The Frailty Index: A Tool for Optimal Geriatric Care

Stephen Evans, MD

Predicting the healthcare outcomes of frail, elderly patients is complicated. When these patients become acutely ill, their risk of death and adverse outcomes is higher than the norm. They tend to decompensate more quickly after experiencing relatively minor events, often to the surprise of both patients and their families. The likely expectation is that the patient will return to the same level of function as prior to admission. However, when the patient’s health declines toward death, family members exhibit signs of both shock and guilt.

The decline in the health of a frail, elderly patient often includes the development or exacerbation of pressure sores, falls, severe infections, and other conditions that can be painful for both the patient and the family that witnesses the decline. Families may be unaware of the reality of the patient’s condition, or unable to acknowledge it, and, as a result, often become angry. This anger increases the risk that lawsuits may be commenced by family members against the physicians, nursing facilities, and hospitals caring for their relatives. The Affordable Care Act, with its goals of cost compression and staff reduction, may actually increase the probability of litigation.

The key to mitigating the anger of families and the potential liability of providers in these situations is the ability to predict and communicate to the patient and their family the likelihood that the patient’s condition will decline. By doing so, both the patient and the family will be better prepared for any adverse clinical events.

Most elderly patients and their families want to receive accurate information about their current and anticipated health status. What they often lack is the support of their providers and education about the risks, benefits, and alternatives to potential treatment. They also need to understand the anticipated prognosis so they can make more appropriate decisions about potential interventions as the end of life approaches.

Historically, physicians have been taught to approach the treatment of a patient by identifying a particular disease entity, then applying clinical practice guidelines specific to that diagnosis, regardless of the patient’s age and condition. However, for more than twenty years, the medical literature has illustrated that the same illness often behaves differently in younger patients than in the frail elderly in their last years of life. Thus, the issue of frailty must be addressed, in concert with the disease entity (or entities), when helping elderly patients and families to better understand future unavoidable events.

In general, it is difficult to obtain an accurate prediction of the likelihood of survival for sick, frail, and elderly patients. Until recently, physicians have had very few valid tools with which to do so. One expert has proposed that “by recognizing frailty and measuring it objectively, clinicians can better engage patients and their loved ones in difficult discussions about treatment plans and prognosis, and, ultimately, deliver better...

continued on page 2
The Frailty Index continued from page 1

palliative care.” A patient’s chronological age is a less accurate predictor of the likelihood of adverse outcomes than frailty and underlying general vulnerability. In a variety of studies, frailty has been shown to be superior to chronological age when using standardized clinical practice guidelines to predict the probability of adverse outcomes. However, the relationship between frailty and adverse outcomes is not yet perfect. Clearly, the severity of illness and expectations for care affect a patient’s eventual outcome. Therefore, development of a tool to measure frailty objectively is vital to effective planning for the patient, as well as in communicating with both the patient and family.

Frailty has been defined variously over the centuries. There is still no consensus on its meaning, despite numerous definitions proposed by different groups of experts, yet it is the most common condition leading to death. Because frailty has been directly linked to biology and, in particular, muscle degeneration, this suggests that frailty is a geriatric syndrome with both biologic and prognostic meaning. “The more individuals have wrong with them, the more likely they are to be frail.”

Because frailty is the most common expression of aging, it also presents the greatest challenges. Elderly patients with multiple chronic medical conditions face increased costs, more invasive testing and less favorable outcomes when the clinician focuses solely on a single disease rather than the patient as a whole. Use of a frailty measurement to evaluate each of the patient’s comorbidities allows for an “apples-to-apples” comparison among patients and provides a framework for discussing beneficial options of care and expectations of care. Additionally, this common framework provides a unified language and approach for the multiple specialties of physicians who provide care to geriatric patients. Both frailty and the patient’s medical condition should influence a patient’s treatment plan, i.e., whether or not the patient should undergo conservative or invasive care or opt for palliative care.

Two models are currently available to test frailty - the phenotype and the cumulative deficit models. The phenotype model measures just five clinical characteristics: weight loss, exhaustion, muscle weakness, slowness, and low levels of activity. These characteristics are scored as non-frail, pre-frail, and frail. In contrast, the cumulative deficit model measures ninety-two variables, which are equally weighted. Each variable is called a deficit, which is defined as “any loss suffered in a particular area over the lifetime of the patient.” This index requires “a simple calculation of the presence or absence of each variable as a proportion of the total deficits.” Frailty is defined as “the cumulative effect of individual deficits.” The likelihood of frailty increases as the number of deficits increase.

In 2007, a secondary analysis of the Yale Precipitating Events Project (PEP) resulted in a modification of the cumulative deficit model to include only 40 variables. The revised version is called the Comprehensive Geriatric Assessment (CGA) and is widely accepted, even by Medicare. Despite the decrease in the number of variables originally used, the CGA validly predicts frailty. The data required for the CGA is easily extrapolated from nursing assessments as well as the history and physical examinations performed by clinicians. The CGA counts deficits from four domains, including functional, social/economic, mood, and cognition, plus deficits related to the number of diagnoses and medications the patient takes. The overall frailty index (FI) is then calculated by a simple ratio:

\[
\text{Number of deficits present} / \text{Number of deficits evaluated} = \text{FI}
\]

The FI score range is 0.0 to 1.0. Patients whose FI is 0.20 or less are not frail. An FI score higher than 0.80 indicates that a patient is considered extremely frail and terminally ill. The

---

11. Rockwood, supra note 5.
FI measures the patient’s accumulated vulnerability, rather than a cluster of deficits. This cumulative score correlates to patient outcomes.13 Patients who are repeatedly hospitalized with subsequent lengthy rehabilitation or long term nursing home stays are very likely to be frail. By using the CGA with such patients, the physician can both assess the risk of adverse outcomes for a specific patient as well as support his/her clinical judgment and treatment plan. The patient receives optimal care and treatment, and the patient and his/her family benefit from clear and realistic expectations about the patient’s future. Further, this creates an opportunity for the clinician to discuss advance directives and orders to limit treatment, such as MOLST, with the patient and their family. Use of this index also may affect how frequently the patient must be seen by the physician to modify or manage the adverse outcomes associated with increasing frailty.

In the hospital setting, use of the frailty index provides a measure of a patient’s actual health status, which impacts treatment. Because healthcare costs are often increased by unwanted and/or non-beneficial care at the end of life, use of this tool can reduce unwanted treatment and hospital stays which have limited benefit and even increased potential for harm.

The use of the frailty index also provides a unifying language among various physicians from specialties that treat the elderly.14 The FI produces valuable information, similar to the results of laboratory and diagnostic testing, which can influence future discussions and decisions. However, the FI is not intended to be a mortality index. It must never be used as a reason to withhold treatment and should not regularly be shared with the family. Rather, use of the FI must focus on predicting patient risk, to allow patients and families to make accurate decisions in accordance with the patient’s wishes. However, it is imperative that all such discussions with patients and families be carefully and accurately documented. This is particularly important when the expectations of the patient and family do not match the actual outcomes.

The beneficial use of the CGA can best be exemplified by the following case study.

An 87-year-old female was admitted to a nursing rehabilitation unit. She had previously been living alone with moderate family support. She had poorly controlled Type 2 diabetes, diastolic heart failure (DHF) with peripheral edema, secondary cellulitis with lower extremity ulceration and poor arterial flow, mild dementia, and widespread degenerative joint disease with pain. The CGA was used to determine how this patient’s comorbidities impacted her care and future rather than her undergoing treatment solely based on disease-specific guidelines. The patient’s baseline FI indicated that she was quite frail.

The patient and her family met with her clinicians. The clinicians presented the patient’s treatment options in plain English so the patient and family could understand them. With the consent of the patient and her family, rehabilitation was initially attempted. However, when the patient failed to make progress in rehabilitation, she and her family were receptive to completing a MOLST. As she continued to deteriorate, the patient and her family requested further orders to limit her treatment in accordance with her wishes and best interests.

The patient celebrated her 88th birthday by going out to dinner with her family. She ate and drank her favorite foods and beverages which were not offered at the nursing home and enjoyed being in a different social environment. Later that same evening, after she returned to the facility, her DHF decompensated. Thereafter, as pre-determined by her and her family and her clinicians, she received only comfort care. She died peacefully the next day with her family present.

Thus, the information obtained by using the FI provided the patient’s clinicians with a reasonable approach to her treatment. It enabled them to learn what this patient and her family really wanted. The patient and her family were also able to

This case demonstrates the professional liability problems faced by a physician when the patient is addicted to prescription painkillers and “doctor shops” to obtain controlled substances.

A lawsuit alleging wrongful death was brought against two physicians who prescribed controlled substances for a patient who died of an overdose of those drugs. The patient was a 33-year-old single female with a history of migraine headaches starting at age 11. She had taken Percocet for her headaches since 1989. In 1992, her neurologist expressed concern that she was addicted to controlled substances and unsuccessfully attempted to treat her with a variety of non-narcotic treatments, medications, and alternative therapies, including acupuncture.

In 1997, the patient was seen in the Emergency Department due to an overdose of Valium. In 1998, she again presented at the Emergency Department with an overdose of Tylenol. Later in 1998, the patient was involved in an automobile accident and received pain medication for her injuries. In 1999, the patient’s father called her primary care physician and informed him that he believed she had taken an overdose of Soma, which had been prescribed for those injuries.

In 2000, the patient was seen at a local urgent care center for treatment of migraine headaches. The professional staff documented that the patient had refused all conventional migraine therapies and insisted that only narcotics would help her. The patient’s urgent care record was flagged to indicate she was a “drug-seeker.”

In August 2001, the patient was involved in a second motor vehicle accident. She claimed that she suffered a “blackout.” A CT scan and an MRI were performed and a diagnosis was made of a seizure disorder. In October 2001, the patient first saw the defendant neurologist for her migraine headaches. She was seen at his office several times per month with complaints of severe headaches, and almost always on an emergency basis. Each time, she was treated with both anti-seizure medications and controlled substances. Occasionally, the defendant neurologist gave her intravenous medications and then prescribed oral controlled substances to be taken at home. This neurologist also frequently provided the patient with samples of pain medications.

In December 2002, the patient’s primary care physician, for the first time, documented in her medical record that the patient had been receiving prescriptions for controlled substances from multiple physicians. In January 2003, this physician contacted the defendant neurologist and advised him of this fact. Following this call, the defendant neurologist decided that he would no longer prescribe controlled substances for the patient. In late January 2003, when the patient returned to his office, the neurologist advised her of his decision. He instead prescribed Bextra, a non-narcotic medication, for her migraines. The patient was advised to return to his office for re-evaluation in six to eight weeks. She failed to do so. However, in March 2003, the patient called the defendant neurologist’s office requesting a prescription refill of a controlled substance. Despite the fact that the neurologist had previously limited his prescriptions for controlled substances for this patient to a 15-day supply, and had determined not to further prescribe them, the patient did receive a prescription.

Unfortunately, at the time the patient called the neurologist’s office, he had just converted from paper records to electronic medical records. Although a warning should have appeared that no controlled substances should be prescribed for this patient, the office staff either ignored or overlooked this warning. A prescription for a 30-day supply of Percocet was prepared for the defendant to sign. Apparently, the neurologist did sign this prescription without first reviewing the patient’s medical records or seeing and assessing the patient.

On July 14, 2003, the patient saw the defendant internist for the first time. The patient complained of back pain and migraine headaches. However, the patient did not provide the defendant internist with details about her past medical history, treatment by other providers, and drug use. Further, the internist failed to elicit the patient’s prior medical history or obtain and review the records of her prior physicians. The internist only documented medications to which the patient was reportedly allergic, all of which, notably, were not controlled substances.
examining the patient, she prescribed a 30-day supply of Soma 350 mg. However, she failed to document the reason she prescribed this drug. On July 16, 2003, two days after this first office visit, the patient telephoned the defendant internist complaining of a migraine headache persisting since the prior evening. She begged the physician for a prescription for Darvocet. The doctor did prescribe 60 Darvocet N 100 tablets for her, with no refills. The patient was advised to take 1 tablet every 4 to 6 hours. She was also told not to take Soma with the Darvocet.

On July 18, 2003, the patient died of a drug overdose. At the time of her death, Darvocet, Soma, and Tigan were found in her system. When the internist called the patient’s family to offer condolences, she was informed that the patient had taken 38 Darvocet N 100 tablets. She also learned for the first time that the patient had a history of doctor shopping, multiple unsuccessful stays at drug rehabilitation programs, and multiple drug overdoses. Further, the family informed her that they had just learned that the patient had been purchasing drugs on the Internet.

The plaintiff’s estate, on behalf of her minor son, commenced a medical malpractice lawsuit against both the neurologist and the internist. The primary allegation against both defendants was wrongful death due to the excessive prescription of controlled substances. MLMIC decided to defend both defendants at trial.

Counsel for the defendants based the defense upon the obligation of the patient to follow the instructions given by the defendants for the proper use of prescribed medications. Experts for the defense testified that the patient had a longstanding history of medication overuse and abuse prior to seeing the defendants. Therefore, they opined that neither defendant was responsible for the patient’s addiction. They also testified that both physicians were intentionally misled by the patient, who very carefully concealed her addiction from them. These experts concluded that the patient was determined to abuse drugs, despite the treatment appropriately provided by both defendants. Unfortunately, the defense was precluded from mentioning the possibility that the patient had committed suicide.

The plaintiff’s attorney commented on several occasions that all of the evidence “cut both ways.” He admitted that the patient had continuously abused medications for many years and had lived a very unhappy existence until the time of her death. However, counsel specifically blamed plaintiff’s addiction to prescribed pain medications on the defendant neurologist. Notably, the defendant neurologist had last prescribed Tigan for the patient in December 2002, more than 6 months prior to her death, and he had not prescribed either the Darvocet or Soma found in her system. With respect to the internist, the plaintiff’s counsel alleged that she failed to elicit an appropriate medical history from the patient and review the records or prior physicians before prescribing an excessive quantity of controlled substances to the patient, thereby causing her death.

After deliberation, the jury rendered a verdict in favor of the plaintiff for $500,000. Of that sum, $250,000 was awarded for financial support for the plaintiff’s son and $250,000 for his loss of the plaintiff’s guidance. The defendant internist was found to be 5% at fault; the defendant neurologist was found to be 20% at fault. The patient was found to be 75% at fault. After the verdict, the case was settled on behalf of both physicians for $246,297.30.
A Legal & Risk Management Perspective

Frances A. Ciardullo, Esq., Fager & Amsler, LLP
Counsel to Medical Liability Mutual Insurance Company

Although this case pre-dates the recent I-STOP legislation and many of the initiatives to control drug seeking behavior by patients, it does illustrate the dangers which exist when a physician fails to pay close attention to his or her prescribing habits, or fails to elicit a good history or review the records of previous physicians.

Effective pain management for patients with acute or chronic pain is a part of quality medical practice. If the treatments are based upon accepted medical practices and sound clinical judgment, then prescribing, administering, or dispensing controlled substances for pain is legitimate and should not result in liability or charges of professional misconduct. In order to guide physicians in this problematic area, the New York State Department of Health has published the following points of information:

- An adequate assessment of the patient and the pain should be performed and documented.
- Pain should be considered a fifth vital sign that is viewed as a fundamental assessment of well-being, and which is regularly monitored.
- Communication is essential. Many patients, for various reasons, are unable to describe adequately their pain. Physicians should initiate conversations to identify pain and qualify/quantify it and its impact on the patient’s life.
- Treatment should be based on the diagnosis, type of pain, intensity and duration of pain, prior therapies, and the impact on the quality of life.
- Ongoing evaluation of pain, patient compliance, and treatment efficacy should be performed and documented.


- The definition of addict under the Controlled Substances law excludes patients using controlled substances for legitimate medical purposes. The term addiction refers to compulsive use of controlled substances for non-legitimate purposes and is associated with loss of control and use despite harm. Many patients are reluctant to seek pain relief because of the fear of addiction. Clarification from their physicians is essential.
- Certain patients with pain, such as those with history of substance abuse or comorbid psychiatric disorders, may require extra attention, monitoring, documentation, and consultation. In the case discussed, both the defendant neurologist and the defendant internist did not pay sufficient attention to the patient’s history and condition. Nor did they appropriately manage her medications. Before prescribing a controlled substance, the cause of the patient’s pain should be documented by objective tests such as x-rays or other modalities. In this case, the patient had refused all conventional migraine therapies and insisted on narcotics to alleviate her pain. This “red flag” should have alerted the neurologist to be extremely cautious in giving her narcotics. When the neurologist learned that the patient had been receiving controlled substances from multiple sources, he quite properly refused to write any more narcotic prescriptions. Nevertheless, his inattention to detail resulted in the patient receiving yet another prescription from him.

Drug seeking patients will often attempt to hide their medication history and usage. This case was no different. When the patient went to see the defendant internist, she did not provide any details about her past medical history or drug usage. The internist failed to elicit a thorough history before giving the patient a prescription for a controlled substance. As a better practice, the physician should have first attempted a trial of non-narcotic medication or physical therapy before beginning to treat the patient with controlled substances.

A physician should not rely upon prescriptions prepared by non-licensed office staff without first checking the patient’s record for him or herself. Doing so may well lead, as in this case, to prescribing medications which the physician does not really intend to prescribe. Further, prescribing pain medications and additionally giving samples of similar medications can result in medication hoarding by patients, who can use their supply if an overdose is intended. It is crucial that warnings on an EMR be heeded. If they are ignored, prescription errors such as what occurred here will occur.

Finally, the Internet is not often recognized as a source of medications for many patients. Although the patient in this case might not have been forthcoming, the physician, when performing a drug history, should ask the patient if he or she has obtained medications, including over the counter drugs and natural remedies, over the Internet.

The recently-enacted I-STOP legislation was designed to prevent the type of scenario that occurred with this case. Physicians who prescribe Schedule II, III, or IV controlled substances must check the statewide registry to ascertain what other medications the patient has received. Compliance with this law will assist practitioners in appropriately managing their patients’ medications and avoiding an unintentional over-prescription of narcotics.
Impact of the Drug Shortage Crisis – An Oncology Perspective

Sylvia B. Bartel, RPh, MHP

The drug shortage crisis has continued to be a challenge for healthcare facilities and providers for the past several years. In 2011, 267 shortages were reported.1 The majority of these shortages involved generic injectable drugs, with oncology and anti-infectives being the major therapy areas affected.2 Drug shortages have touched everyone involved in clinical care including providers, patients, payers, pharmacists, and risk managers. Not having adequate drug supplies has resulted in changes in drug treatment plans, inventory management processes, and adverse patient outcomes. It is hard to imagine that patients presented with life threatening conditions need to be concerned about access to older generic drug products. In the past, supply was never a concern. In the current climate, the pharmacy often receives calls from patients who would like reassurance that there is an adequate drug supply for their entire planned course of treatment. It is understandable that patients would react in this manner. Drug shortages have resulted in safety concerns, increases in drug expense, reimbursement issues, patient harm, an increase in medication errors, and ethical dilemmas.

The reasons for the drug shortage crisis are multifactorial and complex. Manufacturing and product supply issues are the most common reasons cited for drug shortages.2 This includes quality issues at the manufacturer level. There may be issues with the physical manufacturing facility as well as product defects, such as bacterial contamination or foreign particles in the drug vials. In addition to manufacturer-based quality issues, lack of economic incentives to produce generic products may contribute to limited quantities of drugs in the market. There have been recent discussions that the lack of an economic incentive to reward quality may be one of the reasons behind the drug shortage.3

Several chemotherapy agents that are critical to patient treatment, including liposomal doxorubicin, cytarabine, and methotrexate, have been in short supply. The limited availability or unavailability of these agents has resulted in interruptions in therapy, treatment delays, changes in dose, and substitution of alternative agents that may or may not have the same efficacy.4

Several surveys, including those developed by the Institute of Safe Medication Practices (ISMP) and the Hematology/Oncology Pharmacy Association (HOPA), characterized the negative impact that shortages have on the care of patients.4,5 One ISMP survey reported that 35% of 1800 practitioners experienced an error that could have led to patient harm as a result of a drug shortage. Twenty-five percent of respondents reported errors that reached a patient and 20% reported adverse patient outcomes. The safety issues resulting from the use of alternative drugs included the inability to, or the delay in, updating computer systems/bar-coding systems with the substituted drug information. This resulted in a reduction in the number of safety checks and an increase in the potential for error. Other safety issues included using expired medications, single dose vials for multiple patients and sterility/stability issues with compounded products.


continued on page 8
Impact of the Drug Shortage Crisis continued from page 7

instead of using products produced from a pharmaceutical manufacturer. Examples of errors and adverse outcomes from this survey include a dosing error where 8 mg of morphine was administered instead of 2 mg, as the 2 mg strength was unavailable. A dosing error of intravenous hydrocortisone which was prescribed at the intended dose of morphine resulted in the death of two patients. The ISMP survey of 2012 reported that the most commonly reported medications involved in adverse events are chemotherapy, opioid analgesics, electrolytes, and antibiotics. Four categories of harm were identified. These included the following: inadequate treatment from the use of an alternative drug; an error with the alternative medication; no treatment being administered; and pharmacy error during the compounding of the product. The HOPA survey reported 93% of 243 respondents noted a delay or change in treatment as a result of a drug shortage. Sixteen percent of respondents reported a near miss as a result of a drug shortage. This survey also revealed safety issues such as the wrong drug being dispensed – doxorubicin for liposomal doxorubicin, incorrect dosing conversions and wrong concentrations. Adverse patient outcomes included increased toxicity, disease progression and a cardiac event.

An example of the patient impact as a result of a drug shortage was reported as occurring when cyclophosphamide was substituted for mechloretamine for treatment of intermediate or high risk Hodgkin’s disease. It was reported that the two year cancer free survival fell from 88 to 75% following the drug substitution. Substitutions should be evaluated carefully prior to incorporation as a standard of care. Outcomes may be adversely impacted.

Institutional management of drug shortages included the development of a task force to provide oversight of the management of actual and potential drug shortages. Responsibilities of this task force include: the development of policies and procedures which outline the proper processes and responses when managing drug shortages; safety checks when drug substitutions are required; enhanced drug inventory management; and a process to monitor impact of drug shortages.

The Medication Supply Task Force, a subcommittee of the Pharmacy & Therapeutics Committee, was formed to provide proactive oversight for the management of actual and potential drug shortages. The objectives of the Task Force include the following: monitoring of commercially available drug supply; identification of alternative drugs or medications in anticipation of a supply interruption; and establishing processes and triggers to alert clinicians of potential supply issues based on current drug usage patterns and drug availability. In addition, the Task Force: has established processes for drug allocation, dose adjustments, and drug preparation, and administration for drug substitutions; provides oversight of potential medication safety issues that could result from supply interruptions such as changes in drug concentrations, dosage, administration, and drug usage guideline changes; communicates drug shortage information to the healthcare team and patients.

The Task Force meets quarterly or more frequently as the need arises. Membership includes the Pharmacy and Therapeutics Committee co-chairs, inpatient physician leader, ambulatory physician leader, chief quality officer, ethicist, pediatric oncologists, and the medical director of satellite locations. Also included are the chief medical officer, chief nursing officer, director of pharmacy infusion, communications director, and a patient family advisory council member. In addition to standing members, the Task Force utilizes specific medical staff experts to review drug supply issues and the impact of the supply issue on patient treatment, and to develop drug allocation strategies, should they be needed. The Task Force also ensures safe medication processes are maintained, such as computer provider order entry changes, pharmacy computer system changes, guidelines, and forms updates for any alternative or drug substitutions which are required. The pharmacy has developed a new/change product check list which assists in ensuring that safety standards are maintained.

Drug supply shortages and interruptions, in addition to increasing drug expenses, impact patient care and clinical operations in several ways. Foremost is the need for increased vigilance to ensure the safety of all steps of the medication use process from the receipt of the drug to prescribing, pharmacy preparation, administration, and monitoring for adverse effects. There may be an associated increase in drug costs from the use of alternative agents, which could result in potential payer reimbursement issues. The steps required to manage drug shortages may also require additional staff resources. Further, changes to the pharmacy inventory management model from a “just in time” to a “supply” model may be required. Additional computer system and technology updates to accommodate substitutions for drugs which are no longer available are also needed. Finally, communication to staff and patients regarding the status of drug supplies and the management of drug shortages is critical.


Sylvia Bartel, RPh, MHP, is currently the Vice President of Pharmacy and Clinical Support at the Dana-Farber Cancer Institute in Boston, Massachusetts. She is also Adjunct Instructor of Clinical Pharmacy at Massachusetts College of Pharmacy and Allied Health.
On January 17, 2013, the US Department of Health and Human Services (HHS) issued a final rule modifying the HIPAA Privacy and Security Rules, commonly referred to as the “Omnibus Rule.” Among the many changes made, there were two which have caused some confusion on the part of covered entities in New York. These changes deal with the release of information regarding deceased individuals and students. The confusion arises because New York rules differ from HIPAA rules, and a covered entity in this state must comply with both. This article will summarize the rules which govern the release of information in these situations.

**Deceased Individuals: HIPAA Omnibus Rule**

Under the new Omnibus Rule, covered entities are permitted to disclose personally identifiable health information regarding a deceased individual to family members and other relatives, close personal friends, and persons identified by the individual who were involved in the individual’s care or payment for care, unless the individual had previously expressed an objection. Such disclosure may be written or oral and do not require a HIPAA-compliant authorization.

**Deceased Individuals: New York Rules**

Although the HIPAA Omnibus rule relaxed the standards for the release of a decedent’s information, covered entities in this State must still adhere to New York rules regarding release of such information. In New York, the rules are more stringent and require a more thorough analysis of the relationship between the person requesting the information and the deceased individual.

In New York, the release of a decedent’s information is governed by Public Health Law §18(1)(g) which permits a “qualified person” to obtain medical information. A qualified person is defined as:

1. a distributee of any deceased subject for whom no estate representative has been appointed by the court (i.e., an Executor/Executrix or Administrator/Administratrix); or
2. an attorney representing a qualified person or the subject’s estate, who holds a power of attorney from the qualified person or the subject’s estate explicitly authorizing the holder to execute a written request for patient information under this section.

Under the first section above, a “distributee” can obtain medical information of a deceased individual as long as the will has not gone to probate, and the court has not appointed someone to be the estate representative. The question arises, who are “distributees?” Although a distributee is often thought of as an “heir-at-law” or “the next of kin”, there is a specific legal definition. When a person dies intestate (without a will), their distributees will be the ones entitled to receive the assets. A “distributee” is “any person entitled to take or share in the property of a decedent under the statutes governing descent and distribution.”

Under New York law, distributees are determined in the following order:

1. Spouse and children. If a decedent leaves a spouse and children, the

---

2. 45 C.F.R. § 164.510(b)(5).
3. New York Estates, Powers & Trusts Law, § 4-1.1; New York Surrogate’s Court Procedure Act, § 103(14).
spouse and children are considered distributees. However, if there is only a spouse and no children, the spouse is the sole distributee. Conversely, if there are children and no spouse, the children are the distributees.

2. Parents.
3. Siblings and children of pre-deceased siblings, if any (nieces and nephews).
4. Grandparents and lineal descendants of predeceased grandparents (1st cousins).
5. Great-grandparents and lineal descendants of predeceased great-grandparents (1st cousins once removed).

To determine the decedent’s distributees, one must start with the first listed and continue down the list until reaching a survivor. No one on a lower level than the survivor is considered a distributee. For example, if the decedent was survived by a spouse or child, then no one on a lower level is considered a distributee, such as a parent or sibling.

It may require complicated analysis to determine exactly who is a distributee of the decedent. Medical providers are not legally required to verify the lines of descent and distribution. However, it is recommended that you obtain a notarized statement from the person requesting the medical record that they are indeed a distributee and that no estate representative has been appointed. Although a signed statement is not required by law, having the requestor affirm the truth of their status under the penalty of perjury provides protection against any claim that the decedent’s information was improperly released. By law, when requesting medical records, the distributee must attach a copy of the certified copy of the death certificate.

There is another category of persons who may obtain a decedent’s medical record under New York law. Public Health Law § 18 permits release of medical records to those who hold a power of attorney from either a distributee or the estate representative. This includes attorneys who represent a distributee or the estate. The power of attorney document must grant access to the medical record. A copy of a certified copy of the certificate of death of the subject must be attached to the written request. Where the written request for patient information is signed by the holder of a power of attorney, a copy of the power of attorney must also be attached to the written request.

Be aware that a decedent may have several surviving distributees. If that is the case, then each person has a separate individual right to obtain medical information regarding the deceased. In other words, each distributee may separately ask for a copy of the medical record, or may sign a power of attorney to obtain copies of the record. These rights exist until and unless the court appoints an estate representative.

### Deceased Individuals: Access to HIV Information

When a deceased patient’s medical record contains HIV-related information, there is no automatic right of access for distributees or attorneys. However, the executor or administrator of an estate shall have access to confidential HIV-related information of a deceased person as needed to fulfill their responsibilities or duties as executor or administrator. Further, the beneficiary or a claimant for benefits under an insurance policy, health service plan, or employee welfare benefit plan may consent to release HIV-related information to the insurer, health service plan, or employee welfare plan of a deceased person whose medical records contain HIV-related information. Neither a subpoena nor a special consent signed by the next of kin or other legal representative is sufficient for release of HIV-related information contained in a medical record of a deceased patient. In those situations, a court order is required for release of the HIV-related information in these records.

### Schools And Release of Student Records

Under the Omnibus Rule, a covered entity is permitted to disclose PHI, without a HIPAA-compliant authorization, to schools about students or prospective students if: (i) the PHI is limited to proof of immunization, (ii) the school is legally required to obtain proof of immunization prior to admitting the individual; and (iii) the covered entity obtains and documents the written or oral agreement from an individual or a minor individual’s parent or guardian, if applicable.

This exception, however, does not exist under current New York state law. Therefore, in New York, a written release must be signed by the parent or guardian of a minor student to release any information, including immunizations, to school authorities. It is also important to remember that it is not permissible to share medical information with a school nurse without obtaining consent from the parent or guardian.

---

4. 45 C.F.R. § 164.512(b)(1)(vi).
5. Public Health Law § 2168 mandates the creation of a statewide immunization registry for New York State providers outside of the five boroughs of New York City for the purposes of collecting and storing mandated information on vaccinations administered to all persons less than 19 years of age. The registry serves as a repository to aid, coordinate, and promote cost-effective disease prevention and control efforts in New York. It is exempt from the HIPAA Privacy Rule because under HIPAA, covered entities are permitted to report information to public health authorities.
New York Court of Appeals: OPMC Consent Orders Can Result in Medicaid Disqualification

Laura L. Spring, Esq., Partner, Sugarman Law Firm, LLP

In a recent decision, the New York Court of Appeals, the highest court in the state, held that the New York State Office of the Medicaid Inspector General (OMIG) may remove a physician from New York’s Medicaid program based solely on a Consent Order between the physician and the Bureau of Professional Medical Conduct (BPMC), so long as the basis for the disqualification is noted in OMIG’s record.

In Koch v. Sheehan, issued on October 22, 2013, the Court of Appeals held that OMIG is “authorized to remove a physician from New York’s medical assistance (Medicaid) program in reliance solely on a consent order between the physician and the Bureau of Professional Medical Conduct (BPMC),” so long as the reason for the disqualification is noted in OMIG’s record.

The fact that the Court of Appeals invalidated OMIG’s determination excluding Dr. Koch from participating in the Medicaid program should serve as no comfort to physicians. The Court’s decision confirms that OMIG is obligated to explain why exclusion was thought to be warranted in a particular case. The Court of Appeals did not, however, indicate how extensive or detailed this explanation must be, and, therefore, it is possible that OMIG can offer nothing more than a perfunctory reason for its determinations.

Moreover, the Court of Appeals stated that OMIG is not bound by agreements between BPMC and physicians settling “in full satisfaction” the charges of professional misconduct brought against the physicians because the two arms of the Department of Health have separate statutory authority and different purposes.

How Should Physicians Proceed When Confronted with a Communication from the Bureau of Professional Medical Conduct?

As Dateline cautioned in its Spring 2010 Issue, the outcome of an OPMC action can have unintended consequences and physicians must proceed with caution when they are the subject of an OPMC investigation. Although there have been a number of cases over the years where physicians successfully challenged an OMIG exclusion that was based solely on a Consent Order, the Court of Appeals’ decision in Koch will make such challenges more difficult and require even greater caution in resolving OPMC investigations.

Physicians must proceed with extreme caution any time they receive a communication from OPMC. If the communication simply requests a copy of a patient’s record, and there is no indication that the physician is the target of an investigation, then there is little to be concerned about. However, if you receive a telephone call requesting an interview, or an unannounced visit from an investigator, you should immediately contact an attorney to guide you through the process. Even if the matter at hand seems straightforward and innocuous to you, you do not know how the investigation will proceed. Do not be lulled into a false sense of security by any statements, action, or inaction during the

1. BPMC is the adjudicatory arm of the Office of Professional Medical Conduct (OPMC).

2. See Catherine Diviney, Esq., The Unintended Consequences of OPMC Actions, MLMIC Dateline, Spring 2010, at 12.


continued on page 12
investigatory process. Always consult your own legal counsel every step of the way.

The Court of Appeals decision makes it clear that physicians are at the mercy of OMIG’s determination if they sign a Consent Order, but OMIG’s own attorney has offered a suggestion on how best to proceed. During the September 9, 2013 oral argument before the Court of Appeals, OMIG’s attorney stated that physicians may ask BPMC to send the proposed Consent Order to OMIG to obtain a preliminary determination of the consequences of signing the Consent Order. There are, however, no guarantees that BPMC will cooperate with such requests or that OMIG will offer a preliminary determination, or even that the preliminary determination is binding, but physicians faced with a Consent Order should consider making the request in hopes of avoiding exclusion from the Medicaid program as the inadvertent result of resolving their OPMC action.

An OPMC investigation is a difficult ordeal for any physician. However, a desire to put the situation behind them should not cause physicians to enter into a Consent Order hastily. In light of the Court of Appeals’ decision in Koch v. Sheehan, physicians must consider the impact signing a Consent Order will have on their participation in the Medicaid program and how that will affect their practice. Physicians should seek the advice and consultation of legal counsel experienced in such proceedings to work through these difficult issues.

Laura L. Spring, a graduate of Pace University School of Law, is a partner at Sugarman Law Firm, LLP in Syracuse, New York and has represented physicians and medical providers in professional liability, discipline defense, and employment-related litigation for over twenty years. The firm defends physicians in medical malpractice claims, as well as providing legal advice and counsel to healthcare providers, including hospitals and nursing homes. Leigh Lieberman, an associate with the firm, and a graduate of Fordham Law School, assisted with this article.

Deleted Emails Result in Penalties for Spoliation of Evidence

Frances A. Ciardullo, Esq.
Fager & Amsler, LLP
Counsel to Medical Liability Mutual Insurance Company

In the Dateline Winter 2013 Special Edition, we alerted readers to the dangers of altering, losing or destroying electronic information which was likely to be used in legal proceedings. Most recently, a New York federal judge issued a written decision discussing the scope of a litigant’s duty to preserve electronic documents and the consequences of a failure to fulfill that duty. In Sekisui American Corporation et al. v. Richard Hart et al., ___F.Supp.2d ----, 2013 WL 4116322, S.D.N.Y., August 15, 2013 (NO. 12 CIV. 3479), a New York Federal Court imposed sanctions upon a medical equipment company for intentionally destroying email messages which were relevant to litigation.

The plaintiff, Sekisui, had purchased a medical diagnostics company from its owners, the Harts, and came to believe that certain warranties contained in the contract of sale had been breached. In 2010, Sekisui served a notice upon the defendant Richard Hart, the former CEO of the purchased company, advising that Sekisui intended to bring a claim for breach of contract. A lawsuit against the Harts was indeed commenced in 2012. However, Sekisui did not place any of its electronic information under litigation hold until fifteen months after the notice of claim was sent. Even more, Sekisui did not notify its IT vendor of the duty to preserve until three months after the complaint was filed. In the meantime, the email messages sent and received by Hart were permanently deleted. The evidence showed that the emails were willfully destroyed as a result of an employee’s direction to permanently delete the messages. No backup tapes were made of the data deleted, and, although some hard copies were printed, the metadata was no longer available. The destruction of the emails was not done with malice, but the court still found that Sekisui was grossly negligent. The failure to implement a timely litigation hold was “inexcusable” given that Sekisui was planning to commence a lawsuit and had full knowledge of the possibility of future litigation.

Under these circumstances, the court determined that an adverse infer-
ence instruction was warranted, advising the jury that 1) relevant evidence was destroyed after the duty to preserve arose; and 2) that the jury was entitled to presume the missing evidence would have been favorable to the defendant Harts. Further, the Court granted the Harts a monetary award for costs and attorney’s fees in bringing the motion.

NYS Regulations Mandate Sepsis Protocols & Reporting

Nancy May-Skinner, Esq.
Fager & Amsler, LLP
Counsel to Medical Liability Mutual Insurance Company

Pursuant to amended regulations, 10 NYCRR §§ 405.2(f)(8) and 405.4(a)(4), (5), (6), (7) and (8), hospitals must adopt “sepsis protocols” for the early recognition and treatment of patients with severe sepsis and septic shock. The protocols must be adopted by the medical staff based upon generally accepted standards of care. The protocols must include components specific to the identification, care, and treatment of adults and children, and must identify when the components will differ for adults and children. The specific components required to be included in the protocols are enumerated in 10 NYCRR § 405.4(a)(4).

Hospitals must submit proposed sepsis protocols to the health department on or before September 3, 2013, and, once approved, must implement the protocols on or before December 31, 2013. The regulations require that the protocols be updated and resubmitted to the health department as requested, but no more often than once every two years, absent hospital-specific concerns by the department. In addition to the adoption and implementation of the protocols, the regulations also require hospit-

als to ensure that staff is trained to implement the protocols, make internal quality improvements, and report relevant data to the health department.


Health Plan Settles with HHS for Data Breach Resulting from Leased Photocopiers

Frances A. Ciardullo, Esq.
Fager & Amsler, LLP
Counsel to Medical Liability Mutual Insurance Company

In the Fall 2010 issue of Dateline, we alerted our readers to an investigation by CBS Evening News which revealed that sensitive data remained embedded in the hard drives of leased photocopy machines which were turned in after the leases expired. In that investigation, CBS purchased used copiers and retrieved thousands of documents, including individual medical records.

As part of its investigation, CBS had purchased a photocopier previously leased by Affinity Health Plan, a not-for-profit managed care plan serving the New York metropolitan area. Affinity was informed by CBS that a copier Affinity had used contained confidential medical information on the hard drive. Affinity filed a breach report with the Department of Health and Human Services (HHS) Office for Civil Rights (OCR), as required by the Health Information Technology for Economic and Clinical Health, or HITECH Act. The HITECH Breach Notification Rule requires HIPAA-covered entities to notify HHS of a breach of unsecured protected health information. Affinity estimated that up to 344,579 individuals may have been affected by this breach.

The OCR commenced an investigation of the data breach. The investigation indicated that Affinity impermissibly disclosed protected health information when it returned multiple photocopiers to leasing agents without erasing the data contained on the copier hard drives. In addition, the investigation revealed that Affinity failed to incorporate the electronic protected health information (ePHI) stored on photocopier hard drives in its analysis of risks and vulnerabilities as required by the Security Rule, and failed to implement policies and procedures when returning the photocopiers to its leasing agents. On August 7, 2013, a settlement agreement was reached with HHS in which Affinity Health Plan agreed to pay $1,215,780 to settle potential violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules. In addition to the $1,215,780 payment, the settlement includes a corrective action plan requiring Affinity to use its best efforts to retrieve all hard drives that were contained on photocopiers previously leased by the plan that remain in the possession of the leasing agent, and to take certain measures to safeguard all ePHI.


The Resolution Agreement and Corrective Action Plan can be found on the OCR website at http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/affinity-agreement.html. •
As many of our insureds may already be aware, MLMIC offers optional “Legal Defense Costs Coverage,” for a nominal, additional premium to those physician and extender policyholders who may qualify for it. Limits of Defense Costs Coverage of either $25,000 or $100,000 are available for an additional premium of $300 or $800, respectively. This coverage is only available by endorsement to our Physicians & Surgeons Professional Liability Insurance Policy form and provides for the costs of defending:

1. an administrative action brought against a physician or extender by a governmental body, such as the Office of Professional Medical Conduct, that involves allegations which could form the basis of a claim of legal liability under the policy; and

2. a governmental proceeding alleging Medicare/Medicaid fraud or abuse related to violation of Medicare or Medicaid guidelines involving allegations that a physician or extender presented an erroneous claim seeking payment for reimbursement.

It is important to be aware that MLMIC will not “participate” in the actual defense of a physician or extender for the coverage afforded under this endorsement; you would be responsible for hiring your own legal representative, but the Company will pay on your behalf covered reasonable expenses for services rendered by the attorney you selected to represent you in your defense.

Current physician and extender insureds, as well as any new such applicants, may apply for this coverage by completing and returning to the Company an “Application For Legal Defense Costs Coverage.” This application can be obtained from the “Download an Application” page of MLMIC.com.

Eligible insureds may check to see if they have already purchased this coverage by referring to the “Defense Coverage Premium” section under the “Who is Insured” section of their “Coverage Confirmation” or “Declarations Page” (for Policy Administrators) that was issued at policy renewal. Indication of a premium charge in this section confirms that this coverage was selected. Of course, it is possible to add this coverage mid-term, in which case an endorsement and invoice would be issued at such time.

If you are still unsure as to whether or not you have secured this coverage and would like to confirm it with the Company, or if you have any other questions, please contact your assigned underwriter at the office located nearest to your practice location.
Tip #14
Managing Drug Seeking Patients

Healthcare professionals share responsibility for minimizing prescription drug abuse and drug diversion. The following tips are intended to provide guidance to healthcare providers when confronted by drug seeking patients. This type of patient can pose significant challenges.

1. Obtain a complete review of the patient’s pertinent history, and conduct a thorough medical evaluation, addressing all objective signs and symptoms of pain.
2. Be cautious of patients who are not interested in having a physical examination, are unwilling to authorize release of prior medical records, or have no interest in a diagnosis or a referral, saying they want the prescription immediately. Be cautious if a new patient has an unusual knowledge of controlled substances, or when a new patient requests a specific controlled drug and is unwilling to try another medication.
3. Document a trial of non-narcotic medication and/or physical therapy before choosing to place the patient on a controlled substance.
4. Document the real source of the patient’s pain in the medical record.
5. Consult the I-STOP Registry. Effective August 27, 2013, New York State physicians must consult the prescription monitoring program registry. The duty to consult arises prior to prescribing any Schedule II, III, and IV controlled substance. Physicians should also access the following Department of Health website, as soon as possible, to establish a Health Commerce System account: https://hcsteamwork1.health.state.ny.us/pub/top.html.
7. Specifically document drug treatment outcomes and the rationale for medication changes.
8. Assess whether further treatment for addiction or pain management is appropriate, and document this discussion with the patient. If necessary, refer the patient for consultation or to a pain management clinic.
10. When writing a prescription for controlled substances, write the quantity and the strength of drugs in both letters and numbers. If only a number is on the prescription, it is easy to alter. Never sign an incomplete prescription.
11. Report patients who are reasonably believed to be a habitual user or abuser of controlled substances to the New York State Bureau of Controlled Substances. This is required by New York State Public Health Law § 3372.
12. Contact the law firm of Fager & Amsler, LLP to discuss how to address the patient who you believe to be selling/diverting narcotics, or may have altered, forged, or stolen prescription pads.

Healthcare law, regulations, and practices are continually evolving. The information presented in Dateline is accurate when published. Before relying upon the content of a Dateline article, you should always verify that it reflects the most up-to-date information available.
The Frailty Index continued from page 3

grasp both her complex care needs and her ever-changing status. They were better prepared to accept the changes in her condition as they occurred. Everyone involved believed that she had received “good medicine” and was correctly served.

In summary, we recommend that hospital nursing staff, physicians, and other providers incorporate the use of a frailty index in their daily practice for those patients who are over age 65, as well as younger, chronically ill patients. Although there is much more to learn about this tool, its use and appropriate communication with concomitant clinical documentation appear to positively affect patient, family, and clinician interactions. The expectations of the patient and their family are much more likely to be reasonable with respect to the need for effectiveness of further treatment and eventual outcomes. It is anticipated that its use will also facilitate and increase the use of MOLST and other orders for limiting treatment at the end of life. When a patient suffers an inevitably adverse outcome and death occurs, the discussions based on the use of the frailty index may also mitigate the potential for litigation by angry families. Finally, regular use of this tool increases the possibility that physicians will more frequently honor patient wishes so that vulnerable frail patients do not undergo unnecessary and sometimes painful and debilitating treatment at the end of life. ❖

Stephen Evans is a fellowship-trained geriatrician practicing in Western New York with IPC of New York. In addition, he serves as Chief Medical Officer for Family Choice of New York Institutional Special Needs Plan.