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TO THE HOUSE COMMITTEE ON JUDICIARY

TWENTY-EIGHTH LEGISLATURE
Regular Session of 2016

Friday, March 4, 2016
2:00 p.m.

TESTIMONY ON HOUSE BILL NO. 2740, H. D. 1 – RELATING TO LIABILITY.

TO THE HONORABLE KARL RHOADS, CHAIR, AND MEMBERS OF THE COMMITTEE:

My name is Gordon Ito, State Insurance Commissioner, testifying on behalf of the Department of Commerce and Consumer Affairs ("Department").

The purpose of this bill is to prohibit health insurers from requiring preauthorization that causes undue delay in a patient's receipt of medical treatment or services. The bill would also require an insurer to defend and indemnify a licensed health care provider for injury to a patient caused by undue delay in preauthorization, impose civil liability on an insurer for any patient injury caused by undue delay in the receipt of medical treatment or services, and require a health care provider to provide treatment without waiting for preauthorization under certain circumstances. The Department submits the following comments.

This bill would add new sections (preauthorization; undue delay; liability) to chapter 431, Hawaii Revised Statutes ("HRS"), applicable to health insurers and limited benefit health insurance, and chapter 432, HRS, applicable to mutual benefit societies, as well as amend section 432D-23, HRS, applicable to health maintenance organizations.

Medical determinations are complex, and not conducive to blanket regulation by the Insurance Code. These medical decisions seek to balance patient safety, effectiveness, and medical appropriateness and are outside the purview of the

Insurance Code. The Affordable Care Act, as well, recognizes that services, except in the case of emergency and patient access to obstetrical and gynecological care, may require preauthorization.

The creation of a mandate to defend and indemnify health care providers for injuries, the imposition of liability on insurers regarding medical decisions, and creation of a mandate to provide treatment without preauthorization are likewise outside the purview of the Insurance Code.

As noted in previous testimony, there may be a subject-title problem with the bill in violation of Article III, section 14, of the Hawaii State Constitution. The title of this bill is “Relating to Liability.” The bill’s contents, however, address several subjects not relating to liability, thereby possibly exceeding the scope of the bill’s title.

We thank this Committee for the opportunity to present testimony on this matter.

March 4, 2016

Representative Karl Rhoads, Chair
Representative Joy San Buenaventura, Vice Chair
Committee on Judiciary
Conference Room 325

RE: HB2740, HD1 Relating to Liability

Dear Chair Rhoads, Vice Chair San Buenaventura and Members of the Committee:

We respectfully oppose HB2740 HD1 which proposes to prohibit health insurance preauthorization requirements that cause undue delay in receipt of medical treatment or services and specifies that insurers, but not health care providers, are liable for civil damages caused by undue delays for preauthorization.

This bill will result in a dramatic shift in the oversight and monitoring conducted by health insurers and it will likely significantly drive up costs of health care generally.

Although the Health Committee revised the bill, its definition of "undue delay" remains vague and will likely only result in more disputes and litigation. The bill defines "undue delay" to mean "an unreasonable delay in medical treatment or services that may cause the exacerbation or worsening of a health condition due to:

(1) The insufficient time to obtain or unwarranted rejection by an insurer of a first-time preauthorization;

(2) Administrative difficulties or delays in receiving preauthorization from insurers; and

(3) Difficulties arising from the non-communication by insurers on the tests and procedures that require preauthorization."

These factors "insufficient time," "unwarranted rejection," "administrative difficulties or delays," and "difficulties arising from the non-communication" are broad phrases that are not clear. Even if the insurer wanted to revise and update its policies, this language is too vague to provide the health insurer with any guidelines by which it could have reasonable policies to avoid these uncertain, but possibly unfortunate, circumstances.

More worrisome is the bill's creation of additional liability upon the health insurer for "any injury that

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occurs to a patient because of undue delay in the receipt of medical treatment or services." There is already existing tort liability under common law for injuries proximately caused by the wrongful party. Here however, the insurer is burdened with the additional duty to defend and indemnify a health care provider. These duties and obligations are typically contractual in nature and dependent upon the relationship established via the contract. This bill would interject itself and place these roles and responsibilities upon the insurer regardless of their prior or existing contractual provisions.

Liability for any injury oftentimes arises from a complex aggregate of a multitude of factors. It is for that reason we have a system where each of the several parties can be included in a case to ensure that all of these factors can be considered by the fact-finder and decision maker as to who is the ultimately contributed to the alleged injury. This new liability would dramatically change this landscape, but more importantly, will place most of any burden upon the health insurer.

The unintended consequence of this bill would be that insurers would diminish or eliminate any prior authorization process. This will result in little to no oversight and ultimately lead to increased costs for all.

It is for these reasons we oppose HB2740 HD1. Thank you for the opportunity to submit written comments.

Respectfully submitted,

Howard Lee
President, CEO

TESTIMONY OF BERT SAKUDA ON BEHALF OF THE HAWAII ASSOCIATION FOR JUSTICE (HAJ) IN SUPPORT OF H.B. NO. 2740, H.D. 1

Date: Friday, March 4, 2016
Time: 2:00 pm
Room: 325

To: Chairman Karl Rhoads and Members of the House Committee on Judiciary:

My name is Bert Sakuda and I am presenting this testimony on behalf of the Hawaii Association for Justice (HAJ) in SUPPORT of H.B. No. 2740, H.D. 1, Relating to Liability is focused on the immunity provisions of this measure as currently drafted.

The Hawaii Association for Justice SUPPORTS the purpose and intent of this measure to protect patients from harm caused by undue delays in treatment due to insurance pre-authorization requirements. While the resolution of insurance processing procedures are ultimately for the medical and insurance industries to work out, HAJ seeks to insure that patients receive needed medical care on a timely basis and are not innocent casualties in the crossfire between doctors and insurers. Any resolution must insure that doctors treat patients without undue delay and that doctors who render such treatment in good faith be properly reimbursed for their services. Thus, HAJ opposes any immunity that would permit or encourage undue delays in providing needed treatment due to insurance pre-authorization issues. This current draft protects patients from undue delays.

Thank you very much for allowing me to testify regarding this measure. Please feel free to contact me should you have any questions or desire additional information.

Friday March 4, 2016
2:00 PM.
Capitol Rm. 325

To: HOUSE COMMITTEE ON JUDICIARY
Rep. Karl Rhoads, Chair
Rep. Joy A. San Buenaventura, Vice Chair

From: Hawaii Medical Association
Dr. Scott McCaffrey, MD, President
Dr. Linda Rasmussen, MD, Legislative Co-Chair
Dr. Ronald Keinitz, MD, Legislative Co-Chair
Dr. Christopher Flanders, DO, Executive Director
Lauren Zirbel, Community and Government Relations

Re: HB 2740 HD1 – RELATING TO LIABILITY

IN SUPPORT

Chair, Vice Chair, and Committee Members:

Hawaii Medical Association **strongly supports** this legislation.

In medicine, moments matter. This bill is a common sense measure and should be enacted as soon as possible to ensure patient safety and encourage health plans approve appropriate care.

Physicians feel strongly about their profession and patients. Among the closely held beliefs concerning prior authorization are:

(1) The physician-patient relationship is paramount and should not be subject to third-party intrusion.
(2) Preauthorization programs should not be permitted to hinder patient care or intrude on the practice of medicine.
(3) Preauthorization programs must include the use of independently developed, evidence-based and, when necessary or available, appropriate use criteria or written clinical criteria.
(4) Preauthorization programs must include reviews by appropriate physicians to ensure a fair process for patients.

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Missing from this process as it currently exists is any semblance of transparency in the prior authorization process.

(1) Advanced notification and education prior to enacting this scrutiny was grossly inadequate.
(2) Guidelines being used are proprietary, and not recognized, national peer reviewed standards
(3) Reviewers are many times on the mainland and not licensed to practice medicine in Hawaii

This bill has the following admirable goals:
(1) Prohibit insurers from requiring preauthorization that causes undue delay in a patient's receipt of medical treatment or services; and
(2) Clarify liability for patient injuries caused by preauthorization delays.

In medicine moments matter. It is only fair that a licensed health care provider should be immune from civil liability for injury to a patient that was caused by undue or unreasonable delay caused by the unilateral placement of the provider in an impossible position by the insurer for the preauthorization of medical treatment services. The insurer should be civilly liable and indemnify the provider for any injury that occurs to a patient because of undue delay in medical treatment.

Thank you for the opportunity to provide this testimony.

THE PROBLEM WITH PRE-AUTHORIZATION REQUIREMENTS FOR MR AND CT STUDIES: THE HAWAII NEUROLOGICAL SOCIETY'S PERSPECTIVE

March 3, 2016

Introduction:

The Hawaii Neurological Society (HNS) represents approximately 40 neurologists who are currently practicing in the State of Hawaii. The HNS is committed to the provision of the very best, timely, neurologic care to our Hawaiian community in a cost efficient manner. The Board and Membership of the Hawaii Neurological Society support the following position statement regarding insurance pre-authorization requirements.

Background:

Neurologists are medical physicians with expertise and skill in the diagnosis and treatment of disorders of the brain, spinal cord, nerves, and muscles. Neurologists are required to complete 4 years of college, 4 years of medical school, and 4 years of residency training in neurology. Most current graduates also seek one to two additional years of subspecialty training before beginning practice. Neurologists demonstrate their particular skill and expertise by successfully completing a lengthy certification and examination process in order to become Board Certified. All neurologists must complete an additional 40 hours of Continuing Medical Education (CME) every two years, and successfully retake the certification exam every 10 years to continue their neurologic practice in Hawaii. We believe that in our community, neurologists are best prepared to make decisions regarding the necessity of MR and CT imaging studies.

Neurologists are a unique medical specialty in their intense reliance on Magnetic Resonance (MR) and Computerized Tomography (CT) imaging studies in order to accurately diagnose disorders of the nervous system. We deal commonly with potentially life threating conditions, and neurologists must accurately diagnose and localize neurologic disorders within the nervous system without error. Neurologists accomplish this based on a complete medical history, a thorough neurologic exam, and often MR and or CT imaging of the nervous system. Accurate localization of the lesion is critical to diagnosis in our field. It is fair to say that in the initial diagnosis of serious neurologic conditions and their later management, most neurologic patients will require MR or CT imaging. Often these studies must be completed urgently based on the potential risks to the patient, for example in acutely evolving stroke or infection.

In the past practicing neurologists in Hawaii have partnered with local imaging centers who commonly make arrangements to perform diagnostic studies such as MR promptly, often on the same day, when possible diagnoses are serious or life threatening. However, in December a prominent Hawaii insurer imposed a pre-authorization requirement on CT and MR studies. This insurer engaged an outside mainland radiology benefit manager (RBM) to provide reviews of Hawaii neurologist's orders for these studies. The RBM requires a neurologist's practice to submit detailed medical records to document the necessity of the requested studies. The RBM reviews are usually not made on the same day, and approval for studies may not be received for several days. RBM reviewers generally do not contact the neurologist or his/her staff if they have questions or deny approval of a study. Without RBM approval of requested imaging studies, our local insurer declines to pay for the studies, thus preventing their performance, and often delaying needed care. To our knowledge, these reviews are usually made by RBM employed staff who are not neurologists, and may not even be physicians. RBM staff are asked to make their decisions based on "RBM Established Guidelines". To our knowledge Hawaii neurologists were not consulted in the establishment of these guidelines, and several HNS members have noted inconsistencies between the RBM Guidelines and those published by Medicare and the American Academy of Neurology.

When studies are denied by the RBM, there is an appeal process, which requires neurologists or their staff to contact a RBM reviewer and request approval. These are termed "peer to peer" reviews, but they actually are not. Lengthy wait times to obtain a RBM reviewer by phone are common. Usually the RBM reviewer is not a neurologist, and if a neurologist's office staff makes the appeal in order to save the neurologist time, they often do not have the skills to communicate the necessity of the study. It is not uncommon for the requested CT or MR study to be approved after appeal, but in these cases, necessary patient care is delayed. The administrative and financial burden imposed by the pre-authorization process, and the lost time in order to make these appeals, falls on the practicing neurologist.

The HNS is not aware that the insurer or RBM consulted practicing neurologists in Hawaii, nor their beneficiaries regarding the imposition of the requirement for MR and CT pre-authorizations. Had they done so, they would have been promptly informed by our members regarding the adverse impact upon our daily practices and our concerns regarding the risk to our patients by delay in the performance of needed studies. We believe that the insurer imposed the pre-authorization requirements for MR and CT studies based solely on their desire to obtain cost savings and avoid overutilization of these expensive studies. We are not aware of data that indicates that Hawaii neurologists have routinely ordered MR or CT studies inappropriately in the past. The insurer has not required pre-authorization for other routine clinical decisions made by neurologists. In Hawaii, neurologists do not own imaging centers and most studies are interpreted by radiologists, thus neurologists do not have a financial incentive to over utilize MR and CT.

From a legal standpoint, it is Hawaii neurologists who establish the Standards of Care for neurologic care in our community, and it is Hawaii neurologists who should determine the necessity for neurologic diagnostic imaging studies.

The Problem With Pre-authorization Requirements:

The membership of the HNS identifies several areas of concern regarding the requirement for preauthorization of neurodiagnostic studies. These may be summarized as: 1. Delay in patient care, 2. Risk of harm to patients, 3. Uncompensated administrative and financial burden on neurologic practices, 4. Change in practice referral patterns, 5. Impediment to the maintenance and recruitment of neurologic private practices in our state, 6. Increased liability risk to neurologists, 7. Interference in shared decision making between patients and neurologists, 8. Geographic impediments to care for off island patients, and 9. Fairness and respect for our profession.

Among these areas of concern, the most urgent is the potential for pre-authorization to delay critical patient care and the risk of harm to our patients. Our specialty is concerned with many emergent and urgent patient problems, which require immediate identification and institution of preventative and restorative treatment. These include stroke, nervous system infection and inflammation, acute demyelination, and increased intracranial pressure, among others. MR and CT imaging is critical to the identification of these disorders. While some patients present with obvious clinical signs and symptoms, many present with subjective or confusing symptoms that must be sorted out by the neurologist. MR imaging is necessary for the identification of these disorders. We firmly believe that some patients will likely be harmed by a delay in their diagnosis by strict adherence to a pre-authorization requirement for imaging studies.

Since our membership believes the preauthorization requirement will delay needed patient care with increased risk of harm to our patients, both the HNS, local insurers, our legislators, and our community should recognize the increased liability risk inherent in these policies.

Additionally, our membership has unanimously voiced concerns regarding the financial and administrative burden placed on their practices by the pre-authorization process, taking them away from direct patient care. For busy neurologists who see many new outpatients, even a small number of denials requiring appeal requires significant time expenditure on a daily basis to appeal the decision and communicate the outcome to their anxious patients. Local insurers have offered no compensation for this additional time which neurologists must spend dealing with denials, and this “lost” time represents time away from direct patient care. Neurologists frequently provide detailed explanations to their patients and their family regarding the need, or the lack of need, for neurodiagnositic imaging, and the decision by the insurer and RBM to deny approval for these studies

commonly creates anxiety and fear for the patient, as well as harm to the confidence in the patient physician relationship.

Anecdotal information from our membership suggests since the institution of preauthorization requirements, referral patterns to neurologists have changed. Primary care physicians understandably do not wish the "hassle factor" of pre-authorization, and so are likely to more quickly refer their patients to neurologists for conditions, which, in the past, they could have comfortably managed by ordering the needed MR study themselves. Moreover, office neurologists who are faced with potentially urgent conditions are more likely to refer their patients to emergency rooms where the patients can receive prompt evaluation, whereas in the past they would have ordered immediate evaluation by an outpatient imaging center. In both cases, patients will have increased difficulty obtaining needed care at increased cost.

Hawaii has a 45% shortage in neurologists, and some islands such as Hawaii, Molokai, and Kauai have had trouble retaining neurologists in their communities. Most Hawaii neurologists report schedules in which they are unable to see new referrals for several weeks. The preauthorization requirement is likely to magnify this problem, further delaying patient care.

An incidental problem has arisen due to the preauthorization requirement and the inability for neurologists to obtain imaging studies promptly. This concerns patients who live on another island and who have to fly to Oahu for their appointment. Before pre-authorization, it was common for the neurologist's office to arrange the ordered MR study on the same day of the visit, in an outpatient setting before their return flight, avoiding the need for the patient and their family to fly back for their study on another day. Returning for the study creates additional delay in care, as well as cost and inconvenience for our off island patients.

Finally, our membership believes they have spent many years in training to be able to make appropriate decisions regarding the need for neurodiagnostic imaging. Training programs emphasize the requirement to practice in a cost effective manner. Neurologists are uniquely trained to make these clinical decisions regarding neurologic imaging. In fairness to our highly trained members, we believe neurologists deserve trust in making these important and costly decisions.

Finally, the HNS recognizes that our local insurers have had a long and valuable partnership with the medical community in Hawaii. We wish to continue this partnership to improve patient care in Hawaii.

The Position of the HNS:

1. We acknowledge the fiduciary responsibility of insurers to reduce the cost of health care, but we believe the decision to institute a pre-authorization policy which applies to Board Certified neurologists was flawed.
2. The HNS believes that the pre-authorization process will lead to unnecessary delays in the provision of care and will increase risk of harm to our patients by delaying needed care.
3. Hawaii's Board Certified neurologists uniquely have the necessary skills and training to make appropriate cost effective decisions regarding MR and CT studies of the nervous system.
4. We strongly believe that financial relationships between our local insurers and outside reviewing companies should be transparent. We oppose compensation relationships that reward RBM companies or their reviewers based on the number or percentage of denials, or decreases in costs expenditures for diagnostic studies, or incentivizes them in any manner to increase denials.
5. The administrative and financial burden of pre-authorization for imaging studies falls disproportionally upon neurologists relative to other medical specialties due to the nature of neurologic practice, reducing the availability of Hawaii neurologists to provide needed care.
6. The HNS will partner with our local insurers to establish a retrospective review program of Hawaii neurologists regarding the appropriateness of their studies, using national Medicare and American Academy of Neurology Guidelines. HNS will support the establishment of constructive educational programs for neurologists who display a pattern of inappropriate ordering.
7. We request that all insurance companies consult with Hawaii's neurologists when considering changes in coverage that will likely effect our ability to provide care to our patients.
8. The HNS welcomes the continued exchange of information and dialogue regarding these issues. The HNS will assist our local insurers in programs that enhance the delivery of neurologic care in our community.

Hawaii Neurological Society Board of Directors

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THURSDAY MARCH 3, 2016

HAWAII RADIOLOGICAL SOCIETY

LETTER OF SUPPORT - PART B

WITH REGARD TO HB2740 which would prohibit health insurance preauthorization requirements that cause undue delay in receipt of medical treatment or services. This specifies that insurers, but not health care providers, are liable for civil damages caused by undue delays for preauthorization:

The Hawaii Radiological Society supports this measure.

Over the last two months the Hawaii Radiological Society (HRS) and the Hawaii Medical Association (HMA) have been aware of the extreme challenges that all provider physicians have faced as they try to get insurance pre-approval for imaging necessary to diagnose and treat our patients. The frustration of dealing with preauthorization via third party reviewers who are thousands of miles away is readily apparent.

HRS and HMA recognize that insurance payers like HMSA are under serious pressure to contain costs. We would like to advise insurance carriers that there is an excellent alternative solution to the use of preauthorization and their indiscriminate denials for necessary medical imaging:

Understanding the daily obstacles and financial stresses faced by Hawaii physicians, HRS and HMA advocate the immediate use of an evidence-based Clinical Decision Support Tool, whereby imaging requests are vetted against the American College of Radiology (ACR) Appropriateness Criteria at the point of care. Providers will receive real-time feedback on the clinical utility of a request, and, if necessary, be guided to either a more appropriate exam or given consideration for direct consultation with a local Radiologist. This will be a useful instrument to complement the expertise of Hawaii's primary providers and imaging specialists. There are 25 years of research and development of this tool, and it is now available FREE through a web portal to all Hawaii physicians. Additionally, the Choosing Wisely guidelines pertaining to imaging are generally aligned with the ACR Appropriateness Criteria.

The need for cost efficiency with value based care is more apparent than ever for Hawaii physicians. Insurance payers must partner with their physician community to implement solutions that remove such haphazard barriers that are inherent in the use of third party Radiology Benefits Management companies and their preauthorization processes. We have the same goal of *hoʻohiki* – keeping our solemn promise to fully deliver the highest quality of healthcare that we can provide.

Please contact us with any concerns or questions.
Mahalo for your thoughtful consideration of these issues.

With Aloha,

Elizabeth Ann Ignacio MD
President, Hawaii Radiological Society
808.250.7058

March 4, 2016

The Honorable Karl Rhoads, Chairman and Members of the House Committee on Judiciary

RE: HB2740 HD1, Relating to Liability

Dear Chair Rhoads and Members of the Committee:

Hawaii Dental Service ("HDS") is strongly opposed to HB 2740 HD 1 as it currently stands.

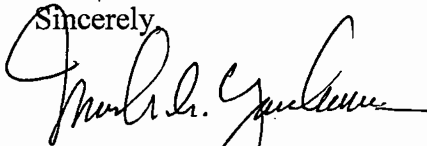
The preamble to the bill states that it is concerned with "certain physician-ordered treatments or services". However, the operative text refers to "a licensed health care provider" rather than a physician. The term "licensed health care provider" arguably extends to dentists and even possibly dental hygienists if a pending bill licensing hygienists passes the legislature.

This would be problematic for HDS for two reasons. First, HDS requires preauthorization when dentists have been found to have repeatedly over-billed or over-treated in the past. Second, Medicaid regulations require ¬ preauthorization for certain treatments and procedures. As a result, the bill in its current form would create a conflict with Medicaid regulations. In other words, HDS cannot comply with Medicaid regulations without risking liability under the current language of HB 2740 HD 1. We assume that this is not the intended effect of the bill.

HDS respectfully requests that this committee amend the bill to include a statement that "nothing in this chapter shall be construed to apply to dental services" in § 431:10A and § 432 and we feel that this would address any ambiguity.

Thank you for the opportunity to clarify this bill's effect on dental services in Hawaii and to request an amendment.

Sincerely,



Mark Yamakawa
President and CEO

FW: House Bill 2740 testimony- in support

Dear Honorable Speaker Souki and House of Representatives Cachola, Evans, Luke, Mikuno and Saiki:

I am in strong support of House Bill 2740 for the following reasons:

The bond between the doctor and the patient is still the most important bond in health care. The doctor knows the health care needs of the patient and understands the urgency of the tests and imaging studies he or she orders. Any delay in treatment compromises the care of the patient. If this delay is because of prior authorization mandated by the insurer, then the insurer is liable for any injury or harm done to the patient caused by this delay.

Respectfully,
Luz Patricia Medina,MD, President of the Maui County Medical Society

Hawaii Association of Health Plans

March 4, 2016

LATE

The Honorable Karl Rhoads, Chair
The Honorable Joy San Buenaventura, Vice Chair
House Committee on Judiciary

Re: HB 2740, HD1 – Relating to Liability

Dear Chair Rhoads, Vice Chair San Buenaventura, and Members of the Committee:

The Hawai'i Association of Health Plans (HAHP) submits testimony in opposition to HB 2740, HD1, which prohibits health insurance preauthorization requirements that cause undue delay in receipt of medical treatment or services and specifies that insurers are liable for civil damages caused by undue delays for preauthorization.

A health plan's first priority is the well-being and care of its members. Health plan utilization review programs, of which prior authorization of certain services is a key component, are a critical means to both control healthcare costs and ensure patient safety. Utilization review controls are designed to protect consumers from arbitrary, capricious and/or misleading information about healthcare services, treatments, and procedures. To help maintain high-quality utilization management standards, organizations such as NCQA and URAC accredit health plans. This ensures utilization review programs meet the needs of federal and state government requirements while protecting consumer rights.

The threat of liability and potential for lawsuits could lessen a health plan's ability to engage in the prior authorization process. As a result of reduced preauthorization, unnecessary procedures could increase and consumer costs could rise and burden the entire healthcare system.

Finally, this bill could be in conflict with current utilization management requirements for the State Medicaid Program and national Medicare Advantage Programs. For these reasons, we respectfully ask that this measure be deferred.

Thank you for allowing HAHP to testify in opposition to HB 2740, HD1.

Sincerely,

Wendy Morriarty, RN, MPH
Chair, HAHP Public Policy Committee

Cc: HAHP Board Members

hmsa

An Independent Licensee of the Blue Cross and Blue Shield Association

LATE

March 4, 2016

The Honorable, Karl Rhoads, Chair
The Honorable, Joy A. San Buenaventura, Vice Chair
House Committee on Judiciary

Re: HB 2740, HD1 – Relating to Liability

Dear Chair Rhoads, Vice Chair San Buenaventura, and Members of the Committee:

The Hawaii Medical Association (HMSA) appreciates the opportunity to testify on HB 2740, HD1, which seeks to (1) limit the ability of plans to require preauthorizations, and (2) clarifies liability for patient injuries caused by preauthorization delays. HMSA opposes this Bill.

HMSA and providers share the same goal – protecting the health and safety of people who trust us with their care. We work together to reach that goal but sometimes disagree on how to get there. While we work every day to balance the needs of our members, physicians, employer groups, and government partners, our first priority always is the needs and safety of our members.

We seriously are concerned that HB 2740, HD1, will encourage plans to minimize preauthorization requirements, resulting in potentially dangerous health consequences for members and increase costs to Hawaii's healthcare system.

<u>Preauthorizations</u>

A preauthorization requirement is designed to (1) improve a patient's health and well-being by preventing overuse of medical services that could unintentionally cause harm, and (2) prevent wasteful services that people do not truly need.

Preauthorizations are required not only of imaging services, but they are required for many other medical procedures, medications, and durable medical equipment. Most notably with public concern over rising drug costs, preauthorizations can help identify an appropriate generic medication in lieu of a more expensive brand named drug. And, a preauthorization for a new prescription may help prevent potentially dangerous drug interactions.

Virtually every health plan, including Medicare and Medicaid, require preauthorizations for numerous services. To comply with Medicare requirements, HMSA's Akamai Advantage plans require preauthorization for the following advancing imaging studies when provided on an outpatient basis (not emergency room or inpatient):

- CT scans
- Coronary CT angiography
- CT colonography (virtual colonoscopy)
- Functional Magnetic Resonance Imaging
- MRI, MRA, MRV
- Nuclear cardiology
- PET scans
- Cardiac Related Procedures

The Centers for Medicare & Medicaid Services (CMS), the National Committee for quality Assurance (NCQA), and the Health Services Advisory Group (HSAG), which oversees Medicaid in Hawaii, all have prior authorization guidelines and definitions on urgent versus non-urgent requests, specific turnaround times, and approval and denial processes. HMSA follows these guidelines and definitions.

Concerns with HB 2740, HD1

As drafted, HB 2740, HD1, poses significant concerns:

- The Bill implies that there are circumstances under which an insurer will require a preauthorization to cause "undue delay." Section 2 of the Bill applicable to Chapter 431, HRS, (insurers) and Section 3 of the Bill applicable to Chapter 432, HRS (mutual benefit societies) include the following comparable provision:

  > *(a) Notwithstanding any provision of the law to the contrary, no insurer shall require preauthorization of medical services or treatments so as to cause an undue delay in a patient's receipt of medical treatment or services.*

  A preauthorization program is in place to ensure the health and safety of our members. It takes a physician no more than seven minutes to complete our online preauthorization form and approvals are made in no more than two calendar days. To protect our members who are faced with emergency or urgent care situations, no preauthorizations are required in those cases.

- The Bill's definition of "undue delay" in Sections 2 and 3 of the Bill may result in unnecessary legal action which will be costly to the healthcare system. As drafted "undue delay means:

  > *...an unreasonable delay in medical treatment or services that may cause the exacerbation or worsening of a health condition due to:*
  >
  > *(1) The insufficient time to obtain or unwarranted rejection by an insurer of a first-time preauthorization;*
  >
  > *(2) Administrative difficulties or delays in receiving preauthorization from insurers; and*
  >
  > *(3) Difficulties arising from noncommunication by insurers on the tests and procedures that require preauthorization.*

  We certainly want to ensure that no action on the part of a plan results in the diminution of a member's health condition. However, as drafted, the Bill lacks clarity with respect to the "exacerbation or worsening" of a health condition. That affords the opportunity for potentially trivial lawsuits resulting from de minimus "exacerbation or worsening" of a member's condition.

- The definition of "undue delay" presents other concerns that further obscure its meaning. The Bill states that undue delay is caused by *"(t)he insufficient time to obtain or unwarranted rejection by an insurer of a first-time preauthorization*". Preauthorizations are not required in an emergency room situation or in the case where a provider is presented with an emergent case. Consequently, we are unclear as to what determines the rejection of a preauthorization to be "unwarranted.

- The Bill additionally provides for undue delay to be attributable to "(*a)dministrative difficulties or delays in receiving preauthorizations from insurers*". This provision is overly broad and ambiguous. HMSA is held to national standards in administering our preauthorization program,

An Independent Licensee of the Blue Cross and Blue Shield Association

including, CMS, HSAG, and NCQA guidelines. We are fully engaged in meeting those standards and fail to understand the intent of this provision.

- “Undue delay” also includes “(d)ifficulties arising from the non-communication by insurers on the tests and procedures that require preauthorization”. This language is extremely difficult to interpret. HMSA has a phone hotline dedicated to preauthorizations that is used every day by providers. In addition, all plans must communicate regularly with their respective physician network on many topics, including preauthorization policies.

  HMSA’s preauthorization program has been in-place for ten years for many health services. We have regularly provided guidance in person, online, through newsletters, and other venues with our provider groups and

- Sections 2 and 3 of the Bill both provide the following provisions:

  > *(c) Notwithstanding any provision of the law to the contrary, a licensed health care provider shall be defended and indemnified by an insurer for civil liability for injury to a patient that was caused by the insurer's undue delay in preauthorization of medical treatment or services.*
  >
  > *(d) An insurer that violates subsection (a) shall be civilly liable for any injury that occurs to a patient because of undue delay in the receipt of medical treatment or services*.

  The Bill unfairly gives the provider immunity from civil liability for “*injury to a patient that was caused by undue delay in preauthorization of medical treatment or services*”, and it holds the health plans solely liable. This provision does not account for situations under which the physician may have contributed to the delay during the preauthorization process. To hold the plan solely liable for any injury is unjust.

  Decisions on medically necessary care of our members have always been done in partnership between the physician and the plan. At times there may be disagreements, but we all strive to resolve those differences to the benefit of the member.

We appreciate the Committee allowing us to testify to express our concerns with HB 2740, HD1. We hope you will consider our concerns with the legislation. Thank you.

Sincerely,

Jennifer Diesman
Vice President, Government Relations.

To: House Committee on Health

From: Shana and Dan Metsch, parents of 9 year old daughter on Hawaii Medicaid

Subject: HB 2740

In support of HB 2740; opposed to any amendment excluding Medicaid managed care insurers

Date: March 2, 2016

Dear House Committee on Health,

We have a daughter that has complex medical issues and relies on her Hawaii Medicaid services for her health and safety. We are deeply concerned that if the Medicaid managed care insurers, such as United and HMSA, are exempted from liability for preauthorization delays, there could be serious consequences for our daughter and other Medicaid members. We have had many experiences of insurance preauthorization delays over the past nine years, and if Medicaid is excluded from HB 2740, our daughter's service delays could endanger her life, as well as other children in the state like her. The Medicaid managed care insurers are just that, insurers. They are responsible for timely approvals, and if they delay, they should be held responsible.

Please assure that Medicaid managed care insurers are not excluded from HB 2740. Medicaid is supposed to ensure that the poor and disabled have equal to access to medical services. Codifying a double standard in law would violate a fundamental federal law ensuring equality of access.

Thank you for the opportunity to provide testimony in regards to HB 2740.

Respectfully submitted,

Shana and Dan Metsch
3647 Kaweonui Road
Princeville, HI 96722
(808) 652-9206
shanametsch@yahoo.com

My name is Carl Vann, a senior undergraduate public health student at the University of Hawaii at Manoa, writing to the Committee on Judiciary on Tuesday, March 1 2016 in support of House Bill 2740 HD1.

Thank you for taking the time to consider this testimony in support of HB2740 HD1, holding health insurance companies liable for injury caused by preauthorization delays. As a student of public health I firmly believe that strong health policy and law in favor of the citizens of the State are of paramount importance to positive health outcomes.

As you all are aware, a provision under the Patient Protection and Affordable Care Act prohibits insurance companies from discriminating against those who may be suffering from pre-existing health conditions, and that allowing insurance companies to circumvent this requirement via unnecessary treatment delays only serves to perpetuate such discrimination. I have no doubt that permitting the continuance of the established behaviors is the same as directly saying to the people of Hawaii that “it is ok for us to suffer and die from chronic heart disease” which, according to the State, has been the leading cause of death for since 2002 (Hawaii State Department of Health, 2015).

Although insurance companies claim that the practice of delaying treatment encourages safety and appropriate utilization of services, when one considers the types of potentially life-saving procedures considered for pre-authorization, the practice seem less like patient safety measures and more akin to cost controlling measures in business. But my health, your health, and the health of the People of Hawaii should not be a business.

While I am in support of HB2740 HD1, I am concerned about the amended text in line 16 on page six, which indicates that the “Act shall take effect on July 1, 2070”. If healthcare delays are a problem in 2016, as it were in previous years, why wait another 54 years to solve the problem? I urge the Committee to either reconsider changing the language to its previously written form, which states that the “Act will take effect upon its approval”, or consider the Act take effect within a more reasonable amount of time that is in favor of the People of Hawaii.

Thank you again for the opportunity to express my concerns. If you have any questions or concerns regarding this testimony, please contact me by phone at (360) 516-9531, or by email at vannc@hawaii.edu.

Linda Rasmussen, MD
Windward Orthopedic Group, Inc
30 Aulike St #201
Kailua, HI 96734
808-261-4658
lindamd1@juno.com

March 1, 2016

Hawaii State Legislature
Committee on Judiciary
Karl Rhoads, Chairman
Joy A. San Buenaventura, Vice Chair

RE: Support for HB2740 Relating to Liability - Insurers rather than health care professionals are liable if there is a delay in diagnostic tests due to preauthorization.

Hearing in Judiciary committee, 3/6/16, 2pm in room 325.

Dear Honorable Representatives Rhoads, San Buenaventura and Committee members,

Frustrating delays in being able to obtain necessary studies for a medical diagnosis are common due to HMSA's requirement for pre authorization. HMSA outsourced this to a Mainland company on December 1, 2015.

You need to know that this is a real problem. I have had 2 MRI's denied in December and I only ordered 4. The Mainland company that makes the decision claimed that I needed to do 4 weeks of physical therapy or chiropractic care. This would cost more money than the MRI and was contraindication in both cases. I am not going to write for something that is not medically necessary. After hours of back and forth hassles with paperwork, I had to talk to the Mainland company's physician and was able to get approval on both denials. The delay resulted in additional time off work and potential increased risk of injury. My speciality is not life and death, but many delays can result in irreversible complications. What about cardiologist where a delay can result in devastating complications, including death?

In 21 years of practice in Hawaii, I have only one malpractice case that went to trial. I was sued for not getting a MRI earlier on a chronic back pain patient who had a rare tumor. The insurer would not approve the MRI, but I was sued. I won the case, but still had to deal with the trauma of being sued.

Please pass this critical bill to remove the liability related to delays from the physician to the insurer.

With Aloha,
Linda Rasmussen, MD
Past President, Hawaii Medical Association
Past President, Hawaii Orthopedic Association
Past President, Western Orthopedic Association

From: mailinglist@capitol.hawaii.gov
Sent: Tuesday, March 01, 2016 9:42 PM
To: JUDtestimony
Cc: alvin.ikeda@palimomi.org
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/1/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Alvin Ikeda	Individual	Support	No

Comments: I support HB2740 because it helps prevent unwarranted denial of patient care.

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To: Representative Karl Rhoads, Chair, Judiciary
Representative Joy A. San Buenaventura, Vice Chair, Judiciary

March 2, 2016

Re: HB 2740 HD1 Relating to Liability

Position: Support

Dear Representatives Rhoads and San Buenaventura:

Lengthy processes involved with pre-authorization of services or prescriptions from health insurance companies can negatively impact a patient's clinical care and progress because time is of the essence. I urge you to support and pass HB 2740.

Very respectfully,
Julienne O. Aulwes, M.D.

Children's Orthopaedics of Hawaii
98-1247 Kaahumanu Street, Ste 122
Aiea, HI 96701
(808)485-8985

March 1, 2016

Hawaii State Legislature
Committee on Judiciary
Karl Rhoads, Chairman
Joy A. San Buenaventura, Vice Chair

RE: Support for HB2740 Relating to Liability - Insurers rather than health care professionals are liable if there is a delay in diagnostic tests due to preauthorization.
Hearing in Judiciary committee, 3/6/16, 2pm in room 325.

Dear Honorable Representatives Rhoads, San Buenaventura and Committee members,

I apologize for being unable to testify in person.

This letter is written in strong support of legislation to hold insurers (as well as other entities such as hospitals or other health care organizations/facilities) responsible for actions which delay diagnostic testing due to preauthorization purposes.

As the only pediatric orthopedic surgeon in private practice, HMSA's recent decision to arbitrarily require widespread pre-authorization for MRI's, CT scans, etc. has had a significant and negative impact on my ability to provide timely care for my young patients.

In addition to the increased workload of such a sweeping policy, this action also raises more opportunities for human error to occur. In one specific case my office received an authorization for a scan for someone that was not my patient and for a scan which, as an orthopedist, I would never order. The authorization was also given for the scan to be done at my office, which is impossible. Despite these 3 major discrepancies, this error was not caught by either HMSA or it 3rd party vendor for it pre-authorization process, the National Imaging Associates.

As a last comment, despite repeated requests from the Hawaii Orthopaedic Association, HMSA has not provided the source or documentation of its claim that Hawaii's physicians inappropriately over-utilize advance imaging more than 30% of the time. If this were true, as a physician leader I would gladly be at the forefront of correcting such wasteful activity. But I simply do not believe this is true and HMSA has done nothing to persuade me otherwise.

Please do not hesitate to contact me directly on this issue.

Sincerely,

Byron Izuka, M.D.
Past President – Hawaii Orthopaedic Association

From: mailinglist@capitol.hawaii.gov
Sent: Thursday, March 03, 2016 6:58 AM
To: JUDtestimony
Cc: kennycass1@yahoo.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740

Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Kenneth B. Kepler, MD	Individual	Support	No

Comments: This bill is urgently needed. I am the medical director of Kihei-Wailea Medical Center, a 7 provider clinic in Kihei. I am Board Certified in Internal Medicine, and have practiced on Maui for 12 years. The recent cumbersome burden of precertifications has clearly harmed my patients. Due to the burdensome requirements unnecessarily and unilaterally imposed on physicians, patients are not getting imaging when it matters. I would suggest the vast majority of CT scans I order are at least semi-urgent and needed in the next day or two. Recently I attempted to get an urgent same day CT scan and I was personally on hold for over ten minutes. My staff was on hold for approximately 50 minutes! This was in spite of notifying the reviewer this was an emergently needed CT scan. This is simply unacceptable in today's medicine. Physicians have already been licensed to practice by the State of Hawaii. Insurance companies are taking that right away. Doctors, who might not be licensed in our state, have not taken a history or examined the patient are determining if a needed image is required. This is simply unacceptable. Insurance companies claim we can order the test and get approval later, but a patient usually cannot pay out of pocket up front for these expensive tests. Thank you for your attention to this important safety matter. Kenneth B. Kepler, MD

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From:	mailinglist@capitol.hawaii.gov
Sent:	Thursday, March 03, 2016 12:48 AM
To:	JUDtestimony
Cc:	richmar@hawaii.rr.com
Subject:	Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740

Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Richard DeJournett M.D.	Individual	Support	Yes

Comments: HOUSE OF REPRESENTATIVES THE TWENTY-EIGHTH LEGISLATURE REGULAR SESSION OF 2016 COMMITTEE ON JUDICIARY HEARING : Friday, March 04, 2016 Time: 2:00 pm Place: Conference Room 325 H.B NO. 2740 HD 1 RELATING TO LIABILITY TESTIMONY ON HOUSE BILL NO. 2740 – RELATING TO LIABILITY. TO THE HONORABLE KARL RHOADS, CHAIR, AND MEMBERS OF THE COMMITTEE: My name is Richard DeJournett M.D. I am a diagnostic radiologist licensed in the State of Hawaii , testifying on behalf of myself. Some Hawaii health care providers have unilaterally decided to impose a preauthorization requirement on all high technology diagnostic imaging procedures. This includes Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), and nuclear cardiac imaging procedures as well as the prescription of some medications. Physicians and hospitals have an incentive to perform imaging studies in providing state of the art healthcare, while payers for healthcare generally have an incentive to control cost or raise premiums to be profitable. The challenge is always to allow alignment of all incentives without endangering patients lives and well being and insuring the best outcomes for patients. Diagnostic imaging utilization has increased significantly in recent years. This increased use clearly demonstrates the positive role imaging is playing in redefining medical practice through safer, less invasive, and more accurate means of collecting diagnostic information. Prior authorization’s effectiveness in reducing imaging utilization is not uniformly accepted. The Medicare Payment Advisory Committee, in its 2005 report to Congress, wrote that prior authorization was costly and ineffective in controlling imaging utilization. The US Department of Health and Human Services has pointed out that "there is no independent data–other than self-reported–on the success of radiology business management companies in managing imaging services". Although there may be savings to the insurance companies associated with preauthorization by denying care, there is an associated cost shift to the other stakeholders in the healthcare system in terms of additional time and effort required to support and defend a preauthorization request especially when denial is routine and without stated reason. Appeal processes are slow and burdensome. Insurance companies have utilized preauthorization of physicians orders as a gatekeeper tool

intended to restrict the physicians lawful right to practice medicine in the legitimate way in which they are trained and licensed and restrict the timely delivery of health care. Prior authorization is a more stringent process for imaging utilization management that is being used by insurance companies and their hired radiology benefit management associates . Prior authorization requires an ordering physician to obtain approval from the insurance company before a study is performed in order to receive payment for that service. The ordering physician is required to contact the management company, often located on the mainland, to obtain authorization on the basis of that company's proprietary guidelines. This approach, without ever having seen or examined the patient, involves reckless endangerment of the patients wellbeing at the least and potentially risking the complication of an unstable medical condition. Prior authorization programs introduce barriers to patient care by introducing a layer of administrative complexity that creates additional burdens for referring physicians . These requirements seem intentionally burdensome and discourage utilization. Because of its cumbersome structure, prior authorization leads to the inappropriate redirection of patient care toward Emergency Rooms or inpatient admission to hospitals which would not require preauthoriation. This significantly increases the cost of health care. High technology imaging facilities presently require American College of Radiology (ACR) accreditation. This accreditation process is an educationally focused evaluation of imaging practices. There is also a peer review assessment of image quality and radiation safety. Qualifications of personnel, equipment performance, and the effectiveness of quality control and assurance measures as well as outcomes data are also evaluated in this process. Radiation protection is a key element of an ACR accredited practice, not the role of an insurance carrier. Diminishing the inappropriate utilization of diagnostic examinations is the goal of the American College of Radiology standards and guidelines which define standard practices (ACR Appropriateness Criteria). This standardized system coupled with commercially available order entry programs allows for physician education at the time of order entry. It provides the means to order the most appropriate tests for the presenting clinical complaints at the time of initiating an order for a procedure. Commercially available Order entry and decision support systems based on the American College of Radiology Guidelines are the appropriate venue for proper control of imaging utilization, not the preauthorization gatekeeper system mandated by some insurance carriers. The American College of Radiology ACR Select program is a straightforward and transparent application of government approved, evidence-based appropriate–use criteria when making clinical decisions. Providers would receive, at the point of care in their office, Computerized Decision Support (CDS) available through an Electronic Health Record (EHR) or web-based portal. There would be real-time feedback on the clinical utility of a request and, if necessary,the physician would be guided to either a more appropriate exam or given consideration for direct consultation with a local Radiologist. This program is backed by 25 years of research and development of the tool which is NOW AVAILABLE FREE through a web portal to all Hawaii physicians. Within the next two years this type of order entry system which has already been federally approved will be mandated by Medicare (CMS). It will be the operating order entry protocol in the near future and it is available now! Most insurance carriers in Hawaii do not utilize an obstructive preauthorization process that interferes with the orderly practice of medicine. All medical insurance carriers would be wise to

implement a physician initiated order entry systems to the mutual benefit of all physicians and their patients. Any delay in the delivery of health care is an undue delay. Passage of this bill will place the responsibility of delay in access to health care squarely on the shoulders of the insurance carriers and their agents where it rightfully belongs. I strongly support the passage of this legislation. Richard DeJournett M.D.

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NANCY CHEN, MD
511 Manawai St, unit 401
Kapolei, HI 96707
808-674-2273

February 6, 2016

RE: HB2740 regarding

To whom it may concern,

I am coming via this letter to support the proposed bill HB2740.
We as physicians have enough administrative burdens to worry about, PQRS, escribe, ARRA, etc. Taking care of patients and make sure we make the right diagnosis and initiate the right treatment is our duty and we went to school many years in order to achieve that knowledge.

We do not need an insurance company to tell us what to do or not to do. A delay in diagnosis will generate a much bigger bill at the end than the order of a simple imaging study.

I believe that physicians should have the right to choose rather or not a study needs to be performed depending on the history and clinical findings.
I will be willing to listen to their desires and protocol, if the insurance company will take care of my professional liability insurance cost and guarantee immunity to any lawsuit.

Sincerely yours,

Nancy Chen, MD

From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, March 02, 2016 8:37 PM
To: JUDtestimony
Cc: sarfeenstra@yahoo.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740

Submitted on: 3/2/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Sarah Feenstra	Individual	Support	No

Comments: I am a psychiatrist practicing in Maui. In my experience, prior authorizations have been tedious and time consuming. They often prevent patients from getting the medications they require. As physicians we have so many demands to balance and not enough time in one day. We are seeing patients, prescribing meds, making phone calls, and writing notes. Prior authorizations add to that workload. I have been frustrated wasting time trying to find the correct PA paperwork that corresponds to patients insurance, and any phone calls I've made to ask questions are usually unproductive. Then you have to take the time to fax this to the pharmacy and wait for approval. The patient is waiting on medications during this whole process. Holding the insurance companies responsible for damages done while patients wait for medication approval is a step in the right direction. Please support this bill and allow doctors to treat patients without restraints. Thank you for your consideration.

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From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, March 02, 2016 8:14 PM
To: JUDtestimony
Cc: rmarvit@juno.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/2/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
robert Marvit	Individual	Support	No

Comments: This is the only way to deter insurance companies from denying access to care and cause many physicians to leave the state

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From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, March 02, 2016 7:46 PM
To: JUDtestimony
Cc: ter@hawaii.rr.com
Subject: *Submitted testimony for HB2740 on Mar 4, 2016 14:00PM*

HB2740
Submitted on: 3/2/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Terri Pacheco APRN	Individual	Support	No

Comments:

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From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, March 02, 2016 7:30 PM
To: JUDtestimony
Cc: rotkin@hawaii.edu
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/2/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Laurence Rotkin MD	Individual	Support	No

Comments: I strongly support HB2740. Prior authorization wastes physician time, and delays patient care. Physicians have little enough time to spend with each patient.

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Sent: Wednesday, March 02, 2016 7:00 PM
To: JUDtestimony
Cc: ginasalcedomd@yahoo.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740

Submitted on: 3/2/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Gina Salcedo MD	Individual	Support	No

Comments: As a provider currently practicing in Hilo, Hawaii, I have observed first hand how the unreasonable use of Prior Authorizations for necessary patient imaging studies have delayed patient care. It has also caused significant problems when Prior Authorizations are requested on many medications as well. I am in strong support of holding the insurers accountable for delayed patient care.

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From: mailinglist@capitol.hawaii.gov
Sent: Wednesday, March 02, 2016 7:00 PM
To: JUDtestimony
Cc: ssmhawaii@aol.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/2/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Scott J Miscovich MD	Individual	Support	No

Comments: I support the intent of this measure, but recommend considering directing the liability at the specific physicians making the decision. The physicians are often out of state. Second, they receive detailed information concerning a patient and make a medical recommendations that effect the ongoing care of a citizen in our state. Often, these are serious decisions that may have life threatening sequela if not considered in a comprehensive and serious process. Furthermore, there should be full and open disclosure by these physicians and the insurance carrier if they are reimbursed in any way that bonus or rewards them for denying more care or refusing to authorize care to the people of our state. To have an out of state, disengaged physicians effectively overriding the decision of a treating physician who often may have a 20 year relationship with a patient is serious and they should be liable for this process. These physicians are therefore practicing medicine and should be held to the same standards and risks as all physicians in Hawaii. They should be required to be licensed in the State of Hawaii and held to the standards of the HMA peer review process.

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Holly Bent, FNP
51-338 Kam Hwy
Kaaawa, Hawaii, 96730
holly.bent@gmail.com

March 2, 2016

RE: HB2740

As a family nurse practitioner in private practice and an emergency department nurse for the last 18 years, I believe insurance companies should be held liable for the delay in patient care, created by the referral process.
What the insurance companies have created with the preapproval process is not what the intended outcome should be, to decrease unnecessary diagnostic testing; yet they have created increased referrals to emergency departments to have outpatient procedures performed.
As a provider it is frustrating to not be able to order a test in a timely manner. This forces increased referrals to our overcrowded emergency departments. While working in both capacities, I have the first hand knowledge of being the sender and the recipient of this new ruling.
In a time where we are trying to decrease costs to the patient, and the health care system, the preapproval process actually increases these costs.
I urge you to consider where the liability should sit when providers are forced to send their patients to emergency departments for immediate testing that should be taken care of in the outpatient setting.

Holly Bent, FNP

From: mailinglist@capitol.hawaii.gov
Sent: Thursday, March 03, 2016 1:47 PM
To: JUDtestimony
Cc: HI.NeuroRad@yahoo.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Greg Reinking	Individual	Comments Only	No

Comments: As a radiologist working in Hawaii, I can attest that the measures of H.B. 2740 are legitimate. The added paperwork, phone calls, etc., required by health care providers to comply with the insurer's pre-authorization process can result in delays of imaging and care of patients in need. A consequential delay in diagnosis can be detrimental to patient care. Therefore, the insurance carriers must be responsible for any delay in diagnosis or other associated consequences resulting from the pre-authorization process enacted by insurance carriers. Specifically, it is the insurers (not health care providers) who must he held fully accountable and liable for civil damages caused by any undue delays for compliance with the pre-authorization process that has been mandated by the insurers.

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From: mailinglist@capitol.hawaii.gov
Sent: Thursday, March 03, 2016 1:30 PM
To: JUDtestimony
Cc: moore4640@hawaiiantel.net
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Douglas Moore	Individual	Support	No

Comments: Aloha: I respectfully support the intent & passage of this bill. I have represented injured workers for 25 years & I have seen the detriment caused by delays in approving immediately needed diagnostic testing to ensure proper & appropriate medical evaluation & treatment. Physicians need the ability to get the necessary diagnostic testing without unwarranted authorization delays. Otherwise, the prompt medical rehabilitation of injured workers will delay their return to work which hurts employers too. Please pass this bill out of committee. Mahalo & aloha

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From: mailinglist@capitol.hawaii.gov
Sent: Thursday, March 03, 2016 1:12 PM
To: JUDtestimony
Cc: mcarney@hawaii.edu
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Michael Carney	Individual	Support	No

Comments: I am a cancer physician caring for women's cancer patients with surgery and chemotherapy for 15 years in hawaii faculty with the University of Hawaii and providing clinical services at Kapiolani, Kaiser and Queens hospitals. The process of pre-authorization truly hurts my patients. It has resulted in inappropriate care, delay in care, and harm. It wastes countless hours of valuable time.

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From: mailinglist@capitol.hawaii.gov
Sent: Thursday, March 03, 2016 12:48 PM
To: JUDtestimony
Cc: netzermd@hotmail.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Craig Netzer, MD	Individual	Support	No

Comments: Dear members of the legislature: Regarding HB2740: HMSA's new prior authorization policy has negatively affected my ability to order scans. In fact, an MRI I thought would be a slam dunk was denied under HMSA's new prior authorization requirement. I had to send my patient to the ER for the MRI, and then to Honolulu for urgent neurosurgery. I have heard similar complaints from multiple physician colleagues, and in 2 cases, the CT scan when finally approved resulted in a diagnosis of cancer (pancreatic, and lung). If I cannot deliver the care my medical license says I am capable of, because the insurance company is interfering, then the insurance company should be liable for the care I am unable to provide. Thank you for your time Craig Netzer, MD Lihue, Kauai, Hawaii

Please note that testimony submitted less than 24 hours prior to the hearing, improperly identified, or directed to the incorrect office, may not be posted online or distributed to the committee prior to the convening of the public hearing.

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From: mailinglist@capitol.hawaii.gov
Sent: Thursday, March 03, 2016 11:50 AM
To: JUDtestimony
Cc: vinceyamashiroya@gmail.com
Subject: Submitted testimony for HB2740 on Mar 4, 2016 14:00PM

HB2740
Submitted on: 3/3/2016
Testimony for JUD on Mar 4, 2016 14:00PM in Conference Room 325

Submitted By	Organization	Testifier Position	Present at Hearing
Vince Yamashiroya, MD	Individual	Support	No

Comments: I am a pediatrician practicing in Honolulu and recently had a teenage patient who had a mediastinal mass on a chest x-ray. Despite the clear diagnosis of cancer, I could not order a CT scan due to the onerous process by HMSA for preauthorization with a mainland company. While this mother was waiting in my office worrying, my office staff and I wasted 1 hour on a busy office day with a mainland company trying to authorize this CT scan. After going up the "chain of command," it was finally approved and this patient was diagnosed with Hodgkin's lymphoma. If insurance companies want to "play doctor," then they must share, if not all, the burden of malpractice should there be a bad outcome due to a delay of diagnosis.

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HB2740 HD1 – Relating to Liability

My name is Leslee Stevenson and I am an internal medicine physician who works just 1 day a week in an emergency room in one of the hospitals on Oahu. I felt that I needed to write because of one patient who I recently saw, who if she was able to get the CT scan of her abdomen and pelvis earlier, when it was initially requested, and denied, could have been spared an admission to the hospital with a severe illness that may even require a severe surgery. Not to go into too much details because of HIPA, this patient had a history of this illness and was treated with oral antibiotics because her physician could not get a CT scan of her abdomen and pelvis and see that her disease was probably a lot worse than she thought. So the patient takes her antibiotics and does better for a few days and then has severe pain to the point that she comes to the emergency room, gets that CT scan of her abdomen and pelvis and now has a severe illness that may require surgery if there is no improvement with her not being able to eat anything and take intravenous antibiotics.

It is outrageous that insurance companies can dictate adequate care for patients, that in the past, physicians did because of their years of training and experience. Unfortunately, insurance companies just care about the financial part of healthcare. We, as physicians, see these patients, hear their stories and truly want to help them. I feel if insurance companies really cared about financial matters, they wouldn't pay their executives ridiculous amounts of money while they claim that they lost money for any particular quarter.

If insurance companies want to dictate the care of patients, they should be responsible for any negative and devastating outcomes. It's easy to sit in a chair, not even speak to a patient, sometimes not even have adequate training and make a decision about patient management. On top of that, how can these people not have a bias on their decision when they are being paid by their insurance companies and probably even get an incentive to save the company money and deny appropriate studies. This even goes for physicians that are hired by insurance companies. These so called physicians should know better than make decisions about treating and managing patients they haven't even laid eyes on.

Since no one can require anyone to do what is right, as in this case, the government has a responsibility to protect patients and make insurance companies liable for decisions they make. I think if this bill passes and becomes law, insurance companies will change their policies. Please protect patients and make the right decision.

Mahalo….Leslee Stevenson, MD

Aloha,

My name is Kayla Furtado and I am just one of the many suffering due to the many hoops we patients need to jump through because of insurance companies having unreasonable requests for prior authorization. Not only is this delaying our care but honestly, it's really quite frustrating and does not use our time wisely.

I am a young person, only 22 years old. I rarely have any large issues that need medical assistance. But for the past year I have been struggling with constant and sometimes extremely sever back pain. I decided why wait any more and just go see the doctor, so I did. My primary doctor is a great woman and knows her profession. But with this prior authorization she is in most ways really unable to do everything she wants as a doctor. Imaging is one of the first things most doctors would like done in order to see where the problem is with a patient. She was unable to do this because I first needed to go to physical therapy. And here I am months have passed and still waiting on the acceptance simply for authorization to get into physical therapy.

One week my back pain got so severe that I had to go down to the emergency room. Even then the best I could get done was an X-ray. I'm sure that if my doctor didn't have to jump through these insurance hoops she would easily order all the necessary imaging , and refer me to a specialist who would know exactly what to do. As of right now my back pain is still here. Every day I just have to "deal with it" because nothing is being authorized. I know for a fact that I'm not alone in this struggle and I feel horribly sorry for the pain other must be going through right now. Something NEEDS to be done because we patients are over it!

Sincerely ,

Kayla Furtado

March 3, 2016

To: Representative Karl Rhoads, Chair, House Committee on Judiciary

From: Edwin Muranaka, individual.

Subject: Support for HB 2740 – Relating to Liability

There is no question that HMSA and other insurers have served the patients of Hawaii effectively. Over the past decade, they have been facing the daunting task of slowing the rapid expansion of healthcare costs. In their efforts, the insurers have long demanded physicians to justify their patient care. It is only reasonable and fair for patients to now hold these same insurers accountable for their denial of that care.

HMSA and NIA's implementation of the current pre-authorization policies lacked examination, analysis, and knowledge of the Hawaii's physician practices. A meeting with NIA Magellan Hawaii representative Kevin Apgar, Manager, Provider Relations, provided additional insight into why HMSA's pre-authorization policies have significantly disrupted and impaired Hawaii patient care.

This meeting revealed that NIA assumed the Hawaii insurance market was identical to the 38 mainland markets they are currently managing. Consequently, NIA simply implemented their preexisting preauthorization methods. Since entering the Hawaii market, however, the meeting demonstrated that NIA has discovered several "unique characteristics" here.

1. NIA was not aware that the majority of Hawaii physicians is independent practitioners and is not members of mainland large multispecialty groups or hospital centers with dedicated departments to process preauthorizations. Most of Hawaii physicians have limited clerical staff to reduce office expenses due to significantly lower HMSA reimbursements for services compared to the mainland. NIA only current solution for the individual physician practices with limited staffing is to hire dedicated clerical personnel to submit pre authorization requests.
2. NIA did not anticipate the volume of preauthorization requests from Hawaii and are not capable of handling the current load or backlog of appeals. Many mainland practitioners ask for payments at time of service, relegating the patient to seek reimbursement from their insurers. Here in Hawaii, the vast majority of physicians submit insurance reimbursements on behalf of their patients and subsequently bill their patient for their deductible. NIA's has proposed no solutions to expedite or reduce the backlog of appeals.
3. NIA was not aware that their clerical staff blindly follows a series of questions, some of which are misleading and subsequently lead to denial of preauthorizations requests.
4. NIA wants the doctors and their staffs to monitor and provide documentations of NIA mistakes. Yet, NIA has only two part-time employees assigned to the Hawaii market to assist physicians and educate their staff. Only after the detrimental effects of the pre-authorization restrictions

have become evident, has NIA begun to visit a limited amount of doctors' offices to mitigate the problems with submissions.

5. NIA did not anticipate that there would be requests for emergent or urgent imaging requests. Three months into instituting the new requirements, NIA is now looking into developing a hotline for processing emergent and urgent preauthorization requests.
6. NIA was not aware that our physicians work Saturdays. Since mainland physicians only work Mondays through Fridays, they anticipated all Hawaii preauthorizations request would be submitted by doctors Monday through Fridays. They are now considering to extend their emergent and urgent preauthorization call centers hours to include a half day on Saturday.

No one disagrees that doctors are not perfect. No one would disagree that every medical test ordered is not absolutely necessary. Nonetheless, it is not reasonable or fair for HMSA to presume that every physician is guilty of always ordering inappropriate tests and deliberately ignoring what is best for their patients. HMSA's preauthorization polices condemn all physicians as guilty until proven otherwise. It is appropriate and reasonable to expect accountability in all aspects of patient care, including the actions and policies of health insurers.

Thank you for the opportunity to present testimony on this matter.

Respectfully,

Edwin Muranaka, M.D.

Written Testimony Presented Before the
Committee on Health
March 04, 2016 2:00 PM
by

Sheryl Kay Visitacion, R.N.
University of Hawaii at Hilo, School of Nursing

HB 2740 HDI RELATING TO LIABILITY

To the honorable Joseph M. Souki and House of Representatives Twenty-Eighth State Legislature, thank you for hearing testimony today related to HB2740 HDI Relating to liability.

My name is Sheryl Visitacion, I am new graduate Registered Nurse in pursuit of my Bachelor of Science in Nursing degree at the University of Hawaii at Hilo. I would like to express my support for the intent of HB2740, Relating to Liability.

With my experience, I have noticed frustration of delays of treatments to patients in need or the discharging of patients due to insurer preauthorization. The communication between health care providers and patients displaces significant amount of stress amongst both parties.

The acuity of care is increasing, but diseases are continuously arising, therefore the essence of time is essential to one's life. Delayed of the time to receive authorization will be an inconvenience to the continuum of care to patient and on to the next.

The bill has the following admirable goal:
Instituting a liability framework for situations where a licensed health care provider delivers medical treatment or services aside an insurer's preauthorization requirements.

Thank you for the opportunity to provide testimony in strong support of this measure and thank you for hearing this important bill.

Sincerely,
Sheryl Visitacion, RN
University of Hawaii at Hilo

LATE

March 3, 2016

Dear Chair Rhoades, Vice Chair San Buenaventura and members of the Judiciary Committee,

I am testifying in **strong support** of HB 2740 HD1.

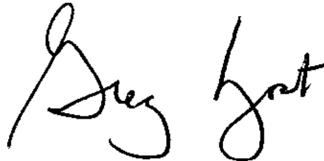
I have been a member of HMSA for over 20 years and have paid over $100,000.00 to them for premiums. I have recently been denied by HMSA for a new breakthrough medicinal treatment that had a 100% cure rate for my condition. I have been waiting about 15 years for this type of treatment to come out and now that it is out, I denied approval from HMSA. I appealed my case in front of a panel of 6 doctors and they still denied me even after seeing 3 of my doctors written request for treatment.

I strongly believe that this bill will help patients like myself to eliminate the preauthorization requirements for treatment.

Subsequently, I was able to get the medication from Gilead the pharmaceutical company that made the medication and not from the insurance company. The medication did cure my condition. It was a small miracle that I was able to get the medication considering the cost. Bottom line is HMSA made the determination that I was not sick enough to receive the treatment. This was a complete conflict of interest.

I am asking for your support in passing HB2740 HD1.

Mahalo,



Greg Yost
gy3@hawaii.rr.com
822-1774
Kapaa, Kauai

HMSA

4/6/2015: Called Ursaline Muhar RE: referred to a different rep.

4/6/15: Spoke to Crystaline, She referred me back to CVS Drug?

Marie@ CVS spoke to me. She is referring me to Senior Advisor
1-808-838-3300 Ext. #1735889

Never received call back from Senior Advisor.

4/6/2015: Went to see Dr. Rogaff regarding situation. He wrote a letter to HMSA regarding his concerns on my health matter.

4/7/15 Spoke to Brain @ Westside Pharmacy He told me that they would be doing the appeal. I am confused as to who is supposed to appeal this.

4/7/15: Called appeal phone Number to verify who is supposed to do the appeal. They are sending me back to CVS to speak to someone else. Speaking to Ryan re: When HMSA made the policy change for drug treatment on Hep C.

Layla (HMSA) Makes no sense. Trying to get something in writing.

Appeals department is supposed to call me back. Layla 4/7/15

All parameters come from HMSA.

Ryan is trying to send me a letter to clarify parameters of Hep C and when the policy was changed. Ryan is supposed to call me back to let me know.

4/7/15: Received call from Francine at HMSA Appeals. She told me I can't have an expedited appeal unless I am dying or in hugh pain. I am emailing HMSA appeals@hmsa.com to comfirm they are trying to process this.

Francine=1-800-462-2085
Mike Gold (CEO HMSA) 1-808-948-5121

4/8/15= Spoke to Adam @ HMSA 1-808-948-6834
Change from expedited appeal to standard via attorney's advice.

4//13/2015 =Spoke to Sarah @ HMSA she told me HMSA implemented the Harvoni exclusion on 12/1/2015

6/3/2015 = Received a call from my attorney. He informed me that HMSA has denied my appeal once again. I have received no notice from HMSA.

He also informed me that HMSA had already given me a June 17th additional appeal. That June 17th appeal was given over a month ago before they turned me down on this appeal. HMSA also will not allow my attorney to go to the new appeal. HMSA also made my attorney aware that if I am showing up to represent myself, HMSA would push back the appeal date. They would keep the date if a wasn't going to show up? Makes no sense?

6/4/2015 Called Sara Scott to see what HMSA is really doing. Have received nothing in writing whatsoever from HMSA? Left message. Also sent a written letter to HMSA- Sara Scott.

6/12/2015: Sent several letters to HMSA about what time and location for the appeals meeting. Received nothing back?

6/16/2015: 10:30 am Monday: Still no word from Sarah Scott. Have not received any letter from them regarding appeals or confirmations of the 17th appeal.

6/17/15 Attended an appeals meeting at HMSA in Honolulu. 7 doctors, myself and my wife. There was no quorum. 4 Doctors were to make this decision.

6/19/2015 Applied for A support pat program at Gilead for free Harvoini

6/19/2015: Went to Dr. Yoon's office to get Yoon's signature on the Support Path forms

6/25/ 2015 Called Support Path. They informed me Dr. Yoon told them I was handling this myself with an Attorney. All they wanted was evidence that I was denied by HMSA for Harvoni.

Sarah Scott-HMSA
P.O. Box 1958
Honolulu, Hi. 96805-1958

June 4, 2015

Re: Case # 20150407-000285

Aloha Sarah!

I am writing in regards to the above referenced case with HMSA.

I have received nothing from HMSA in writing regarding this case.

Can someone let me know what is happening? I need to move forward on this as soon as possible. My health is not good with this Hep C virus actively increasing in my liver.

Please respond in writing at your earliest convenience.

Thank you for your Kokua.

Sincerely,

Greg Yost
HMSA Member #R220340105

Sarah Scott-HMSA
P.O. Box 1958
Honolulu, Hi. 96805-1958

June 5, 2015

Re: Case # 20150407-000285

Dear Sarah,

I hope this finds you well.

Just want to clarify a couple of things for all involved in my HMSA policy.

In your letter dated June 4, 2015 to my attorney you mentioned that I was upset because I had not received an update on my appeal with HMSA.

This is really not the case. I am very upset that HMSA has denied my claim at all. As you know I have been insured with HMSA going on twelve years. This amounts to approximately $100,000 of insurance premiums paid to HMSA by me alone. I have paid consistent rate increases over the years and was told that I had the "Gold Standard of Health Care" with HMSA. I was under the impression that I needed insurance for "God for Bid situations" in order to protect my family for financial ruin?

Well the "God for Bid" situation is here and HMSA not willing to step up to the plate and allow me treatment prescribed by my Doctor to be cured.

HMSA has changed the rules on me without any notification in policy whatsoever. HMSA has been aware of my chronic illness for 10 or more years. There is no language in my policy that I can find that excludes treatment if HMSA deems I am not sick enough yet in their eyes to receive treatment. A Health Insurance Company qualifying a Chronic Illness that is known to progress and increase over time seems like a bit of conflict of interest.

HMSA is a large, for profit, dishonest corporation. Pay more for less is what you are asking your "members" to do.

Here what I intend to do if you continue denying me of my right as a HMSA member to be treated of this chronic and dangerous illness.

I am going to every news agency that will listen. 60 minutes, 20/20, Joe Moore, Channel 2 news and anyone else I can find. I am also going to take out full-page advertisements in the Honolulu Star Bulletin, Garden Island, Maui and the Big Island newspapers and let everyone know that HMSA is basically lacking integrity as a Health Care provider.

Furthermore, I am going to create a class action law suite against HMSA. Should not be hard. I already have several Honolulu attorneys on the sidelines.

Time to break the old "Corporate Seal for good old HMSA". Might want to get in a quick rate increase to help things along for HMSA.

This is a simple situation for fix. Do the right thing and treat your client per the Doctors orders.

Thank you for you Kokua!

Sincerely,

Greg Yost
HMSA Member #R220340105

Adam Brown-HMSA
P.O. Box 1958
Honolulu, Hi. 96805-1958

June 5, 2015

Re: Case # 20150407-000285

Dear Adam,

It has come to my attention that Sarah Scott has left town and is not due back until after the June 17th appeal date. Sara Scott promised my attorney to address my request to have Rafael del Castillo accompany me for the appeal on June 17th.

Please be advised that I am waiting written confirmation from HMSA that this is acceptable.

Thank you.

Sincerely,

Greg Yost
HMSA Member #R220340105

Sarah Scott-HMSA
P.O. Box 1958
Honolulu, Hi. 96805-1958

June 12, 2015

Re: Case # 20150407-000285

Dear Sarah,

I hope this finds you well. I am writing to confirm two things:

1. HMSA recognizes that Mr. del Castillo is my authorized representative;
2. HMSA has declined to allow Mr. del Castillo to be at my appeal hearing.

I also want to make sure there is no confusion: I will be present in person for the hearing, but I would appreciate knowing the time and place so I can make arrangements for travel.

Sincerely,
Greg Yost
HMSA Member #R220340105

Sarah Scott-HMSA
P.O. Box 1958
Honolulu, Hi. 96805-1958

June 12, 2015

Re: Case # 20150407-000285

Are you recording this meeting?

Can I record this appeal?

If you are recording this do I get a copy?

Do doctors always diagnose severity of condition correctly?

Does HMSA always change their policies without notification as it suites them?

Is this just about money and not the patient?

Do liver functions effect other organs such as digestion, pancreas, kidneys, ect?

Is it normal for a doctor to wait for disease to progress before treating?

Do Doctors usually believe the patient when they come in with ailments?

Why doesn't HMSA believe that I am sick enough for treatment?

Would you want this verdict for yourselves if you had the same situation?

What if my liver is closer to 3 than to 2 on their scale? Are the tolerances you use that precise?

Who exactly is on this board? Is the Doctor here paid by HMSA? Is this not a conflict of interest? What is the Doctors field of expertise on HEP C?

When did each of you receive this file? Have you read the file?

Are you aware that I did not receive this file until Monday and have no time to review it?

Will you move forward on this if I sign a confidentiality agreement?

Why is do you make CVS a part of this denial process? Who exactly does this denial and why?

Does HMSA negotiate with the drug companies?

Why are Doctor and the insurance agency generally at odds against each other? Is the insured/ patient really being served the highest and best in this environment?

Sarah Scott-HMSA
P.O. Box 1958
Honolulu, Hi. 96805-1958

June 15, 2015

Re: Case # 20150407-000285

Aloha panel! I would like to thank each of you for hearing this case. It is very important to me as my health is everything. Without health we can't function and live productive lives.

My name is Greg Yost.

I have been a resident of Kauai for the past 32 years.

I went to Citrus College in California. I was a college swimmer and high level water polo player for Citrus College for 2 years. I am also an avid surfer/ water man on Kauai. I know my body well.

I have been in the real estate industry since February 6th, 1985. Thirty years now.

I have been a member of the Kalaheo Missionary Church for approximately 30 years and actively support the church.

As far as health care I have been an HMSA member for 12 years with Pacific Ocean Properties group plan. This is a PPO with dental and vision. I have been told that this was the GOLD Standard in Health care in Hawaii.

I have been a patient of Dr. Michael Murray in Koloa for 31 years. He has been my primary care Doctor. I was diagnosed with Hep C Genotype 1-A sometime in August of 2004. I am sure I have had this disease for well over 35 years and it is starting to effect of my health in a big way.

HMSA has been aware of this virus and diagnosis since 2004.

Since diagnosis I have gone to the MAYO clinic for a Liver Biopsy. This was in 2010. HMSA supported this treatment at that time. The Mayo Clinic Doctor thought I could wait on treatment for a few more years since I did not want to take interferon for the required one year, especially, knowing the side effects of that drug and also knowing it may not work anyway. Based on the Mayo Clinics findings and my desire not to take interferon everyone agreed that I could wait a few years in hopes better medicine came to market. The Mayo Clinic specialist did feel it important to treat the growing virus in the up coming years.

I have continued to do holistic approaches to maintain health, along with accupture, Dr. Lam's treatment in Honolulu to no avail. I have sustained from any alcohol which is not easy in Hawaii with having a beer or two a way of life here.

I am now symptomatic.

Life with Hep C is a battle. I always have the nagging thought in mind that I can develop Liver Cancer. It is a worry to my family and particularly my wife since she too could be infected?

I was first diagnosed when a friend told me he tested positive for Hep C. My friend told me I should get checked too. So I did. The reason I did so was because a doctor many years prior shared with me that I had high liver enzymes. This was on a routine check up. This was many years prior to being diagnosed. Anyway, I came back positive. This was pretty devastating. Upon diagnosis I started learning about the virus.

My knowledge of Hep C has caused me to live pretty clean, but I still know that the virus can progress anytime. It is really a time bomb.

Here are the Risks I face as long as you go without a cure:

I am at risk for developing

- Cancer
- Cryoglobulinemic vasculitis, liver inflammation (found in up to 15% of Hep C patients, highest incidence in patients 40 and older) which can progress to
  - cancer,
  - serious vasomotor deficits,
  - kidney disease,
  - pulmonary disease
  - neuropathy
  - chronic and debilitating joint pain (arthralgias),
  - chronic and debilitating muscle pain (myalgias), and a
  - potentially permanently compromised immune system
- increasing fatigue

- Increasing fatigue, itching and head aches, a feeling of low grade fever, night sweats and lack of ability to concentrate are all happening to me now. This is effecting my work and my family monetarily.

It is my understanding that if cured and the Viral load is 0 my liver still has the ability to regenerate itself. This is the only organ with this ability.

If I get to the stage 3 Liver disease the liver will not be able to regenerate and permanent damage is done.

The meaning of metavir 3: ***severe disease***
Your long-term prognosis if the disease progresses to metavir 3-4, even if you are cured at that stage

The real truth here is that HMSA has the contractual obligation to treat me based on my health alone and not based on certain stages of this chronic illness.

Respa and Hawaii law require this.

From what I have gathered HMSA is asking me to get into a later stage of the disease. metavir 3: : ***severe disease***
This is not reversible damage to the liver if allowed to progress. This is a much more expensive proposition for HMSA and will ruin my life.

The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure. Patients who are cured of their HCV infection experience numerous health benefits, including a decrease in liver inflammation

I believe this committee is required by law to apply Hawaii's statutory medical necessity criteria in reaching its decision. I will review and discuss the elements.

First, we would not be having this conversation if Harvoni was specifically excluded from coverage under the Guide to Benefits for my HMSA plan. That means that Harvoni is covered under my HMSA plan if it is medically necessary according to the statutory criteria. These criteria are:

1. Is my Hep C infection a medical condition? No one could reasonably dispute that
2. Is my doctor's prescription of Harvoni to treat my Hep C infection? Yes and it will cure it.
3. Is Harvoni the most appropriate treatment for my Hep C infection given the potential benefits and harms to me? Certainly a cure for a chronic and life-threatening condition is the most appropriate treatment. Harvoni will not only cure my Hep C infection in 12 weeks, it will do so with the least side effects.
4. Is Harvoni known to be effective in curing Hep C infections in patients with genotype 1a who have had no prior treatment? Harvoni is FDA approved as a cure for Hep C based upon scientific evidence so there can be no question that it is known to be effective

5. Is Harvoni the most cost effective alternative treatment for me compared with other alternative treatments, or no treatment. Cost effective does not mean HMSA's money. It means avoiding the costs I endure every day because I have a chronic liver infection. It means avoiding the costs of complications of a severe infection, such as cancer, kidney disease, pulmonary disease, and more, for which I am at substantial risk if I have to wait for treatment until my infection is severe. It means avoiding the potential for cirrhosis and liver transplant if my disease suddenly begins progressing and I do not receive the cure quickly enough. Rapid progression has been documented and thus is an additional risk I face. The costs associated with the additional risks are all burdens upon me and the health care system and must ultimately be paid by HMSA.

All our military veterans are allowed to be treated with Harvoni. I know of one in particular that has just been cured in the 12 week program with Harvoni.

What we really have here is a moral issue. The denial of my health care benefits are immoral at best. No doctor would deny this. I have paid approximately $100,000 in insurance premiums to HMSA over the last 12 years. I have paid every increase in insurance premiums. These insurance increases take place almost every quarter. 10% or more. I just received another notice of increase as of July 1'2015. Instead of $1,000.00, I am expected to pay $1,168.80. More than a 15% increase. I really wonder what I am paying for?

As a business HMSA has already received enough from me alone to pay for my treatment. If they would like to refund my 12 years worth of payments I will pay for this myself and go elsewhere for insurance. I was always told I needed insurance to protect my family and that is what is important to me. Paying a $1,000.00 insurance premium every month in s hardship on my family. I thought I was doing the right thing. Now I am wondering. This whole thing has become a emotional hardship for me and is becoming more of a financial hardship to pay insurance premiums that do not take care of their members.

I truly hope you all do the right thing. I do believe Hawaii law and RESPA is clear on these matters.

To whom it may Concern,

My name is Greg Yost and I am a client of HMSA.

I have been an athlete my whole life. I have been a high-level collegiate swimmer and water polo player in my youth.

Being an athlete in am very in tune with my body.

At this point I can tell you for certain that I do not feel well at all. It feels as though I have a low-grade fever all the time. Constant head aches.

I am lacking in energy and I am not able to focus on work.

Hepatitis C directly causes these symptoms.

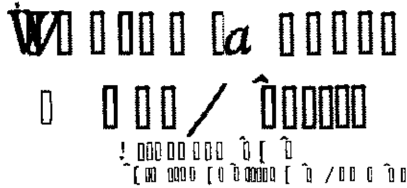
This situation is causing stress in my family due to lack of income this year. This is all Hep C related.

Please do the right thing and allow treatment, otherwise I will have no choice but to seek damages in court.

Thank you.

Sincerely,

Greg Yost



May 7, 2015

Via facsimile to (808) 952-7546 and 1st class mail, certified

Sandy Satterfield
Director
HMSA Member Advocacy and Appeals
P.O. Box 1958
Honolulu, Hawai`i 96805-1958

RE: Gregory Yost, HMSA # R000020340105001;
<u>Denial of Harvoni Therapy for HCV Reference #3936704</u>

Dear Ms. Satterfield:

I represent Gregory Yost, the above-referenced HMSA member in connection HMSA's denial of precertification for Harvoni therapy for Mr. Yost's chronic Hepatitis C viral infection ("Hep C"), a copy of which is enclosed. The denial was issued on the joint letterhead of CVS/Caremark Specialty Pharmacy and HMSA. The CVS-HMSA joint letter gave as its reason:

"The request was denied for the following reason:
Does not have a Metavir fibrosis score of F3-4."

The denial provides no analysis of the coverage according to Hawaii's statutory medical necessity criteria, which is mandatory. I have enclosed a copy of the statute for your convenient reference and provide the following reasons why the Harvoni treatment Mr. Yost's treating physicians have ordered is medically necessary under Hawaii law and therefore must be preauthorized by HMSA and CVS:

Harvoni is a covered health intervention under Mr. Yost's HMSA Plan

My review of Mr. Yost's HMSA plan discloses no specific exclusion for Harvoni (aka ledipasvir/sofosbuvir) by Gilead Sciences, Inc., and as a prescription medication, FDA-approved for treatment of Hep C, Harvoni is undoubtedly covered under Mr. Yost's plan. This fact, taken together with the fact that Mr. Yost's treating providers, unanimously, recommend that he commence the Harvoni 12-week treatment regimen right away, triggers the requirement that HMSA apply the statutory criteria in deciding whether to preauthorize treatment and coverage for Mr. Yost. It is a misuse of the indicators of progressive disease for predicting liver-related morbidity and mortality to establish coverage thresholds. Active disease is active disease – a medical condition, in this case one that threatens serious injury or premature death, as well as extrahepatic manifestations of injurious nature, reduced functionality and productivity, reduced

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Rafael G. del Castillo, Managing Member

enjoyment of life, infectious disease public health concerns, and increased health care and related costs – which must be treated appropriately.

Mr. Yost is diagnosed with condition chronic Hepatitis C viral infection, a medical condition

Mr. Yost was diagnosed with chronic [illegible] when he was under the care of Joseph Michael Murray, M.D., his primary care doctor. Tests at that time confirmed that the infection was genome type 1a, and Mr. Yost's viral load was approximately 1.5 million. Mr. Yost was trained as high-level collegiate swimmer and water polo athlete to be highly sensitive to changes in his body and to develop an acute sense of the demands he can endure. Despite having chronic Hep C for over a decade, he still considers himself an athlete, but he is unable to live an athlete's life-style. He feels unwell all of the time, as if he has the flu. He suffers from fatigue and constant headaches, making it extraordinarily difficult to focus at work. He suffers from persistent itching. Each of these are common symptoms of chronic Hep C viral infection and they are expected to accelerate because Mr. Yost is well past his 50th birthday.

Mr. Yost's Hep C symptoms have cost him more than pain and suffering and loss of quality of life. H[illegible] estate mark[illegible] al stress for him and [illegible]. Mr. Yost's employer for the past 20 years, Frank Supon, President and Principal Broker for Pacific Ocean Properties, states he has noticed that Mr. Yost's condition has adversely affected his productivity. Mr. Supon has written requesting that HMSA/CVS reverse its initial denial of Harvoni treatment for Mr. Yost. Mr. Supon's letter of May 5, 2015—which also refers to the fact that Pacific Ocean Properties has contracted with HMSA for 20 years to provide prepaid health care coverage for its employees—is enclosed.

Following his diagnosis, Mr. Yost's treating providers have urged him to remain "treatment-naïve" with respect to his chronic Hep C for as long as possible due to the substantial side effects and mediocre effectiveness of existing treatments. All hoped better treatments would eventually be found. In the meantime, Mr. Yost has followed a life-style regimen it was hoped would slow the progression of the destruction of his liver.

Mr. Yost underwent a liver biopsy on March 9, 2010 at the Mayo Clinic, which showed progressive extension of scarring (fibrosis) into the area in which the liver carries on is functions essential for the continuation of life (parenchyma), and remodeling of the hepatic architecture. The biopsy showed that Mr. Yost had notable evidence of inflammation (mononuclear lymphocytes) five years ago, with both portal and periportal fibrosis. Liver biopsy nonetheless may miss advanced fibrosis in as many as 30% of patients, as it is only as good as the pathologist's interpretation. As noted by Geller and Petrovic in Biopsy Interpretation of the Liver, 2009), even mild fibrosis on the first biopsy is associated with rapid progression to cirrhosis in chronic Hep C. *Id.* at 115. Mr. Yost's most recent lab tests confirm his viral load is over 6 million IU/ml, more than quadruple the number on the date of his first diagnosis. A February lab test recorded borderline severe liver fibrosis, but as discussed below, the purpose of

these tests is predictive of morbidity and mortality, and not for the purpose of arbitrarily setting the degree of infection an HMSA member must be suffering before he is eligible for the proven cure Harvoni offers in more than 96% of patients as shown in three level 3 clinical trials. Such a coverage policy is dangerous and fails to meet any known standard of care.

Of course, there are significant problems with over-reliance on biopsy interpretation and lab results because chronic Hep C is frequently waxing-and-waning in its presentation. Moreover, it has long been established that progression is non-linear over time, and is more rapid in later stages. Any test represents a frozen moment in time. The facts show that it is far from as simple as the rule on which the denial is purportedly based suggests. Thus, it constitutes a significant departure from the standard of care to impose a level of severity as a prerequisite for coverage of Harvoni, inasmuch as the values could vary from week-to-week.

Mr. Yost sought Dr. Stephen Rogoff's assistance with beginning treatment in August 2014, potentially with Sovaldi, before Harvoni was approved, because his symptoms were increasing alarmingly, suggesting that his infection was accelerating as expected with his advancing age and the length of time his infection had been active. Mr. Yost decided to seek treatment because he was fearful the damage to his liver would become irreversible. Dr. Rogoff was naturally aware that Harvoni's demonstrated efficacy in clinical trials and that FDA approval was anticipated. Given the very significant risk of harm and uncertainty of results inherent even in the new Sovaldi treatment, which required co-administration of the antiviral ribavirin with its significant side effects increasing the risk of serious side effects, Dr. Rogoff advised Mr. Yost to wait for the approval of Harvoni, which had proven effective without the co-therapies. I have enclosed a copy of Dr. Rogoff's letter explaining this fact and confirming that Mr. Yost's treating providers unanimously agree that Harvoni is medically necessary for Mr. Yost at this time, without delay. Dr Rogoff's letter furthermore reviews Mr. Yost's symptoms and the effects on him, also reviewed in detail herein.

Harvoni is the most appropriate health intervention for Mr. Yost.

HMSA's medical policy of delaying treatment with Harvoni for patients with chronic genotype 1a Hep C until their infection is severe fails to meet the current standard of care for treatment of Hepatitis C, which calls for promptly treating all patients with chronic Hep C viral infections of type 1a. The American Association for the Study of Liver Diseases ("AASLD") has classed Harvoni as the first choice of alternative therapies for type 1a Hep C infected patients among the available alternatives (Viekira Pak with ribavirin is also classed as the second first choice, but the augmentation with ribavirin adds a wider range of significant side effects to the Viekira Pak side effects, and thus Viekira Pak should not be considered more economically efficient compared with Harvoni even if the cost of coverage for the Viekira Pak regimen is marginally lower). The AASLD has based the standard of care on its conclusion that, "Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions." Prompt treatment is also of

consequence to infectious disease control and public health which is a responsibility HMSA shares as a consequence of the privileges it enjoys in selling prepaid health care in Hawaii.

Mr. Yost is treatment-naïve, and thus has not previously been treated with IFN, PEG-IFN, or RBV. As has been the case with a majority of genome 1a patients, Mr. Yost's treating providers concluded that treatment with the pre-Harvoni DAAs was not an economically efficient alternative for him because those alternatives failed offer reasonable prospects for a cure and are attended by significant serious side effects impacting on quality of life and productivity. The evidence shows that patients with Hep C virus genotype 1a tend to have the highest relapse rates among genome type 1 patients following a typically difficult course of treatment with the treatment alternatives available prior to the approval of Harvoni. Mr. Yost is treatment-naïve at this stage simply because he has followed a course of controlled lifestyle and other mitigating measures in attempting to control his Hep C because the costs and risks of the IFN and PEG-IFN regimes was simply too high. Hep C is nonetheless progressive and Mr. Yost's viral infection is active and his disease is progressively destroying his liver, which will lead to far more costly disabilities (including the potential cost of a liver transplant with its attendant costs to Mr. Yost and the economic cost in the health care system known to be greater than $500,000), along with other required health interventions, and the increased risks of permanent injury or loss of life.

Genome type 1a is known to be the most resistant to the treatments available prior to the new medications such as Harvoni which have cure rates of over 95% in genome 1a patients. Mr. Yost's treating providers have previously considered and concluded that he should not attempt the once-standard therapy involving treatment with up to 10 million units of synthetic (pegylated) interferon per week, for approximately 48 weeks, to achieve a 1-in-4 chance of a cure. Treating with interferon theoretically increases the immune system's ability to detect the stealthy Hep C virus, <u>in some patients</u>. In addition to its low cure rate, interferon's normal "virus effect" involves significant side effects with which everyone who has had a viral infection is familiar: fever, nausea, achy and sore muscles, joint pain and fatigue. These are common symptoms of chronic Hep C without treatment, although not all of the chronic Hep C symptoms, and thus may be increased during treatment. In addition to these "flu symptoms," patients can experience severe psoriasis, irritability and insomnia, trouble breathing, chest pain, high fever and chills, fatigue, headaches, decreased appetite, nausea and vomiting, weight loss, muscle aches, bone marrow suppression, weight and hair loss, depression and mood changes, decreased white blood cells and platelets, elevated liver enzymes, difficulty concentrating and impaired memory as side effects of treatment with interferon. Patients treated with interferon experience these symptoms more-or-less continuously during treatment as they are a natural reaction to excess interferon in the system, and they may not experience a cure in any event.

Thus, treatment with interferon presented substantial risks of harm to Mr. Yost with questionable benefits. Mr. Yost's treating providers have likewise not recommended adding ribavirin to interferon to achieve an increased potential for cure to somewhere between 1-in-3

and 1-in-2 chance as treatment with ribavirin adds a lengthy list of additional significant common side effects to the interferon side effects, including anxiety, tarry stools, congestion, cough or hoarseness, crying, depersonalization, diarrhea, labored breathing, discouragement, dry mouth, dryness of the throat, dysphoria, euphoria, feeling sad or empty, feeling unusually cold, fever or chills, general feeling of discomfort or illness, hyperventilation, irregular heartbeats, irritability, joint pain, loss of interest or pleasure, lower back or side pain, nervousness, painful or difficult urination, pale skin, paranoia, quick to react or overreact emotionally, rapidly changing moods, restlessness, right upper abdominal or stomach pain, runny nose, shaking, shivering, shortness of breath, sleeplessness, sore throat, sores, ulcers, or white spots on the lips or in the mouth, sweating, tender, swollen glands in the neck, tightness in the chest, trouble with concentrating, trouble with sleeping, trouble with swallowing, troubled breathing with exertion, unable to sleep, unusual bleeding or bruising, unusual tiredness or weakness, voice changes, and wheezing. Thus, treatment with interferon augmented by ribavirin presented very substantial risks of harm to Mr. Yost without presenting an acceptable increase in potential benefits.

Mr. Yost has thus led an austere lifestyle to restrain the progression of his Hep C viral infection, while enduring the associated symptoms which have cost him lost productivity and quality of life for several years, and continuously decreased the time available for his liver to recover and regenerate following elimination of the Hep C viral infection. Mr. Yost's treating providers have unanimously concluded that starting the 12-week Harvoni treatment regimen will not cause Mr. Yost appreciable increased symptoms or side effects, and will result in the very substantial benefit of curing his chronic Hep C, restoring him to a healthy and productive life, and affording him the expectation that there is time remaining for his liver to regenerate to a healthy organ. In three phase 3 clinical trials, less than 1% of patients diagnosed with genotype 1 Hep C permanently discontinued the 12-week treatment regimen due to adverse events. 16% or fewer patients enrolled in the 12-week regimen experienced fatigue, 14% or fewer experienced headache, and fewer than 7% experienced nausea, diarrhea, or insomnia. None of the known interactions are a factor in Mr. Yost's case.

Neither Mr. Yost's present lifestyle management regimen nor the alternative of interferon or interferon augmented with ribavirin offers Mr. Yost an appreciable benefit of a cure or survival compared with the known side effects of treatment and the eventual destruction of his liver. No other class I treatment, Viekira Pak with ribavirin or Olysio + Sovaldi with ribavirin which entail similar costs for the medications, offers Mr. Yost the potential benefits Harvoni offers him (less than a 3% chance he will not be cured) coupled with a significant reduction in the potential harms to him as a consequence of the side effects he would have to endure during alternate treatments, or the continuation of the progressive destruction of his liver. Harvoni is the obvious choice for him and that is why his treating providers have unanimously recommended it. Moreover, Harvoni is the only health intervention that meets this medical necessity criterion. Dr. Rogoff confirms in his letter that Mr. Yost's treating physicians have unanimously concluded that there is no medically sound rationale for waiting until Mr. Yost's

hepatic injury advances as a result of his viral infection given the potential benefits and harms to him of treatment with Harvoni at this time. Dr. Rogoff also emphasizes the certainty that delay will result in greater harm to Mr. Yost because once liver cells are fibrotic they cannot regenerate.

Harvoni is known to be effective in curing Hep C genome type 1a

Harvoni is FDA-approved for treatment of Hep C. It proved highly effective in level 3 clinical trials in achieving a sustained virologic response, which is considered a cure. The first Harvoni level 3 clinical trial was conducted with 895 treatment-naïve patients (patients who, as with Mr. Yost, had not undergone prior treatment with interferon) of median age 54 years, 16% of whom had cirrhosis. Of this cohort, 67% were diagnosed with genotype 1a. Patients were randomized into 4 groups, one receiving Harvoni for 12 weeks, another receiving Harvoni + ribavirin for 12 weeks, a total of 431 patients, the third receiving Harvoni for 24 weeks, and the fourth receiving Harvoni + ribavirin for 24 weeks, bringing the 24-week group total to 434. Patients with cirrhosis were stratified into the 4 groups, as were genotypes 1a and 1b. 99% of patients in the 12-week group (210 of 213) experienced sustained virologic response. 98% of those diagnosed with genotype 1a experienced sustained virologic response (142/145), and the treatment proved nearly as effective in the patients with cirrhosis. None of the cohort had on-treatment failure and only one experienced relapse.

The third Harvoni level 3 clinical trial cohort was a randomized, open-label trial, also in treatment-naïve Hep C patients—none of whom was cirrhotic—of median age 55 years, all diagnosed with chronic genotype 1 viral infection (80% were type 1a). The patients were randomized, and 1/3 assigned to each of the following three treatment groups and stratified by genotype (1a vs 1b): Harvoni for 8 weeks, Harvoni for 12 weeks, or Harvoni + ribavirin for 8 weeks. 96% of the 12-week group (208 of 216 patients) experienced sustained virologic response. In the 12-week group, which had superior response to either 8-week group, none of the patients experienced on-treatment virologic failure, and only 3 patients, or less than 1.5%, relapsed. Type 1a patients comprised 172 of the total, and 165 experienced sustained virologic response.

The evidence thus clearly demonstrates that Harvoni is known to be effective in treating chronic genome type 1a Hep C in treatment-naive non-cirrhotic patients like Mr. Yost, according to properly designed, managed, and evaluated scientific clinical trials.

Harvoni is the most cost effective alternative health intervention for Mr. Yost

The 12-week Harvoni treatment constitutes the most economically efficient use of resources for Mr. Yost given the expected benefits and harms to him of the available alternative treatments, including no treatment (continuing with the coping strategies he has used to follow a lifestyle which supports his immune system, but adversely impacts his quality of life, functionality, and productivity). The cost effectiveness of the respective alternatives for treating the genome type 1a Hep C infection must be compared on an individualized basis for Mr. Yost,

taking into account all of the costs associated with each, including non-treatment. One of the key, and most significant, risks relevant to the cost effectiveness analysis is the fact that virtually 50% of patients with chronic Hep C may suffer a critical Hep C assault on an organ with no forewarning symptoms other than general lethargy, painful joints, or frequent itching. The longer HMSA delays Mr. Yost in curing his Hep C viral infection, the greater the risk that he will suffer such an injury, including the potential failure of his liver, which could result in premature death unless he is fortunate enough to have a successful liver transplant. The medical transplant and care associated with the transplant is presently approximately a half million dollars.

Many patients suffer chronic extrahepatic manifestations which can range from mild to severe, and all of which increase their health care costs. Notably, Mr. Yost has been experiencing significant extrahepatic Hep C symptoms for several years. Dr. Murray advised him in no uncertain terms that a viral load of over 6 million IU/ml was cause for great concern and prompt action. Mr. Yost sought Dr. Rogoff's advice in August 2014 because the increasing intensity of his symptoms raised the probability that his infection was accelerating. Mr. Yost's September 2014 abdominal scan report also states that his right kidney is showing effects, and that he has fatty infiltration to his liver. Renal failure is a known risk of chronic Hep C.

The many rheumatologic manifestations associated with chronic hepatitis C virus (HCV) infection include arthralgia, myalgia, arthritis, vasculitis, and sicca syndrome (which classically combines dry eyes, dry mouth, and another disease of connective tissue such as rheumatoid arthritis, lupus, scleroderma or polymyositis). Arthralgia is the most common extrahepatic manifestation. Experts believe pruritus in people with liver disease is due to the accumulation of toxins (such as bilirubin) that are not effectively processed or filtered by the damaged liver.

Other conditions reported in patients with chronic HCV infection which increase the cost of health care for Hep C patients in diagnostic and treatment measures, and the costs to them in terms of their reduced productivity and quality of life include fibromyalgia, systemic lupus erythematosus (SLE), antiphospholipid syndrome, osteosclerosis, type II cryoglobulinaemia (for which Mr. Yost is at risk because type II cryoglobulinaemia tends to occur in patients over the age of 50 years, and has serious consequences because it can cause blocked arteries, damage to skin, joints, muscles, nerves and kidneys), porphyria cutanea tarda, corneal ulceration, Bechet's disease (which can cause eye inflammation leading to blindness), vasculitis, sialadenitis and salivary gland stones, diabetes, idiopathic lung fibrosis, and hypothyroidism.

Setting aside the very significant infectious disease-related costs of failing to eradicate an active Hep C viral infection when the opportunity presents, the alternatives available to Mr. Yost compared with Harvoni are far less economically efficient. As previously discussed, even if Mr. Yost had not been advised to avoid the interferon treatment, the potential that he would be cured following treatment with interferon and even peginterferon is far lower than with Harvoni. Thus, Mr. Yost could undergo the interferon course of treatment and remain infected. The cost of the treatment and the significant cost to Mr. Yost to the extent he predictably suffered the common

effects would be incurred for naught, and Harvoni would become his only possible treatment following such an experiment.

Similarly, augmentation of interferon with ribavirin would increase the cost of covering the medication expense and the number of serious potential side effects without appreciably increasing the potential for a cure. Likewise, both Viekira Pak with ribavirin or Olysio + Sovaldi with ribavirin present very similar costs to cover the medication and cure rates comparable to Harvoni, but that is where the favorable results end because both would be far more costly to Mr. Yost due to the numerous serious potential side effects of ribavirin, which he has previously been advised to avoid.

The alternative of no treatment with continuing lifestyle measures which have, for the past decade, diminished Mr. Yost's quality of life increasingly, as well as his productivity and ability to produce an income and advance his career, compares unfavorably with Harvoni for total cost. The alternative Mr. Yost has pursued for the previous ten years has resulted in spreading the Hep C virus and putting at higher and higher risk of extrahepatic organ assaults and other manifestations. These not only impact upon his quality of life and productivity, but also present the very real risk of premature death or permanent and significant injury. Harvoni will result in a cure and the disappearance of his symptoms within a few months, and the treatment generally involves relatively mild side effects. For the foregoing reasons, no alternative health intervention is as economically efficient as Harvoni for Mr. Yost. In the event HMSA fails to reverse the decision, be assured I will pursue every possible remedy on Mr. Yost's behalf to compensate him for any injury he suffers, including any long term or permanent condition that may be attributed to the improper and unlawful denial of Harvoni, which promises to result in substantially higher costs to him, and costs for resulting future health care services.

Sincerely,

Rafael del Castillo

Encl
cc: Lisa Lemon, Health Branch, via 1st class mail

Jouxson-Meyers
& del Castillo
Attorneys at Law
a Limited Liability Law Company

TRANSMITTAL

TO: Greg Yost

FROM: Rafael del Castillo

DATE: April 13, 2015

RE: Case plan and financial arrangements, coverage of Harvoni

I have had an opportunity to review your case and this is a brief overview of the plan. I will follow up with an engagement agreement which we can discuss.

Based upon my conversation and agreement with HMSA Member Advocacy and Appeals made on your behalf, I recommend a three-phased plan. HMSA has agreed that we will have the opportunity to submit information in the first round of appeal from the initial denial, made without benefit of additional "information" we can provide – namely why the treatment meets medical necessity criteria and is not specifically excluded. I recommend this course because I believe it offers the best chance of resolving the case early, avoiding litigation, which will be expensive, and avoiding delay in starting your treatments.

We have approximately two weeks to submit the initial appeal, which will consist of a letter, with attachments, explaining why the treatment is covered and is medically necessary. (If we need an extension of time, HMSA will grant it.) If the initial appeal results in a second denial, the case must be fully prepared for submission to the appeals committee because that is the last stage of internal appeals, and will comprise the record that the federal court relies upon to decide whether the denial was wrongful. It will be difficult to rescue the case from a failure to construct the full record and argument for the last internal appeal.

As I mentioned to you previously, if it becomes necessary to file a complaint in Federal court to force HMSA to pay for the treatment, the statute provides for recovery of the attorneys' fees and costs incurred. The statute does not provide for recovery of fees incurred in internal appeals. (To the extent it is possible to show that the preparation for the final appeal was preparation for the court case, the fees and costs may be recoverable.) You should assume that you must prevail in order for the court to award you the fees and costs incurred.

I require an initial retainer of $1,500 against billings for the time I anticipate will be required for the first phase of your appeal. (I have a tiered rate schedule, a copy of which is attached.) I will bill against the retainer for actual time and costs, but not to exceed the $1,500. I will refund any remainder to you in the event HMSA reverses its denial. If the denial is upheld in the first phase, I will hold any remainder and apply it to the retainer for the second phase

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Rafael G. del Castillo, Managing Member

appeal which will be $1,500 as well. I will not be able to predict whether the second phase will require more than $1,500 until I have an opportunity to review the reasons given for the denial. I thus am not prepared to commit at this time to capping the fees and costs.

In the unhappy event the denial is upheld by the HMSA appeals board, I will require a $5,000 retainer to file a complaint in Federal court against HMSA for coverage of your treatments. In the event your whole retainer is used in the litigation, I will request that you replenish the account in $1,000 increments.

I plan to send HMSA a letter today requesting the totality of the information and documents they relied upon in the initial appeal. This usually forms the basis for HMSA to re-evaluate as we invariably provide additional information and that affords HMSA room to change its mind without losing face. I will copy you on the letter request.

April 6, 2015

RE: Gregory Yost

To Whom It May Concern:

This letter is in appeal of your denial of Harvoni for treatment of Mr. Yost. I have seen Mr. Yost in counseling for his hepatitis C treatment since August 2014 when he approached me wanting to initiate therapy. My advice at the time was to wait until Gilead's all oral regimen was approved. My recommendation to begin Harvoni dates back to then and this predates your policy change to limit therapy to only those with stage III fibrosis.

Further, Mr. Yost has symptoms of his Hep C and is currently suffering. I can find no other medically plausible reason for his constellation of complaints including headache, fatigue, pruritis, anorexia, right upper quadrant pain, and cognitive deficits. He is currently symptomatic from his viral infection that is treatable with current medicines. It is my medical opinion he should institute therapy with Harvoni now.

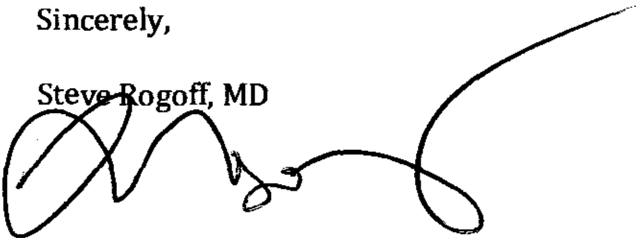
In addition, there is no medical reason to wait until his hepatic injury advances. Once fibrotic, those cells cannot regenerate. The only reason to not provide for a known cure for his known disease is financial and this seems against the way I've been trained to practice medicine.

Further, Mr. Yost was not informed of your policy change re: therapy availability for his Hep C. He has been with HMSA for 11 years and it would have been advised for you to reach out to him to let him know about your policy change. I imagine claims data would allow you to know he had Hep C before you changed your policy.

I am in no way asking you to change your policy. I am only advising Mr. Yost to start therapy for his Hepatitis C as I believe we can cure current symptoms and prevent further liver damage. His biopsy and labs demonstrate some fibrosis and liver damage and it is likely to progress without therapy. To wait until symptoms and fibrosis worsen or until cirrhosis develops seems unbased in science, only in financial matters.

Sincerely,

Steve Rogoff, MD



KAUA'I MEDICAL CLINIC

An Affiliate of Hawai'i Pacific Health

4/14/2015

RE: Gregory K Yost

To Whom It May Concern:

Mr. Yost was seen by me and has lived with chronic hep c for many years. My recommendation is for treatment. He has been waiting for Harvoni for years and now that it is available, has been denied coverage. Regardless of his liver status and degree of fibrosis my recommendation is the same. Although he does not have any clear syndromes associated with chronic hep c, he feels he has chronic symptoms that are related due to no other clear cause. Unfortunately the only way to tell if these are related to his hep c is to treat and cure it. Please reconsider approving Harvoni 1 tab daily for 12 weeks.

Sincerely,

James Yoon, DO
KAUAI MEDICAL CLINIC MAIN
INTERNAL MEDICINE - KMC MAIN
3-3420 Kuhio Hwy Ste B
Lihue HI 96766-1098
Dept Phone: 808-245-1500

RE: GregoryYost

To Whom It May Concern:

This letter is in support of approval for Harvoni (Ledipasvir-Sofosbuvir) for treatment of Mr. Yost's symptomatic Hepatitis C, genome 1a. I have seen Mr. Yost in counseling for his hepatitis C treatment since August 2014 when he approached me wanting to initiate therapy. My advice at the time was to wait until Gilead's all oral regimen was approved. My recommendation to begin Harvoni dates back to August 2014, which incidentally predates HMSA's subsequent medical policy revision to generally limit therapy to stage III or greater fibrosis of the liver. Harvoni is covered, not specifically excluded from coverage, under Mr. Yost's HMSA Plan. It is also the least expensive alternative among the new oral regimens considering all costs involved in treatment.

HMSA's medical policy on Harvoni is not consistent with the current standard of care for treatment of Hepatitis C. The American Association for the Study of Liver Diseases has classed Harvoni 1A as the first choice of alternative therapies for Hep C infected patients among the available alternatives (Viekira Pak with ribavirin is also classed 1A, but ribavirin adds a wider range of significant side effects to the Viekira Pak side effects which are comparable to Harvoni, and thus Viekira Pak should not be considered more cost effective than Harvoni even if the cost of the medication is marginally lower). The AASLD has concluded that the standard of care requires treatment of all Hep C infected patients based upon its findings that, "Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions."

Mr. Yost is treatment-naïve, and thus has not previously been treated with IFN, PEG-IFN, RBV, or any HCV direct-acting antiviral (DAA) agent. Consistent with the majority of genome 1a patients, treatment with the pre-Harvoni DAAs would not be a cost effective alternative for Mr. Yost due to the significant known side effects impacting on quality of life and productivity, and the high potential for relapse despite a course of therapy. The AASLD has also found that the "introduction of DAAs into HCV treatment regimens increased the risk of drug interactions with other concomitant medications used by patients." The AASLD concluded that combinations of DAAs require close and continuing attention for potential drug interactions and thus the pre-Harvoni alternatives are not as cost effective as Harvoni. The evidence also shows that patients with Hep C virus genotype 1a tend to have the highest relapse rates among genome type 1 patients undergoing certain regimens. Mr. Yost is treatment-naïve at this stage simply because he has followed a course of controlled lifestyle and other mitigating measures in attempting to control his Hep C because the costs and risks of the IFN and PEG-IFN regimes was simply too high. Hep C is nonetheless progressive and Mr. Yost's viral infection is active and his disease is progressively destroying his liver, which will lead to far more costly disabilities (including the potential cost of a liver transplant with its attendant costs to Mr. Yost and the economic cost in the health care system known to be greater than $500,000), along with other required health interventions, and the increased risks of permanent injury or loss of life.

There is no medically sound rationale for waiting until Mr. Yost's hepatic injury advances as a result of his viral infection. Once fibrotic, those cells cannot regenerate. The only reason to not provide for a known cure for his known disease is financial and this seems against the way I've been trained to practice medicine.

ıave advised Mr. Yost to start therapy for his Hepatitis C as I believe we can cure ymptoms and prevent further liver damage. His biopsy and labs demonstrate some ınd liver damage and it is likely to progress without therapy. To wait until symptoms osis worsen or until cirrhosis develops is contrary to the standard of care and can only be ed as a short-term effort to save money and possibly shift the cost of Mr. Yost's ms and eventual damage to him and to other third parties in the future.

Mr. Yost is experiencing the known symptoms of Hep C and is currently suffering from a ellation of complaints including headache, fatigue, pruritis, anorexia, right upper quadrant and cognitive deficits, for which I can find no other medically plausible reason or cause. ; therefore currently symptomatic from his Hep C viral infection which is treatable with ent medicines. It is my medical opinion he should institute therapy with Harvoni now. I rred Mr. Yost to infectious disease specialist James Yoon, DO, and it is my understanding t Dr. Yoon requested preauthorization for Harvoni for Mr. Yost and that an HMSA Medical rector denied coverage initially based upon HMSA's policy. As I have explained, the medical licy is contrary to the standard of care for Hep C infected patients generally. Insofar as the otential benefits and harms of treatment with Harvoni for Mr. Yost, and the total costs of pproving Harvoni compared with the available alternatives and the costs to Mr. Yost of not commencing treatment at this time, I have concluded that Harvoni is medically necessary for Mr. Yost at this time and that he should commence treatment immediately. I have spoken with Dr. Yoon about Mr. Yost's individual case, and he concurs completely with me that treatment with Harvoni is medically necessary for Mr. Yost at this time and accords with the standard of care.

I also note in addition to the foregoing facts that HMSA failed to inform Mr. Yost of its supposed medical policy revision affecting his choices of effective therapies availability for his Hep C. He has been with HMSA for 11 years and thus HMSA knew or should have known that he was a Hep C patient affected by the propose medical policy revision. HMSA should, at the least, have reached out to him to let him know a medical policy revision was scheduled for adoption. I imagine claims data would allow you to know he had Hep C before you changed your policy. Given the complexity and dynamic nature of health insurance benefits and medical advances, it only seems minimally fair for HMSA to ensure that all of its members understand their health care options and are able to make informed decisions by providing the affected members with written disclosures of coverages and benefits and information on any changes affecting coverage principles of any proposed changes in exclusions or restrictions on coverage.

Please contact me if you have any questions.

Sincerely,

Steve Rogoff, M.D.

To whom it may Concern,

My name is Greg Yost and I am a client of HMSA.

I have been an athlete my whole life. I have been a high-level collegiate swimmer and water polo player in my youth.

Being an athlete in am very in tune with my body.

At this point I can tell you for certain that I do not feel well at all. It feels as though I have a low-grade fever all the time. Constant head aches.

I am lacking in energy and I am not able to focus on work.

Hepatitis C directly causes these symptoms.

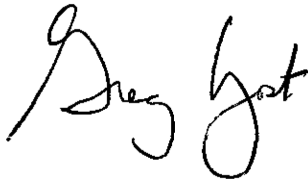
This situation is causing stress in my family due to lack of income this year. This is all Hep C related.

Please do the right thing and allow treatment, otherwise I will have no choice but to seek damages in court.

Thank you.

Sincerely,

Greg Yost



KAUA'I MEDICAL CLINIC

An Affiliate of Hawai'i Pacific Health

4/23/2015

RE: Gregory K Yost

To Whom It May Concern:

Medical verification that Mr Gregory Yost does have hepatitis C.,that he has seen our local Infectious Disease specialist who is recommending treatment with Harvoni.
As his Primary Care Physician, I support the recommendation to treat with Harvoni x12wk
Any questions please feel free to call me.

Sincerely,

Joseph Michael Murray, MD
KAUAI MEDICAL CLINIC KOLOA
FAMILY MEDICINE - KMC KOLOA
3-3420 Kuhio Hwy Ste B
Lihue HI 96766-1098
Dept Phone: 808-742-1621

KAUA'I MEDICAL CLINIC

An Affiliate of Hawai'i Pacific Health

5/11/2015

RE: Gregory K Yost

To Whom It May Concern:

I am Gregory Yost's Primary Physician ,and have been for many years. I am very concerned about the progression of chronic hepatitis C viral infection and disease related symptoms,which increasingly impact on his quality of life and his career. In August 2004 ,Mr Yost was diagnosed with chronic hepatitis C viral infection, genome type 1a. At that time his viral load,measured by pcr was approximately 1.5million IU/ml. According to his latest lab test ,his viral load is over 6million. As his body fights harder against the infection ,he has experienced increasingly debilitating symptoms. Chronic hepatitis C is known to accelerate in patients 50years of age and older,leading to increased symptoms,morbidity,and mortality.

For all the reasons,it is unquestionably medically necessary at this time for Mr. Yost to begin the 12-week Harvoni treatment regime.
Feel free to contact me with any concerns.

Sincerely,

Joseph Michael Murray, MD
KAUAI MEDICAL CLINIC KOLOA
FAMILY MEDICINE - KMC KOLOA
3-3420 Kuhio Hwy Ste B
Lihue HI 96766-1098
Dept Phone: 808-742-1621

LATE

Written Testimony Presented Before the
Senate Committee on Health
March 4, 2016 2:00 P.M.
By
Krystle Bala, RN
University of Hawaii at Hilo

HB2740 HD1 RELATING TO LIABILITY

To The Honorable Joseph M. Souki, House of Representatives Twenty-Eighth State Legislature
The Honorable Della Au Belatti, Chair, Committee on Health
The Honorable Richard P. Creagan, Vice Chair Committee on Health
Members of Committee on Health, thank you for hearing the testimony today related to HB2740 HD1 Relating To Liability.

My name is Krystle Bala. I am a new Registered Nurse finishing my Bachelor of Science in Nursing at the University of Hawaii at Hilo. I am testifying my support of HB 2740, Relating to Liability.

Based on my experience at work, I have noticed an increased census due to delayed discharges and high admissions. This has caused health care providers with additional stress on providing safe and effective care to round on all patients. This also includes the high number of patients versus the limited bed space. Therefore, time is essential to avoid any unnecessary delays in medical treatment and services.

Thank you for your support and time on this measure,
Krystle Bala, RN

LATE TESTIMONY

First, we should review the documentation of Hawaii's historical below-national-average use of imaging procedures, which was provided by The Harvey L Nieman Health Policy Institute and published in the Star-Advertiser. In summary, that data confirmed that between 2006 and 2013, that Hawaii physicians ordered 36% fewer Medicare related Medical Imaging procedures versus the national average. This is in stark contradiction to the biased and unsupportable position presented by the HMSA employed physician Mark Muguisha in an article published January 28, 2016 that stated "Recent review by NIA that doctor's order 30% more imaging then needed and Hawaii has even higher trends". This is simply a blatant falsehood.

We acknowledge and support the high value of modern high-resolution imaging in both defining and ruling out disease, which is one of the foundations of current accurate diagnosis, medical management, and treatment. To be able to define abnormal tissue and blood vessels as small as 1 to 2 mm, and to distinguish between benign and malignant processes is truly amazing. We contend this imaging is key in defining patient care, has a low cost/ benefit ratio, and provides patient and physician confidence, whether positive or negative. As an example, prior to high-resolution CT imaging for appendicitis. the surgical false-positive rate was around 30% and this has now been reduced to near zero with the use of preoperative CT scans.

The negative affect on the practice of medicine Hawaii and on patient care cannot be over stated. And the dichotomy of money being paid to an Hawaiian based insurance company to ensure good health is now being patent to a mainland consultant solely to reduce medical imaging for the same patient population is obvious. By HMSA's own admission, NIA denials are proximally 20%, matching thier contracted prediction. **And their denials are issued anomalously**, without specific reasons and without the expertise of our physicians, without examining the patient, and often without adhering to their own "Guidelines "(which are now *requirements* and are not true guidelines, and are without a peer reviewed basis, as recently admitted to Dr McCaffrey during an interview with an NIA member). There is no analysis of the percentage denials or overturned denials per NIA employee, and therefore there is no account ability on the part of HMSA/NIA. Any imaging denial undermines of the Hawaii MD/patient relationship and questions the integrity of the insurance company. This is another nail in the coffin of our ongoing difficulty in recruiting physicians. The shortage of Hawaii physicians based on recruitment difficulty is well published, and now an HMSA has now made even harder. Our physician shortage just got worse.

The often touted desire of HMSA to work in collaboration with physicians has also not been realized. Following a 'goodfaith meeting' that The Hawaii Neurological Society recently set up with HMSA/NIA our local neurology offer also been denied, and met with deafening silence. At a January 11, 2016 meeting between the Hawaii Neurological Society with HMSA/NIA, the Hawaii neurologist offered to enter a productive relationship and develop a retrospective review system, but to no avail. And to emphasize the lack of NIA expertise, the NIA neurologist 'expert' present that meeting was an 89-year-old retired San Diego physician that has not actively practiced medicine since 1998. The Hawaii Neurological Society position was unanimous in defined the following issues with this new program, and is summarized as follows:

1. Delay in diagnosis.

2. Risk of harm to patients

3. Uncompensated administrative and financial burden on small physician practices.

4. Forced change in referral patterns.

5. Impediment to physician recruitment.

6. Increase in physician liability and risk.

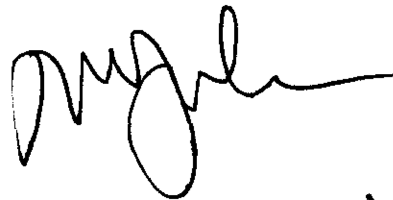
7. Interference with shared decision-making between physicians and the patient.

8. Geographic impediment to the care of neighbor island patients.

9. Lack of fairness and respect for highly trained and conscientious positions.

In summary, the Hawaii Medical Association and community of physicians we represent strongly opposed the HMSA/NIA global imaging pre authorization program because it seriously undermines the patient/physician relationship, delays diagnosis and puts patient at risk, and questions HMSA's commitment to provide optimal care. Our physicians have a proven track record of being very conservative in their reliance on the imaging and would like to offer the following bumper sticker advice: "Slow down HMSA, this ain't the Mainland".

STEPHEN M. HOLMES, MD



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