Arroyo, Tiana Sent: Tuesday, June 12, 2018 10:15 PM To: 'Wilma.Robinson@hhs.gov' <Wilma.Robinson@hhs.gov> Subject: Questions Dear Mrs. Robinson: My name is Tiana Arroyo. I am a nurse currently pursuing a Masters in Health Care Law at Loyola University. Over the next 2 terms I will be writing my final thesis around the subject of "American's right to healthcare". Initially, I wanted to reach out to CMS via email, but found no direct link in their webpage to an email address. I am reaching out to your office with a few questions to see if you could provide me with some information, direct me to the appropriate agency that may be able to help me, or provide me with a direct email address to CMS. I am looking for information related to: 1. The transition of Medicare and Medicaid into managed care and for-profit insurance case management (any regulations, policies, laws). 2. Under what authority do private/for-profit insurance companies conduct medical necessity reviews and utilization review/case management? 3. Is there any agency that handles investigations related to Private/For-Profit/Commercial insurance companies denying medically necessary care against clinical care guidelines or against known clinical best practices? 4. Information related to IPRO Any assistance getting information needed related to these questions will be most appreciated.

Exhibit 2: Letter to the Centers for Medicare and Medicaid (CMS) 1/2

Thank you for the opportunity to write to your office,

Tiana Arroyo

Exhibit 2: Letter to the Centers for Medicare and Medicaid (CMS) 2/2



| From: | Arroyo, Tiana |
|----------------------------|--|
| Sent: | Tuesday, June 12, 2018 8:52 PM |
| To: | 'Public.Affairs@oig.hhs.gov' |
| Subject: | Questions |
| Follow Up Flag: | Follow up |
| Flag Status: | Flagged |
| Good Morning: | |
| next 2 terms I will be wr | b. I am a nurse currently pursuing a Masters in Health Care Law at Loyola University. Over the ting my final thesis around the subject of "American's right to healthcare". While conducting m and it very difficult to get information around the health insurance business in the USA. |
| to the appropriate agen | r office with a few questions to see if you could provide me with some information, or direct me by that may be able to help me. In the research I have done so far, and in the courses I have answers to these questions when referring to Federally funded healthcare programs and plans |
| but very little informatio | n for Private/For-Profit/Commercial insurance companies (these are different terms I |
| | |

Exhibit 3: Letter to Office of the Inspector General (OIG)

- Who prosecutes or investigates Private/For-Profit/Commercial insurance companies for allegations related to Fraud and Abuse?
- 2. Are the above companies held to the same Fraud and Abuse Laws managing commercial plans, as they are when managing federally funded health care plans/programs?
- Is there an agency or department that monitors, investigates and prosecutes Private/For-Profit/Commercial insurance companies for compliance or violations with the Sarbanes-Oxley Act?, or are they exempt from the Sarbanes-Oxley Act?
- 4. Is there any agency that handles investigations related to Private/For-Profit/Commercial insurance companies denying medically necessary care against clinical care guidelines or clinical best practices?

I want to thank you for any help or guidance you may be able to provide.

Thank you,

Tiana Arroyo

516-996-5609

tarroyo1@luc.edu

Exhibit 4: Letter to Equal Employment Opportunity Commission (EEOC)

| From: | Arroyo, Tiana |
|--|---|
| Sent: | Thursday, June 14, 2018 1:28 AM |
| To: | 'info@eeoc.gov' |
| Subject: | Question |
| ollow Up Flag: | Follow up |
| Flag Status: | Flagged |
| Good Morning: | |
| | . I am a nurse currently pursuing a Masters in Health Care Law at Loyola University. Over the ting my final thesis around the subject of "American's right to healthcare". |
| | office with a few questions to see if you could provide me with some information, or direct me e where I may be able to get this information. |
| nformation on the natur have any publications rel | 's and to the present, I have seen how healthcare has transformed. I am trying to get e of complaints that the EEOC received specifically from healthcare providers. Does your office ated to the nature of complaints the office received in the past few decades that discusses , nurses and other healthcare providers? |
| decades, reporting chang | is any significant data that shows how active healthcare providers were in the last few ges that affected patient's care and decision making from feeling harassed, abused and asked to put an enterprise's or corporation's best interest over clinical decision making. |
| Any information will be v | ery appreciated. I want to thank you for the opportunity to write to your office. |
| Tiana Arroyo | |
| tarrovo1@luc.edu | |

Exhibit 5: Diagnosis-Related Group (DRG) Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 ²⁵¹ 1/2

| DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 (for analytical purpose) | DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 (for analytical purpose) |
|--|--|
| 308 Cardiac Arrythmia and Conduction Disorder | Acute Ischemic Stroke With Use of Thrombolytic |
| California: | California: |
| Hospital charge: \$19,384 - \$189,927 | Hospital charge: \$92,129 – 259,671 |
| CMS will pay: \$8,763 - \$15,333 | CMS will pay: \$33,757 - \$77,221 |
| | |
| NY: | NY: |
| Hospital charge: \$10,232 - \$95,761 | Hospital charge: \$51,981 – \$122,989 |
| CMS will pay: \$6,976 - \$10,717 | CMS will pay: \$19,936 - \$23,194 |
| | |

In N.Y. under the Medicare DRG Inpatient Prospective Payment for Hospitals, Medicare pays \$6,976-\$10,717 for a hospital stay to treat a patient for new onset atrial fibrillation, regardless of how long they remain in the hospital. The insurance company wants the patient discharged and to keep as much, or possibly all, of the payment. However, a premature discharge may put this patient at risk for developing a stroke. This could have severe consequences and even risk of death from a stroke if the patient is not properly treated, or does not make it back to the hospital with the early onset of symptoms of an evolving stroke.

The treatment for a patient that will receive thrombolytic therapy (clot-busting medicine) will cost Medicare \$19,936-\$23,194 in N.Y. and \$33,757-\$77,221 in California. If the patient is outside the window of time to be treated with thrombolytic therapy, they are at risk of residual or permanent disability and even death. Patients with commercial plans are at greater risk of financial ruin than Medicare/Medicaid patients because commercial plans pay higher prices for procedures and treatments and may incur higher premiums, deductibles, cost-sharing co-payments and co-insurance depending on the commercial health insurance plan.

Hope lies in the price discrepancies shown in these tables among facilities. The exorbitant price differences between facilities tells us that we still have many hospitals operating for the primary purpose of serving the community while others are spending profligately. Medicare has come under fire for paying for a growing number of potentially cosmetic surgeries, expensive surgeries that have limited utility and a number of interventions that do not appear to be cost-effective.²⁵² In addition, the DRG Summary for Medicare Inpatient Prospective Payment for Hospitals²⁵³ needs to further clarify Average Covered Charges, Average Total Payment and Average Medicare

²⁵¹ DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 @ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient2014.html

²⁵³ DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014, available at <u>https://www.cms.gov/Research-</u> <u>Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient2014.html</u>

Exhibit 5: Diagnosis-related Group (DRG) Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 ²⁵⁴ 2/2

Payments. For example, in the case of organ transplants, the question arises: do the charges and payments for Inpatient Prospective Payment include the charges for an organ procurement organization (OPO) to recover the organs? The average Medicare payment for a liver transplant is listed²⁵⁵ from \$31,102.08 in Memphis, TN to \$78,724.93 in Chicago, IL (price data only provided for four states); is that the price to transplant the liver with a separate charge for the OPO to recover it?

²⁵⁴ DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 @ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient2014.html

²⁵⁵ DRG Summary for Medicare Inpatient Prospective Payment Hospitals, FY2014 @ https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient2014.html

Exhibit 6

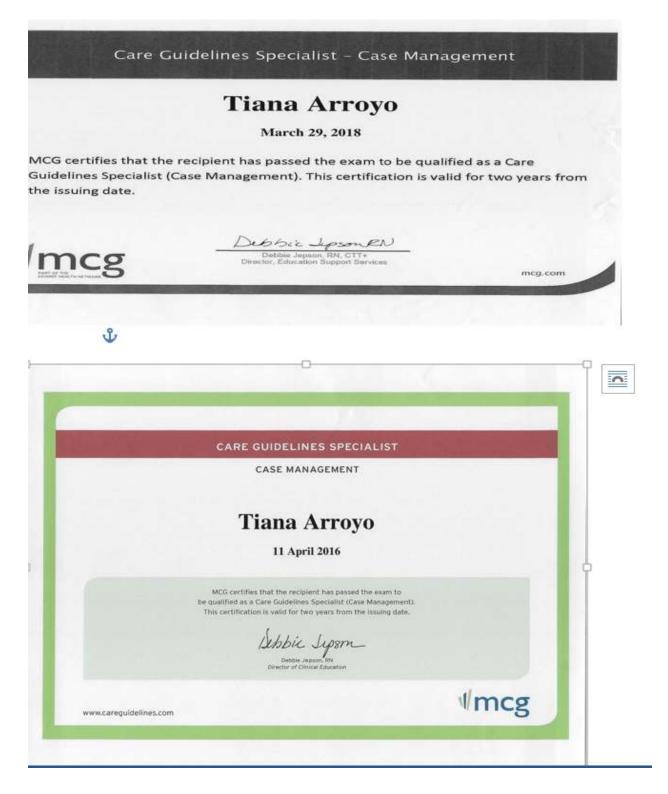


Exhibit 7: Utilization Review for Medical Necessity for For-Profit Payer: Case Presentation

Summary of the minimally-to-know patient information required to determine if a patient that presents with new onset atrial fibrillation meets the criteria for in-patient admission: 68F, presented to ER with palpitations, dizziness. EKG shows atrial fibrillation. Diagnosis: New onset atrial fibrillation. Admitted to telemetry to observe heart rhythm and start antiarrhythmic therapy.

Under HIPAA, insurance companies are gaining access to electronic medical records, which is an excess of information, with patient data that the insurer does not need to know, and in contradiction with HIPPA's own "minimum necessary" rule.

Milliman Care Guidelines, Part of the Hearst Network:²⁵⁶ ORG M-505 Atrial Fibrillation 22nd edition - Ambulatory to 1 day in-patient stay

Admission is indicated for 1 or more of the following(1)(2)(3)(4)(5)(6)(7)(8)(9): Admission is indicated for one or more of the following: Initiation of antiarrhythmic drug therapy for patient at high risk of adverse effects as indicated by one or more of the following: Syncope: Heart failure (e.g., pulmonary edema with dyspnea, Tachypnea, or Hypoxemia) (15)

Patient whose sinus rhythm has never been observed on ECG

Hospitalization

Optimal Recovery Course 1 day admission to the hospital and discharged the next day (day 2)

Under the MCG guideline, this patient meets criteria. A-1 means atrial fibrillation could be treated as ambulatory or with a **one-day in-patient stay if patient meets criteria**. The guideline should not be used to override the treating physician's judgment. However, this case should be approved for a one-day inpatient stay based on the guideline's own admission criteria. In a DRG payment system, Medicare will pay a set price (see Exhibit 5) for the diagnosis regardless of how long the patient stays in the hospital. Insurance companies often deny in-patient stays for such patients by further adding their own language to the criteria, such as: "patient's vital signs are stable, they could be discharged." The case now has to go through the appeal process - that means time, lost productivity, misuse of resources and money. If the patient is prematurely discharged and develops a stroke, the cost of care for a stroke (see Exhibit 5) is almost three-fold the cost of care for roperly treating the patient for the initial atrial fibrillation. The patient is also at risk of dying.

Diagnostic errors contribute to approximately 10% of patient deaths, and medical error reviews suggest they account for 6-17% of adverse events in hospitals; furthermore, diagnostic errors are the leading type of paid malpractice claims and are almost twice as likely to have resulted in the patient's death compared to other claims.²⁵⁷ Nonetheless, the case described here does not represent a diagnostic error, but rather a known, willful commission of wrong doing.

²⁵⁶ Milliman Care Guidelines, Part of the Hearst Network, ORG M-505 Atrial Fibrillation 22nd Edition

²⁵⁷ Improving diagnosis in Health Care, Quality Chasm Series, Sept 2015, Institute of Medicine

Exhibit 8: MCG Criteria for In-Patient Admission 1/4

Inpatient & Surgical Care > Optimal Recovery Guidelines > Cardiology >Atrial Fibrillation (M-505)

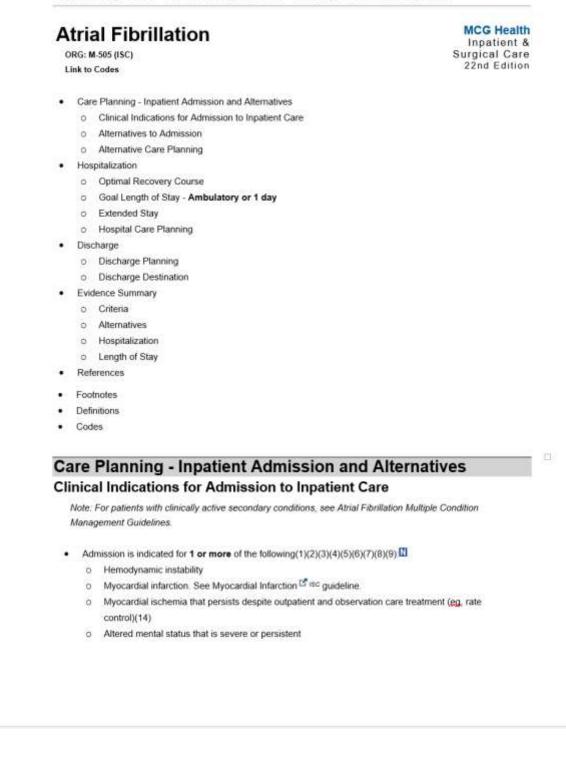


Exhibit 8: MCG Criteria for In-Patient Admission 2/4

- o Syncope
- Heart failure (eg. pulmonary edema with dyspnea, Tachypnea, or Hypoxemia)(15)
- Patient has implantable cardioverter-defibrillator that has fired more than once within past 24 hours or needs immediate adjustment of settings that cannot be done other than in inpatient setting.(16)
- o Suspected accessory pathway (eg. Wolff-Parkinson-White syndrome) on ECG
- Medication toxicity (eg. digitalis) causing arrhythmia(17)
- Underlying medical condition that necessitates inpatient care (eg. thyrotoxicosis, pneumonia)(18)
- Initiation of antiarrhythmic drug therapy for patient at high risk of adverse effects as indicated by 1 or more of the following:
 - Significant structural heart disease (eg, reduced ejection fraction, congenital heart disease, valvular, heart disease)
 - Underlying sinus node or atrioventricular conduction disturbances (eg. tachy-brady syndrome)
 - Prolonged QT interval
 - Need for treatment with antiarrhythmic drugs that have significant proarrhythmic potential (eg. dofetilide, sotalol, procainamide)
 - Patient whose sinus rhythm has never been observed on ECG
- Persistent symptomatic Tachycardia (eg, chest pain, dyspnea) despite outpatient and observation care treatment (eg, rate cannot be sufficiently controlled)
- Elective or urgent electrical cardioversion that cannot be performed on outpatient basis or during observation care.^[A] See Atrial Fibrillation: Observation Care ^[C] ISC guideline as appropriate.(19)(20)(21)

| Da y | Level of Care | Clinical Status | Activity | Routes | Interventi | Medications |
|---------|---|---|--------------------------|---|---|--|
| 1 | ICU, R Intermediate Care, or telemetry(C) Readmissio n Risk Assessment Extended Stay Risk Assessment Discharge planning | Clinical Indications metFI Tachycardia with possible chest pain, palpRation, dyspnea Possible Hemodynamic instability | Activity as tolerated | Det as tolerated Parenter al medicatio ns | Possible cardioversio n, electric or pharmacolo gic Candiac monitoring | Anticoaguiation Medication for ventricular ratio control Possible medication for pharmacologis cardioversion |
| 2 | ICU, intermediate care, or telemetry to discharge Complete | Hemodynami c stability Sinus rhythm or acceptable ventricular rate | • Ambulator y | Oral hydratio n, diet, and medicati | Cardiac monitoring Possible PT/PTT # anticoagulat | Anticoagulation n^{#1} Possible medication for rhythm or rate |

Exhibit 8: MCG Criteria for In-Patient Admission 3/4

| Da y | Level of Care | Clinical Status | Activity | Routes | Interventi ons | Medications |
|---------|--|---|-----------------------|--|---|--|
| 1 | ICU, IR Intermediate Care, or telemetryICI Readmissio n Risk Assesament Extended Stay Risk Assesament Discharge ptenning | Clinical Indications metFI Tachycardia with possible chest pain, palpRafion, dyspnea Possible Hemodynamic Instability | Activity as tolerated | Diet as tolerated Parenter al medicatio ns | Possible cardioversio n. electric or pharmacolo gic Cardiac monitoring | Anticoagulation Medication for ventricular ratic control Possible medication for pharmscologik cardioversion |
| 2 | ICU, intermediate care, or telemetry to discharge Complete | Hemodynami e stability Sinus rhythm or acceptable ventricular rate | • Ambulator y | Oral hydratio n, diet, and medicati | Cardiac monitoring Possible PT/PTT # anticoagulat | Anticoaguiatio n ^{#1} Possible medication for rhythm or rate |

| discharge planning | No evidence of myocardial ischemia | ons | ed | control |
|-----------------------|--|-----|----|---------|
| | Mental status | | | |
| | at baseline | | | |
| | Anticoagulati | | | |
| | on regimen for next level | | | |
| | of care | | | |
| | established | | | |
| | Discharge | | | |
| | plans and | | | |
| | education understood | | | |
| | | | | |
| (4)(6)(24)(25)(26)(4 | 4)(2) | | | |

Recovery Milestones are indicated in **bold**.

Goal Length of Stay: Ambulatory or 1 day

Note: Goal Length of Stay assumes optimal recovery, decision making, and care. Patients may be discharged to a lower level of care (either later than or sooner than the goal) when it is appropriate for their clinical status and care needs.

Exhibit 8: MCG Criteria for In-Patient Admission 4/4

Note: Milliman Care Guidelines, Part of the Hearst Network

Hearst Network has proprietary rights to the Milliman Care Guidelines and does not give copies to the public, even if a patient requests them to dispute their discharge, denial of care or denial of payment for services rendered. Only paid subscriber organizations and their staff have access to the guidelines.

Exhibit 9: Letter to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 1/2

| | | lle <mjankuski@jointcom< th=""><th>mission.org></th><th></th></mjankuski@jointcom<> | mission.org> | |
|--|--|---|---|-----------------------------|
| Sent: | | ber 11, 2018 10:16 AM | | |
| To: | Arroyo, Tiana | | | |
| Cc: | SIGInquires | | | |
| Subject: | To submit your | question online to The Joi | nt Commission | |
| Importance: | High | | | |
| Follow Up Flag: | Follow up | | | |
| Flag Status: | Flagged | | | |
| 1. Please go to <u>www.join</u> t | commission.org | | | |
| 2. Click on Standards Inte 3. Click on Contact Us | | | | |
| | | Log In Request Guest Access | Contact Us Careers JCR | Nyb Store (Press Ripor |
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| Accreditation Ce | rtification Standard | s Measurement | Topics 2.) Cli | ck Here |
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| Standards Inte Please take a moment to Do you want to be alerted to The Joint Commission stand Commission Resources | erpretation to review any applicable o New Standard's FAQs? S dards are NOT available on th | e FAQs below o | Click on act Us in that entence. AQst evailable in print and electronic fo | w mats,and may be |
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Exhibit 9: Letter to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 2/2

| | / Question via |
|--|--|
| * Email Phone | CONTRACT THE |
| Questions | |
| Select Accreditation/ | Certification Manual or Health Care Setting * |
| Disease Specific Care | |
| Select the appropriat | e chapter/honic * |
| | ion Requirements (CPR) - |
| LAND AND DOLL AND | |
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| | question here * (Limited to 4000 characters) sestion that apply to the associated Manual/Chapter in each form. You may select *Submit & Add New Quest |
| Please submit only o | ing an unrelated topic. Your contact information above questions will be prepopulated on the form for these |
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| Please submit only of for questions repart additional submissio 1 am an RN purs right to healthco the profession of | ing an unrolated topic. Your contact information above guestions will be prepapulated on the form for these to: using a Master of Jurisprudence in Healthcare Law. I am currently writing my thesis on the ire. One of my examples refers to the insurance companies constant: attack to "deregulate" if medicine. One of the sources I read states "JCAHO Managed care accreditation program. |
| Please submit only of for questions regard additional submission 1 am an RN purs right to healthcr the profession of established in 19 | ing an unrolated topic. Your contact information above guestions will be prepapulated on the form for these to: using a Master of Jurisprudence in Healthcare Law. I am currently writing my thesis on the ire. One of my examples refers to the insurance companies constant: attack to "deregulate". |

Exhibit 10: Letter to Utilization Review Accreditation Commission (URAC)

| From: | Arroyo, Tiana |
|----------|-------------------------|
| Sent: | Thursday, June 14, 2018 |
| To: | compliance@urac.org |
| Subject: | Questions |

Good Morning:

My name is Tiana Arroyo. I am a nurse currently pursuing a Masters in Health Care Law at Loyola University. Over the next 2 terms I will be writing my final thesis around the subject of "American's right to healthcare".

4:35 AM

I am reaching out to your office with a few questions to see if you could provide me with some information.

- 1. I read through your Accreditation Process. What kind of businesses apply for Utilization Review Accreditation?
- 2. Does the C in URAC stands for commission?
- 3. Is URAC under/reports to a government authority?
- 4. Are there any laws, statutes or regulations pertaining to the establishment of URAC?
- 5. The tab about Case Management describes the standards and Measures that URAC uses for Case Management Accreditation. Are the standards and measures the same for hospitals and health insurance companies?
- 6. When an agency is URAC accredited for case management, is that for federally funded healthcare plans and private/commercial plans?
- 7. Is utilization review part of case management?
- 8. Case Management/Utilization Review requires applying Clinical Care Guidelines, mainly Inter-Qual or MCG?
- 9. Is the use of evidenced based clinical care guidelines mandatory when conducting CM/UR reviews?
- 10. Under the section for measurements, there is no criteria listed to measure quality of care by properly applying clinical care guidelines. How are URAC case management/utilization review accredited facilities/insurance companies measured in this area?
- 11. URAC was established in 1990, who conducted CM/UR accreditation before URAC?

Please feel free to share any other information you feel will help me with the thesis topic "American's right to healthcare". I want to thank you for providing me the opportunity to write to you,

Tiana Arroyo

tarroyo1@luc.edu

EXHIBIT 11: New York State Charity Care Funds 2008

| Charity Care |
|---|
| https://www.health.ny.gov/facilities/hospital/indigent_care/2008_indigent_care_repor .htm#exec_summary |
| Since 1983, New York State has set aside a pool of money to underwrite a portion of the uncompensated care costs |
| incurred by hospitals. Initially termed the Hospital Bad Debt and Charity Care (BDCC) Pool and more recently the |
| Hospital Indigent Care Pool (the Pool), this Pool currently distributes \$847 million in Medicaid funds to public and |
| voluntary hospitals through multiple sub-Pools and multiple allocation formulas. |
| In an effort to assure greater transparency and accountability, in 2007, the Legislature, at the urging of the Governor |
| required the Commissioner of Health in conjunction with the Chairs of the Senate and Assembly Health Committees |
| and with the assistance of a Technical Advisory Committee, to evaluate the types and amounts of services provided |
| by hospitals and the costs incurred by hospitals in relation to the receipt of monies from the Indigent Care Pool. In |
| addition, the 2007 legislation instructs the Commissioner to review the relationship between the Indigent Care Pool |
| awards and the Patient Financial Aid Law (Section 2807-k(9-a)) of the Public Health Law). Enacted in 2006, the |
| Financial Aid Law requires hospitals to offer steep discounts from typical charges to uninsured patients with incomes |
| at or below 300 percent of the Federal Poverty Level (FPL). As required by the Legislation, this report sets out the |
| Commissioner of Health's findings and recommendations. |
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Note: This report is not available at the original link where it was obtained - page currently "not found". The above note is from the report.