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Chair's Column: Navigating Stark and AKS: Resources from the ABA

By John H McEniry IV, Fagron North America, Fairhope, AL

As you know, comprehensive proposed updates to the already complex Stark Law and Anti-Kickback Statute regulations were recently released. Health Law Section (“HLS”) Vice Chair Clay Countryman remarked that the morning they were released felt like a birthday party thrown by CMS and OIG where health lawyers got to unwrap each rule, study its impact, and identify new opportunities available for their clients. CMS and OIG undoubtedly provided us with a lot of information to digest! Fortunately, the HLS is ready to fill you in on what you need to know about both sets of proposed rules. Here’s a summary of the gifts we have planned to help our members navigate these developments:

- **Redline versions of the Stark and the AKS/CMP proposed rules** are now available exclusively to you as a free benefit of your Health Law Section membership. Thank you to Clinton Mikel of the Health Law Partners for this resource!
  
  - Redline of the Stark Law
  - Redline of AKS/CMP

- Sign up now for a 2-hour CLE webinar, "Head Start: What You Need To Know Now About the Newly Proposed Stark Regulations," being held Wed, October 30 at 10am – Noon EST. Register now for free and you will also receive a free recording to listen to even if you can't make the live times.

This exclusive Health Law Section webinar will feature CMS speakers:

- Kimberly Brandt, Principal Deputy Administrator for Operations
- Lisa Ohrin Wilson, Senior Technical Advisor
- Matthew Edgar, Health Insurance Specialist

Note if you've already preregistered, you'll receive notice early next week. A separate AKS "Head Start" webinar will be announced shortly.

- The **Health Law Policy Committee** is coordinating with HLS Interest Groups to prepare comments to both proposed rules. If you are interested in participating in the drafting of these comments, please contact HLS Director Simeon Carson (simeon.carson@americanbar.org) and specify which rule, Stark or AKS.

- At the upcoming **Washington Health Law Summit**, which will be held on December 9-10, the HLS will feature a keynote address from CMS Principal Deputy Administrator for Operations Kimberly Brandt regarding the Stark Law. Additionally, there will be a plenary panel, “All Things Stark in 2019,” featuring Lisa Ohrin Wilson from CMS. Register now.

- Substantive articles on both Stark and AKS are being drafted for **The Health Lawyer**.
During last year’s ABA Annual Meeting, the ABA House of Delegates passed the HLS Resolution and Report on Stark Law. In the coming months, the HLS will communicate with Hill staff on further reforming the Stark Law.

I hope you find these resources helpful as you navigate complex issues presented by Stark and AKS. If you have ideas for other ways the HLS should be respond to these or other critical health law regulations, please contact HLS Director Simeon Carson (simeon.carson@americanbar.org).

Further, if you are not a member of an Interest Group or Task Force, please consider joining one. Interest Groups and Task Forces address specific substantive issues and practice areas in health law. In addition to providing timely and relevant information, these groups offer opportunities for participation, interaction and networking amongst HLS members with common interests. As part of your HLS membership, you may join up to three Interest Groups and Task Forces at no additional cost. Please visit Section Interest Groups to learn more about these great benefits to your HLS membership.
Select Federal, State, and Tribal Legal Actions to Reduce Inappropriate -
Opioid Prescribing and Increase Access to Naloxone

By Tina Batra Hershey, JD, MPH, University of Pittsburgh Graduate School of Public Health, Pittsburgh, PA

Introduction

The misuse of prescription and non-prescription opioids is one of the greatest public health threats facing the United States today. Drug overdose is a leading cause of injury-related death, with 70,237 drug overdose deaths in 2017. Of those deaths, 47,600 (67.8 percent) involved opioids, with increased rates across states, age groups, race/ethnicity, and urbanization. According to the U.S. Centers for Disease Control and Prevention (CDC), overdose deaths involving prescription opioids were five times higher in 2017 when compared to 1999.

Under the Controlled Substances Act, opioids are defined as “any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.” Opioids include prescription medications that can be naturally derived from the poppy plant or synthetically produced (e.g., oxycodone, hydrocodone, fentanyl, morphine), as well as illegal drugs (e.g., heroin, illegally produced fentanyl). Many prescription opioids are Schedule II drugs under the Controlled Substance Act as they have a high potential for abuse.

Opioid overdose deaths in the United States demonstrate three distinct waves. The first wave began in the 1990s and can be attributed to the overprescribing of prescription opioids. In 2010, the second wave began, with increased overdose deaths due to heroin. Synthetic opioids, particularly illicitly manufactured fentanyl, characterize the third wave, which began in 2013. From 1999-2017, almost 400,000 people died from an overdose involving any opioid, including prescription and illicit opioids.

Though suburban and rural white Americans have been featured most prominently in news stories, American Indian and Alaskan Natives (AI/AN) have also experienced a steady increase in opioid overdose deaths. AI/AN overdose death rates from prescription and illicit opioids are higher than those for other racial and ethnic groups, which may be due to historical trauma as well as the lack of access to prevention, treatment and other resources. Further, there may be substantial racial mis-classification that affects this data, leading to an under-reporting for AI/AN overdose rates.

Recently released preliminary data indicate that drug overdose deaths may have decreased by approximately five percent in 2018, the first such drop in nearly three decades. While this decrease is modest, it may mark the beginning of the end to one of the worst public health epidemics to face the nation. Legal actions taken at all levels of government may have helped to achieve this potential turning point in the crisis, particularly those that targeted inappropriate prescribing and use of prescription opioids, as the number of deaths caused by prescription opioids decreased the most. In addition, legal actions related to increased access to the overdose-reversing drug naloxone may have contributed to the reduction in opioid overdose
This article provides an overview of select federal, state, and tribal legal actions to reduce inappropriate prescribing of opioids and increase access to naloxone.

Emergency Declaration

One major strategy utilized by various levels of government was framing the opioid crisis as a public health emergency, thereby mobilizing resources and avoiding certain legal obstacles to response efforts. At the federal level, President Trump directed then Acting Health and Human Services Secretary Eric Hargan to declare the opioid crisis a national public health emergency on October 26, 2017. This allowed the federal government to waive certain requirements for Medicaid coverage, provide best prescribing practices and training to providers, and expedite National Institutes of Health research funding for treatment for opioid use disorder and overdoses. The federal public health emergency declaration regarding the opioid crisis has been repeatedly renewed, with the most recent renewal on July 17, 2019.

Eight states also declared emergencies due to the opioid crisis in order to overcome statutory and regulatory barriers and create a coordinated response to reduce the number of overdoses: Alaska, Arizona, Florida, Maryland, Massachusetts, Pennsylvania, South Carolina and Virginia. Massachusetts was the first state to issue such a declaration on March 27, 2014 in response to the significant number of opioid overdose deaths and opioid addiction across the state. Pennsylvania was the last state to issue a declaration thus far, on January 10, 2018. The eight state declarations vary in their terms, but include provisions related to increased distribution of naloxone, mandating prescribing restrictions, improving cross-agency data sharing and coordination, and strengthening access to medication-assisted treatment.

Several tribal nations have also declared an emergency due to the opioid crisis. The Mashpee Wampanoag Tribal Council declared a state of emergency in 2016 after 11 tribal members died from overdoses in just over one year. Other tribes that have declared an emergency include Red Lake Nation, White Earth Nation, and the Bad River Band of Lake Superior Chippewa. These tribal declarations were issued to stem the alarming tide of overdose deaths in tribal communities.

Prescribing Limitations for Opioids

In March 2016, the CDC issued a voluntary guideline (the CDC Guideline) that provides recommendations for primary care clinicians who prescribe opioid pain medication for treating chronic pain (pain lasting longer than three months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care. The three main focus areas in the guideline include: (1) determining when to initiate or continue opioids for chronic pain; (2) opioid selection, dosage, duration, follow-up, and discontinuation; and (3) assessing risk and addressing harms of opioid use. The CDC Guideline was associated with an accelerated decrease in certain opioid prescribing practices, including the overall rate of opioid prescribing, the rate of high-dosage opioid prescriptions, and the percentage of patients with overlapping benzodiazepine and opioid prescriptions. There is concern, however, that some providers have been misapplying the CDC Guideline to the detriment of patients; therefore, the CDC is evaluating the impact of the CDC Guideline on patients and may issue updated recommendations in the future.
States have also issued prescribing restrictions, guidelines, and requirements. Massachusetts was the first state to limit the duration of initial opioid prescriptions in 2016, setting a seven-day supply limit for initial opioid prescriptions. Other states enacted legislation limiting opioid prescriptions in 2016 and 2017; by October 2018, 33 states had passed legislation that includes some form of limitation, guidance, or requirement regarding opioid prescribing. These state laws vary widely in their characteristics, with most limiting initial opioid prescriptions to a certain number of days (usually seven but ranging from three to 21). Most of the states focus on general opioid prescribing limitations and set exceptions for chronic pain treatment, similar to the CDC Guideline. Eight states -- Alaska, Connecticut, Indiana, Louisiana, Massachusetts, Nebraska, Pennsylvania, and West Virginia -- also set limits on any opioid prescriptions for minors.

Another way states are restricting opioid prescriptions is by limiting dosage, as there is evidence that monitoring total daily dosage for patients in addition to monitoring duration of initial therapy may reduce misuse of prescription opioids. These laws establish morphine equivalent daily dose (MEDD) or milligrams morphine equivalent (MME) thresholds. MEDD or MME allows for comparisons across different types of opioid formulations and strengths. The first such policy was implemented in Washington state in 2007; by 2017, 22 states had enacted MEDD policies, with progressively lower MEDD thresholds.

Tribal nations have also implemented opioid prescribing and dispensing restrictions. For example, the Confederated Salish and Kootenai Tribes of the Flathead Nation voted to adopt a controlled substance utilization and dispensing limitation policy to provide guidance to tribal health pharmacy staff, clinicians, nurses, administrators, and recipients regarding quantity limits and acceptable parameters for the utilization of certain controlled substances. The tribal nation adopted the CDC Guideline regarding treatment for acute pain; under the policy, tribal health pharmacists are required to contact prescribing physicians for medical documentation for patients who receive prescriptions over the limits recommended in the CDC Guideline. In addition, the tribal policy outlines expansion of pain management resources, including access to pain specialists and non-pharmacological options.

**Prescription Drug Monitoring Programs**

Prescription drug monitoring programs or PDMPs are electronic databases that track controlled substance prescriptions in a given state in order to capture prescription drug usage by patients to assist prescribers with identifying unsafe use or misuse of prescription opioids without hindering the practice of medicine. While 49 states, the District of Columbia, and Guam have legislation authorizing the creation and operation of a state PDMP and all are now operational, the laws vary tremendously with respect to the drugs monitored, who has access to the data, and which agency administers the program.

In states with mandatory PDMPs, prescribers are required to query the PDMP prior to initially prescribing or dispensing a controlled substance to a patient. Failure to do so can result in disciplinary action by an appropriate state licensing board, generally the medical board or the board of pharmacy. While previous studies found limited or no impact from PDMPs in relation to prescription drug misuse, such studies did not differentiate between voluntary and mandatory PDMPs. A recent study found that laws that mandate that prescribers query PDMPs...
increased PDMP utilization rates; moreover, such PDMPs were significantly associated with a reduction in prescription drug abuse.56

The Indian Health Service (IHS) has also started a drug monitoring program that mandates participation with state PDMPs for both prescribers and dispensers.57 Under this policy, the IHS Area Director ensures that a memorandum of understanding is signed with the state PDMP that establishes the requirements for data disclosure to the PDMP.58 Prescribers must register with the state PDMP and request a report as a normal process for accepting a new patient.59 Prescribers must review PDMP data when opioid prescriptions for acute pain exceed seven days, when progressing from acute to chronic pain therapy, and periodically during opioid therapy for chronic pain.60 Pharmacists must access PDMP data prior to processing an outside prescription for a controlled substance and every three months prior to reissuing or refilling a chronic controlled substances prescription.61

Electronic Prescribing of Controlled Substances

In 2010, the U.S. Drug Enforcement Administration (DEA) issued regulations permitting the electronic prescribing of controlled substances (EPCS) in order to address issues of diversion.62 The DEA believed that EPCS would prevent diversion from stealing prescription pads and writing false prescriptions; altering a legitimate prescription to obtain a higher dosage; and altering a prescription record at the pharmacy to conceal diversion.63

EPCS allows the secure transmission of prescriptions for controlled substances, including opioids, from the point of prescribing to the point of dispensing (i.e., a pharmacy). Under DEA protocols, prescribers are authenticated prior to prescribing the controlled substance, with the e-prescriptions sent via specially equipped electronic health records (EHRs).64 In many states, the EHR can access PDMP data, which may prevent doctor shopping by patients.65 One study found that the overall number of opioid prescriptions decreased significantly in a New York emergency department after New York State implemented its EPCS mandate in 2016.66

EPCS is permitted in all 50 states67 and 26 states now require electronic prescribing for opioids, controlled substances, or all prescriptions.68 The SUPPORT for Patients and Communities Act, signed into law in October 2018, requires the use of electronic prescribing for all controlled substances under Medicare Part D by January 1, 2021.69

In Pennsylvania, EPCS will become mandatory for prescribers on October 24, 2019 for Schedule II-V controlled substances.70 Pennsylvania’s mandatory EPCS law was passed as lawmakers recognized “to combat the current opioid epidemic, health care clinicians need up-to-date tools and technology that support appropriate prescribing of prescription opioids. EPCS has the potential to … reduce prescription forgery, diversion, and theft in Pennsylvania.”71

Access to Naloxone

Naloxone is a prescription medication that quickly reverses an opioid overdose.72 Typically physicians and others authorized to prescribe medications may issue such prescriptions only to patients under their care (i.e., there is a physician-patient relationship); under this traditional model, providers may prescribe naloxone to their individual patients who may be at high risk of
opioid overdoses but not to others who may be in need.\textsuperscript{73} In addition, dispensing of naloxone is limited to pharmacists or physicians.\textsuperscript{74} Naloxone access laws vary across jurisdictions but may allow providers to prescribe naloxone to a patient’s family members and others likely to assist in the event of an overdose (i.e., third party prescriptions).\textsuperscript{75} Prescription via standing order is another method of increasing access to naloxone, where a prescriber (e.g., state or local health officer) issues a prescription for naloxone to be provided to any individual who meets the standing order’s criteria rather than a named person.\textsuperscript{76} All 50 states and the District of Columbia have passed laws that improve access to naloxone by laypersons.\textsuperscript{77} In addition, states have passed laws that provide immunity protections for prescribers, dispensers, and administrators of naloxone to alleviate liability concerns and further improve access to naloxone.\textsuperscript{78}

To facilitate naloxone deployment in tribal communities, IHS and the Bureau of Indian Affairs (BIA) entered into a memorandum of understanding in December 2015 to issue naloxone to BIA law enforcement officers.\textsuperscript{79} IHS pharmacists developed a comprehensive training program for law enforcement officers to effectively administer naloxone in response to suspected opioid overdose.\textsuperscript{80} By December 2017, IHS had trained and provided no-cost naloxone for more than 300 BIA officers and certified 47 BIA officers as naloxone trainers.\textsuperscript{81}

Tribal nations are also taking steps to improve access to naloxone in their communities to reduce the number of opioid-related deaths. For example, the Paiute Indian Tribe of Utah (PITU) has an opioid overdose recognition and naloxone administration policy along with procedures for training on the use of naloxone.\textsuperscript{82} In addition to PITU Health Department staff, any PITU community member who wishes to possess a naloxone rescue kit will be trained to recognize the signs of an opioid overdose and how to administer naloxone.\textsuperscript{83}

Another way jurisdictions are increasing access to naloxone is by passing overdose Good Samaritan laws that provide immunity or liability protections to individuals who report an overdose, as well as individuals experiencing an opioid-related overdose.\textsuperscript{84} Such individuals may fear arrest or criminal prosecution for possession or use of illegal drugs, providing drugs to someone who overdoses, and probation violations.\textsuperscript{85} New Mexico was the first state to pass a 911 Good Samaritan law in 2007; by 2018, 46 states and District of Columbia had passed such laws,\textsuperscript{86} as well as some Indian Tribes.\textsuperscript{87} Similar to naloxone access laws, these 911 Good Samaritan laws vary widely in terms and in the extent that they provide protection for individuals who report overdoses.\textsuperscript{88} Generally, 911 Good Samaritan laws provide immunity from arrest, charge, or prosecution for controlled substance possession, drug paraphernalia offenses, and/or being under the influence for the person requesting aid and the individual experiencing the opioid-related overdose.\textsuperscript{89} More expansive laws also provide immunity for parole or probation conditions and violations of protection from abuse or restraining orders.\textsuperscript{90}

Conclusion

The opioid crisis has had a devastating impact on communities across the United States. Many legal actions implemented by the federal government, as well as state and tribal governments, have targeted prescription opioids (e.g., prescribing restrictions, PDMPs), as well as increased access to, and use of, naloxone to reverse overdoses. The nation may now be seeing results from those legal efforts, as provisional data recently released by the government indicate a slight decrease in overdoses,\textsuperscript{91} particularly from prescription opioids, the first wave of the crisis. The
data are preliminary; moreover, overdose deaths from fentanyl rose in many jurisdictions.\textsuperscript{92} Thus, it is imperative that all jurisdictions continue to utilize legal actions to combat opioid addiction and overdose deaths, perhaps targeted towards heroin and fentanyl, to ensure an end to this public health crisis.

2. Id.
10. See supra n. 8.
11. See supra, n. 1, n. 8. A graph depicting these three waves can be found at https://www.cdc.gov/drugoverdose/epidemic/index.html.
12. See supra, n. 1.
18. Ahmad FB, Escobedo LA, Rossen LM, Spencer MR, Warner M, Sutton P, Provisional drug overdose death counts, National Center for Health Statistics, 2019, retrieved from https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm#dashboard, accessed July 29, 2019. “Provisional data are based on available records that meet certain data quality criteria at the time of analysis and may not include all deaths that occurred during a given time period. Therefore, they should not be considered comparable with final data and are subject to change.”


20. Id.

21. Id.


27. Id.

28. Id.

29. Id.


31. See supra, n. 22.


34. See, e.g., Markus PA and Thomas AL, Prudent Prescribing: An Overview of Recent Federal and State Guidelines for Opioid Prescriptions, ABA eSource, September 27, 2018, retrieved


40. Id.

41. Id.

42. Id.


45. Id.


47. Id.

48. Id.


51. See supra, n. 49.


53. Haffajee RL, Jena AB, Weiner SG, Mandatory use of prescription drug monitoring programs, JAMA, 2015; 313(9):891-892. Forty states mandate prescriber use of PDMPs. Prescriber Mandated Use of Prescription Drug Monitoring Programs (PDMPs/PMPs) –


56. Id.


60. Id.


65. Id.


69. Id.


71. Electronic Prescribing of Controlled Substances FAQ, Pennsylvania Department of Health, August 2019, retrieved...


73. Davis CS and Carr D, Legal changes to increase access to naloxone for opioid overdose reversal in the United States, Drug Alcohol Depend, 2015; 157:112-120.

74. Id.


76. Id.


78. See supra, n. 73.


80. Duvuvier H et al, Indian Health Service pharmacists engaged in opioid safety initiatives and expanding access to naloxone, J Am Pharm Assoc, 2017; 57:S135-S140.


83. Id.


85. Id.


88. See supra, n. 73.
About the Author

Tina Batra Hershey, JD, MPH is an Assistant Professor in the Department of Health Policy and Management at the University of Pittsburgh Graduate School of Public Health and an Adjunct Professor at the University of Pittsburgh School of Law, where she teaches courses on healthcare compliance, health law and ethics, and healthcare fraud. Ms. Hershey is also the Associate Director of Law and Policy at the Center for Public Health Practice at Pitt Public Health. At Carnegie Mellon University’s Heinz College, she is an Adjunct Instructor of Health Law, Compliance, and Ethics.

Ms. Hershey is actively involved in state and national programs involving legal preparedness, as well as efforts to enhance Tribal legal preparedness for public health emergencies. She is a frequent national speaker on legal preparedness issues and has co-authored two public health emergency law manuals and bench books. Her research interests also include law and policy issues related to the delivery and quality of healthcare services, as well as health equity and the social determinants of health.

Before coming to Pitt Public Health, Ms. Hershey was a healthcare attorney in Washington, D.C., and Pittsburgh. Her practice included counseling clients regarding contractual issues and federal and state fraud concerns, including anti-kickback, self-referral, false claims, and false billings issues; negotiating civil settlement and corporate integrity agreements; developing and evaluating corporate compliance programs; and conducting health regulatory due diligence.

Ms. Hershey is a cum laude graduate of Villanova University, where she earned a Bachelor of Arts in Psychology with minors in Biology and History. At The George Washington University, she earned a Juris Doctor (with honors), as well as a Master of Public Health in Health Policy. She is a member of the Pennsylvania and District of Columbia Bars. She may be reached at TBH16@pitt.edu.
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Goodbye, RUGS! Hello, PDPM: Fundamental Changes to SNF Medicare Payment

By Mark A. Johnson, Esq. Hooper Lundy & Bookman, PC, San Diego, CA; Matthew I. Lahana, Esq. Hooper Lundy & Bookman, PC, San Diego, CA; Michael Lesnick, Axiom Healthcare Group, Roseville, CA

Introduction

On October 1, 2019, Medicare payments to Skilled Nursing Facilities (SNFs) began to be reimbursed under a new payment methodology called the Patient Driven Payment Model (PDPM).\(^1\) This is the first truly significant change to SNF Medicare payment methodology in more than 20 years. The last time the Centers for Medicare & Medicaid Services (CMS) changed the reimbursement methodology for SNFs, from a cost-based model to the Prospective Payment System (PPS), nearly 11 percent of all SNF providers went into bankruptcy.\(^2\)

Any transition, especially one of this magnitude, requires providers to prepare for the change by gaining an understanding of how the new system will work, including the technical and mechanical aspects of the new system. More importantly, providers need to understand what has to happen on a day-to-day basis at the “ground level” to avoid the types of serious problems the last major transition caused for this profession. This article aims to point SNFs in the right direction.

The Past and Present: The Prospective Payment System from RUGs to PDPM

In 1998, CMS changed the Medicare reimbursement methodology for SNFs from a cost-based methodology, where SNFs were paid based on what they spent, to the PPS,\(^3\) where payments were based on patient characteristics instead of cost. This change was expected to reduce program costs while maintaining or improving patient care. Under the PPS, providers would complete a series of assessments for each patient, called the Minimum Data Set (MDS), and those assessments were used to determine which category (payment level) each patient was assigned to. The categories were called Resource Utilization Groups (RUGs).\(^4\) Under the RUGs category system there were effectively only two areas of the patients’ clinical needs assessed: therapy and nursing. Further, the overwhelming emphasis was placed on delivering therapy services to patients. Once a patient received enough therapy, even a very modest level of therapy, nothing else mattered. In other words, once the patient received the minimum level of therapy required to be assigned to a “Therapy RUG,” none of the other clinical criteria captured in the MDS data had any significant influence on how much Medicare would pay for that patient’s care.

Under PDPM the profession will see dramatic changes in how patients are assigned to payment categories. Therapy, although still an essential part of care for most patients, is deemphasized, and the more clinically complex needs of patients (nursing, non-therapy ancillary (NTA) services, diagnosis and other complex services) become the primary drivers for payment.

Adding to the discussion, under the old RUGs model there was only one consideration regarding placement in a therapy category: the volume of therapy delivered: how many minutes of therapy...
delivered to each patient. The minutes of therapy were captured in the MDS assessment tool (along with over 100 other elements of care). But only the number of therapy minutes determined how a patient would be classified into a Therapy RUG category. This created an incentive to deliver therapy to patients, and the overwhelming majority of providers focused on the delivery of therapy services.

In fact, in recent years, 90 percent of Part A covered SNF days are paid using a Therapy RUG category, and only a small fraction of payment is influenced by non-therapy conditions (i.e., nursing needs). The PPS’s overutilization of therapy services under the RUGs model has been roundly criticized by many groups, including CMS, the Department of Health and Human Services’ Office of Inspector General and the Medicare Payment Advisory Commission (MedPAC).

In an attempt to address the overemphasis on therapy services, CMS introduced the Resident Classification System, Version 1 (RCS-1) in 2017. The RCS-1 proposed rule called for the use of the same MDS assessment tool as the RUG-IV system with some modifications and additions. RCS-1 attempted to align payments with resource use instead of therapy-related financial incentives. To accomplish this, RCS-1 classified patients into separate groups for each of the four case-mix adjusted components: (1) physical therapy/occupational therapy (PT/OT); (2) speech-language pathology (SLP); (3) NTA services; and (4) nursing. Each of the four categories has its own case-mix indexes and per diem rates, with the per diem rates for PT/OT and NTA services variable based on changes in a patient’s resource use over a stay. The SLP and nursing component per diem rates would be added to the PT/OT and NTA services component variable per diem rates to arrive at the full per diem. Instead of a consistent rate throughout an assessment period, rates are highest at the beginning of a patient’s stay and decrease over time.

While RCS-1 was never implemented, it did not disappear. In May 2018 it was significantly revised and reintroduced as the PDPM.

**The Future: Patient-Driven Payment Model**

PDPM considers a much broader range of clinical characteristics, patient diagnoses and overall medical needs when assigning patients to payment components.

**Clinical Components Under PDPM**

An MDS assessment will be used to identify a classification for each of the five following clinical components:

- **Nursing** - The identification of medically complex conditions that require more nursing services;
- **NTA services**;
- **PT**;
Each of these five components has its own set of categories and payment rates that correspond to those categories. The following shows the number of categories each clinical component will have:

<table>
<thead>
<tr>
<th>Clinical Component</th>
<th># of Categories</th>
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<tbody>
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</tbody>
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PDPM attempts to limit the emphasis on delivering more therapy minutes by reducing the financial incentives to deliver more minutes of therapy present in the RUGs model. PDPM also aims to provide more accurate reimbursements for medically complex patients through its emphasis on a much broader range of characteristics, including the non-therapy medically complex needs that require more nursing services. PDPM removes therapy minutes as the basis for payment, and instead replaces it with mutually exclusive patient groups based on patient characteristics and additional adjustments. Under PDPM, there are now five unique areas of clinical need assessed. The therapy component, previously driven under PPS only by the number of minutes delivered, is separated into three parts under PDPM, each of which is driven by patient clinical characteristics. The clinical characteristics pointing to the needs for specific types of therapy, not minutes delivered, are assessed in deciding how much to pay for therapy services.

**“Non Case-Mix” Components Under PDPM**

In addition to the clinical components, there is one rate component — the “non case-mix” component — which pays providers for the non-clinical resources, or “overhead,” needed to deliver care to patients. These include dietary services, housekeeping, laundry, administration, medical records, rent and facility maintenance.

**Calculating the Per Diem Rate**

The corresponding payment rates for each of the clinical components are summed up and added to the “non-case mix” component to determine the full per diem payment rate for each patient. With five separate case-mix adjusted components that will be combined to arrive at the actual payment rate, there will be far more "categories" (possible combinations) under PDPM than under RUG-IV, where there were 66 categories. Under PDPM there are literally thousands
of possible combinations. However, it is anticipated that any given provider will probably see only a few hundred of the possible combinations.

Further, the initial payment amount will decrease over the length of stay, which is different from the RUGs model. For the therapy components (PT, OT and SLP), the rate for each discipline will be reduced by two percent each week after day 21. For NTA services the amount paid in the first three days of the stay will be increased by 300 percent. This 300 percent increase in the first three days for the NTA component reflects the significant additional costs incurred at the beginning of the stay for patients with medically complex conditions. The reductions in payment over time are expected to have some impact on the average length of stay because they reduce the financial benefit (the payments to providers).

**MDS Assessments Under PDPM**

One of the major changes in the transition from RUGs to PDPM is the reduction in the number and frequency of the MDS assessments. Under RUGs, providers were required to complete a series of MDS assessments at various points in the patient’s stay. For any individual patient there could be five or more separate assessments during the course of the patient’s stay. Under PDPM there is only one assessment required, and it is at the beginning of the stay.

This reduction is not an indication that the MDS assessment becomes less important or less meaningful. The MDS assessment actually becomes more important than ever before. This is because all of the elements of the MDS matter now: They all will contribute to the categories the patients are assigned to, and therefore the amount Medicare will pay the SNF. Under the old system, even though there were a series of MDS assessments, the only component that mattered for the overwhelming majority of patient assessments was the number of therapy minutes delivered, because that ultimately determined the reimbursement rate. Providers will need to place significantly more focus on the MDS assessment under PDPM because the per diem rate is set by an individual patient’s clinical characteristics, and not the minutes of therapy services delivered.

CMS has indicated that it believes providers will save money as a result of the decrease in the number of required MDS assessments, about 183 hours per provider per year, which translates to $12,092.13. That is not necessarily the case. Rather, providers will need to place more focus on the MDS process, and failure to do so can result in potentially costly problems including under/over payments.

**Volume of Therapy Services Under PDPM**

As noted above, since PDPM deemphasizes the focus on the volume of therapy services delivered to patients, the number of therapy minutes will not determine how much a SNF will be paid by Medicare. However, the number of minutes of therapy will still be reported in the MDS, and CMS will still be monitoring the volume of therapy delivered to patients in order to compare the number of therapy minutes delivered under PDPM to the number of therapy minutes previously delivered under RUG-IV.
**PDPM In Practice**

MedPAC acknowledges that the transition to PDPM will require “considerable changes” to the SNF profession, but those changes have the potential to be very positive for SNFs, therapy service providers, Medicare, and most importantly, patients. Specifically, because a patient’s per diem will be higher at the beginning of the stay, and less as time passes, patients should have a shorter length of stay because facilities are incentivized to increase the efficiency of rehabilitation and therapy services.14 Only time will tell whether the belief MedPac expresses will be realized.

Moreover, changing the payment incentives from an almost exclusive focus on the number of therapy minutes delivered to a broad range of clinical characteristics will provide additional incentives for SNFs to develop the capabilities and programs necessary to care for more medically complex patients, which means more options for those patients. The addition of NTA services as a component should also increase reimbursement for patients with medically complex conditions and encourage providers to admit more of those types of patients. The same is likely true for the increased focus on nursing services, i.e., the clinical characteristics that point to the need to more nursing time. All parties are interested in whether these changes to nursing and NTA services will be enough to motivate providers to care for more medically complex patients.

**Conclusion**

Although the shift to PPS 20 years ago resulted in significant unintended consequences, the transition to PDPM has been more methodical. Financially, the transition to PDPM is supposed to be budget-neutral.15 Additionally, CMS intends to continue providing the annual market basket increase (inflating the rates). Whether any individual SNF performs better or worse financially depends on many factors, and success requires preparation and a forward focus on the areas that will help ensure success under PDPM. With proper planning, there is opportunity for all stakeholders to benefit.

2. Laura A. Dummit, United States General Accounting Office, *Nursing Homes: Aggregate Medicare Payments Are Adequate Despite Bankruptcies*, https://www.gao.gov/assets/110/108613.pdf (finding Medicare’s SNF payments under PPS as “sufficient” while analyzing the factors that led to 1,800 of the nation’s 17,000 SNFs to file for bankruptcy protection).
4. RUGs have gone through four iterations, with the most recent revision in 2010, which is referred to as RUG-IV. (See 74 Fed. Reg. 40288 (Aug. 11, 2009), https://www.govinfo.gov/content/pkg/FR-2009-08-11/pdf/E9-18662.pdf).

8. Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Medicare Payment Policy, Chapter 8, page 200 (Mar. 2017), http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf?sfvrsn=0 (MedPAC is a nonpartisan legislative branch agency that provides Congress with analysis and policy advice on the Medicare program.).


10. NTA services primarily consist of laboratory services, radiology, wound care, and drugs, including costly IV services.


About the Authors

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The Supreme Court Limits Agency Deference: Implications of Kisor v. Wilkie

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Introduction

On June 26, 2019, in a splintered 5-4 decision, the United States Supreme Court issued its decision in the case of Kisor v. Wilkie. At issue was the fate of Auer deference (sometimes referred to as Seminole Rock deference), which is the legal doctrine expressing that a court will defer to an agency’s reasonable interpretation of its own genuinely ambiguous regulation. In the end, the doctrine of Auer deference narrowly survived, but the Court significantly constrained its application. This article will examine Kisor’s implications for healthcare providers and suppliers and their legal counsel.

Kisor’s Claim for Disability Benefits

James Kisor is a veteran of the Vietnam War who initially sought disability benefits from the Department of Veterans Affairs (VA) in 1982, alleging that he suffered from post-traumatic stress disorder (PTSD) resulting from a military action in which he participated during the war. The VA’s evaluating psychiatrist acknowledged Mr. Kisor’s participation in the military action, but concluded that Mr. Kisor did not suffer from PTSD. On this basis, the VA denied Mr. Kisor disability benefits. In 2006, Mr. Kisor moved to reopen his claim for disability benefits after a new psychiatric evaluation found that Mr. Kisor in fact suffered from PTSD. The VA granted Mr. Kisor benefits from the date of his motion to reopen, rather than from the date of his first application, as he had requested.

Under a VA regulation codified at 38 C.F.R. § 3.156(c)(1), the VA will reconsider its decision on a claim if it receives “relevant” official service department records that were not considered at the time the claim was initially decided. In other words, the VA will consider an individual’s request for benefits retroactively to the date of the initial claim if he or she produces “relevant” service department records that were not previously considered. Although Mr. Kisor produced additional service records with his request to reopen the claim determination that the VA did not consider at the time of its denial of the initial claim, the VA found that such records were not “relevant” because they did not address the reason for initial denial, such as whether Mr. Kisor suffered from PTSD.

Mr. Kisor initially appealed the VA’s denial of retroactive benefits to an Administrative Law Judge (ALJ), then to the Court of Appeals for Veterans Claims, and finally to the Court of Appeals for the Federal Circuit. The Court of Appeals for the Federal Circuit affirmed the VA’s denial of retroactive benefits based on Auer deference, such that the VA’s interpretation of its ambiguous regulation was entitled to deference. The Supreme Court granted certiorari to decide whether to overrule Auer.
**Auer Deference**

*Auer* deference attempts to address those scenarios in which a regulation is genuinely ambiguous. For example, a regulation may not directly or clearly address every issue that could arise, or a regulation may be susceptible to more than one reasonable reading. In such cases, a court will defer to the agency’s interpretation of its own genuinely ambiguous regulation. The Supreme Court summarized that, “we have often thought that a court should defer to the agency’s construction of its own regulation. For the last 20 or so years, we have referred to that doctrine as *Auer* deference, and applied it often.”

*Auer* deference has roots dating back to the 1945 case of *Bowles v. Seminole Rock & Sand Co.*, where the Court “declared that when ‘the meaning of [a regulation] is in doubt,’ the agency’s interpretation ‘becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation.’” *Auer* deference is “rooted in a presumption about congressional intent – a presumption that Congress would generally want the agency to play the primary role in resolving regulatory ambiguities.”

**Kisor Upholds and Constrains Auer Deference**

A. *Auer* deference upheld

In *Kisor*, the Supreme Court concluded that *Auer* deference should not be overruled. However, in so holding, the Court clarified and reinforced limitations of *Auer* deference. The Court noted, “[W]e presume that Congress intended for courts to defer to agencies when they interpret their own ambiguous rules. But when the reasons for that presumption do not apply, or countervailing reasons outweigh them, courts should not give deference to an agency’s reading, except to the extent it has the ‘power to persuade.’”

B. **Constraints on Auer deference**

The Court acknowledged that it previously had sent “mixed messages” regarding *Auer* deference and a court’s proper application of the doctrine. Therefore, *Kisor* served to outline and “reinforc[e] some of the limits inherent in the *Auer* doctrine.”

1. **Auer deference should be afforded only if a regulation is genuinely ambiguous**

First, a regulation must be genuinely ambiguous before *Auer* deference is afforded. “[B]efore concluding that a rule is genuinely ambiguous, a court must exhaust all the ‘traditional tools’ of construction.” A court should not state that a regulation is ambiguous just because that regulation is challenging to interpret. The Court acknowledged that “[a]gency regulations can sometimes make the eyes glaze over. But hard interpretive conundrums, even relating to complex rules, can often be solved.” Traditional tools of construction that a court must exhaust include analyzing the regulation’s text, structure, history and purpose.
2. **Even if a regulation is genuinely ambiguous, the agency’s interpretation must still be reasonable**

If, after applying the tools of construction identified above, a regulation remains genuinely ambiguous, then the agency’s interpretation must still be reasonable before *Auer* deference is afforded. Applying traditional tools of construction will assist the court to determine the outer bounds of a reasonable interpretation of the regulation.\(^\text{16}\)

3. **Even if a regulation is genuinely ambiguous, and the agency’s interpretation is reasonable, courts must then evaluate whether *Auer* deference is appropriate**

After finding that a regulation is genuinely ambiguous, and the agency’s interpretation is reasonable, a court must next consider whether applying *Auer* deference is appropriate. The Court noted that, “not every reasonable agency reading of a genuinely ambiguous rule should receive *Auer* deference.”\(^\text{17}\) Courts are required also to consider whether the context of the agency interpretation warrants that the interpretation receive controlling weight.\(^\text{18}\) *Auer* deference is appropriate where the following criteria are satisfied:

\begin{itemize}
  \item (a) The agency interpretation is an authoritative interpretation that was made by “the agency”;\(^\text{19}\)
  \item (b) The agency interpretation implicates its substantive expertise;\(^\text{20}\) and
  \item (c) The agency interpretation reflects its fair and considered judgment. To meet this criterion, the agency interpretation may not be based on a “convenient litigating position,” or constitute a “\textit{post hoc} rationalizatio[n] advanced” to “defend past agency action against attack,” or create an “unfair surprise” to regulated parties.\(^\text{21}\)
\end{itemize}

C. **Mr. Kisor failed to establish that *Auer* ought to be overturned**

In order to establish that *Auer* ought to be overturned, the appellant, Mr. Kisor, was required to first establish that *Auer* deference was incorrect, and then also overcome *stare decisis.*\(^\text{22}\) The Court found that Mr. Kisor failed to meet this burden.

1. **Mr. Kisor failed to establish that *Auer* deference is incorrect**

In arguing that *Auer* deference was incorrect, Mr. Kisor raised statutory, policy and constitutional claims:

\begin{itemize}
  \item Statutory claims
\end{itemize}

Mr. Kisor argued that *Auer* deference is inconsistent with the Administrative Procedures Act (APA), which requires reviewing courts to “determine the meaning or applicability of the terms of an agency action.”\(^\text{23}\) Mr. Kisor argued that when a court applied *Auer* deference, it abdicated its responsibility to determine the meaning of a regulation.\(^\text{24}\) The Court disagreed, stating that, as clarified and restrained, in applying *Auer* deference courts exercise independent review over the meaning of agency rules in many ways: by applying traditional methods of construction to
determine whether a regulation is genuinely ambiguous and the agency’s interpretation reasonable; and by considering whether an agency’s interpretation is authoritative; implicates the agency’s substantive expertise; and reflects the fair and considered judgment of the agency.\(^{25}\) The court also found that the APA did not mandate a standard of review that a court should use to determine the meaning of an ambiguous rule, and that it could meet the statutory requirement by reviewing an agency’s interpretation for reasonableness.\(^{26}\)

Mr. Kisor also argued that *Auer* deference circumvents the APA’s rulemaking requirements. Section 553 of the APA requires that an agency use notice and comment procedures before issuing legislative rules, which are rules that create policy.\(^{27}\) However, the APA allows an agency to develop “interpretive rules” without undergoing notice and comment.\(^{28}\) Mr. Kisor argued that when a court gives *Auer* deference to an interpretive rule, such a rule in effect becomes binding on the public. The Court again disagreed, stating that “an interpretive rule itself never forms ‘the basis for an enforcement action’ – because … such a rule does not impose any ‘legally binding requirements’ on private parties. An enforcement action must instead rely on a legislative rule, which (to be valid) must go through notice and comment. And … the meaning of a legislative rule remains in the hands of courts, even when they sometimes divine that meaning by looking to the agency’s interpretation.”\(^{29}\)

b. Policy claims

Mr. Kisor next argued that *Auer* deference creates incentives for agencies to issue vague regulations so that they may later impose a preferred interpretation of the regulations. The Court dismissed this argument. The Court noted that such an argument was repeatedly raised by critics of *Auer* deference; however, there was a dearth of evidence that this concern had ever actually come to fruition. The Court further noted the competing incentive for agencies to develop regulations to have sufficient clarity to ensure compliance.\(^{30}\)

c. Constitutional claims

Finally, Mr. Kisor argued that *Auer* deference violates “separation of powers” principles by vesting in a single branch the law-making and law-interpreting functions. The Court dismissed this argument as well, stating that “even when agency ‘activities take legislative and judicial forms’ they continue to be ‘exercises of executive power.’”\(^{31}\)

2. Mr. Kisor failed to overcome stare decisis

The Court noted that the doctrine of *stare decisis*, (*i.e.*, the special care taken to preserve precedent) “cuts strongly against Kisor’s position.”\(^{32}\) The Court noted that Mr. Kisor was asking not only for *Auer* to be overturned, but in effect, a long line of precedential cases. Therefore, overturning *Auer* would create uncertainty surrounding “many settled constructions of rules.”\(^{33}\) Finally, the Court stated that, even if it were wrong about *Auer*, Congress had the authority to alter the decision of the Court through the legislative process.\(^{34}\)

In summary, the Court concluded that *Auer* deference ought not to be overruled. However, in so holding, the Court clarified and reinforced the limitations of *Auer* deference. Ultimately, the
Court remanded *Kisor* to the Court of Appeals for the Federal Circuit to analyze Mr. Kisor’s appeal in the context of the limitations reinforced in its decision.35

**Implications of Kisor in Healthcare**

The healthcare industry is replete with sub-regulatory guidance that serves to interpret an agency’s regulations. Such guidance documents include, but are not limited to, Office of Inspector General (OIG) Fraud Alerts, Advisory Opinions and Special Bulletins; Centers for Medicare & Medicaid Services (CMS) Manuals and coverage articles; National Coverage Determinations (NCDs); and Local Coverage Determinations (LCDs). In evaluating whether such documents are entitled to *Auer* deference, attorneys representing healthcare providers and suppliers are well advised to consider the following:

· Does the agency interpretation constitute a legislative (i.e., substantive) rule, which would be required to undergo notice and comment rulemaking prior to serving as the basis of an enforcement action, or does the agency’s interpretation merely serve as an interpretive rule? Note that in the Medicare context, the Medicare Act has adopted notice and comment provisions applicable to Medicare policy that differ from the requirements set forth in the APA.36

· Is the agency interpretation an authoritative statement of official agency policy? *Kisor* provides the following illustrations as examples as to courts’ analyses:

  - Official staff memoranda published in the Federal Register, but which were not approved by an agency’s head were afforded *Auer* deference;37
  - A speech offered by a “mid-level official” was not afforded *Auer* deference;38
  - An informal memorandum memorializing a telephone conversation between employees did not constitute an “authoritative pronouncement” entitled to *Auer* deference;39 and
  - Where an agency “disclaimed the use of regulatory guides as authoritative,” a court may not defer.40

With respect to the final example, note that in December 2018, the Justice Manual of the United States Department of Justice was revised to state that, “Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation.”41

In the context of Medicare reimbursement, federal regulations codified at 42 C.F.R. §§ 405.1060 and 1062 state that (1) NCDs are binding on fiscal intermediaries, carriers, quality improvement organizations (QIOs), qualified independent contractors (QICs), ALJs and attorney adjudicators, as well as the Medicare Appeals Council (the Council);42 and (2) LCDs, program memoranda and manual instructions are not binding on ALJs, attorney adjudicators and the Council, but ALJs, attorney adjudicators and the Council must give substantial deference to such policies. A question arises as to what, if any, deference would be afforded to a Local Coverage Article (LCA).43
Does the agency interpretation reflect the fair and considered judgment of the agency? For example, is the “interpretation” raised as a convenient litigating position? Did the agency provide proper notice of its interpretation so as to avoid an “unfair surprise”? Does the agency’s interpretation reflect a different policy from that previously espoused by the agency?

**Conclusion**

Although *Auer* deference survives following *Kisor*, *Kisor* constrained its application (to such an extent that the dissent describes the doctrine as a “paper tiger.”) Limitations to *Auer* deference imposed by the Court provide an opportunity for counsel representing healthcare providers and suppliers subject to an agency interpretation adverse to their clients’ interests to challenge that agency’s interpretation. Challenges may include whether an underlying regulation is genuinely ambiguous; whether the agency’s interpretation is reasonable; whether the agency’s interpretation is an authoritative statement of agency policy; whether the interpretation implicates the agency’s substantive expertise; and whether the interpretation reflects the agency’s fair and considered judgment. In addition, arguments may exist that an agency’s interpretation of a regulation constitutes a “substantive” policy that would require notice and comment rulemaking before it could serve as the basis for an enforcement action.

1. *Kisor v. Wilkie*, 139 S.Ct. 2400 (2019). Justice Kagan delivered the opinion of the Court joined by Justices Ginsburg, Breyer, and Sotomayor. Chief Justice Roberts concurred in the judgment, based on his agreement that overturning multiple precedent cases was not warranted. Justice Gorsuch, joined by Justice Thomas, delivered the dissent and was joined in part by Justices Kavanaugh and Alito.
5. *Id.* The records Mr. Kisor produced included two service records confirming his participation in the military action, which Mr. Kisor alleged was the basis for his PTSD diagnosis.
6. *Id.*
8. *Id.* at 2411.
9. *Id.* at 2411, *citing Seminole Rock*, 325 U.S. at 414. The dissent dismisses the importance of the language included in *Seminole Rock*, dismissing *Seminole Rock’s* statements surrounding deference to agency interpretations as “dicta.” *Kisor*, 39 S.Ct. at 2428.

The majority opinion states also that agency deference has roots dating back much further than *Seminole Rock*: “*Seminole Rock* itself was not built on sand. Deference to administrative agencies traces back to the late nineteenth century, and perhaps beyond.” *Id.* at 2411, *citing United States v. Eaton*, 169 U.S. 331 (1898). The dissent disputes that *Eaton* placed significant weight on an agency’s interpretation, stating “As it had in *Eaton*, the Court … began with an extended discussion of ‘the plain words of the
regulation,’ which led it to conclude that the text ‘clearly’ supported the government’s position. Only after reaching that conclusion based on its own independent analysis did the Court proceed to add that ‘[a]ny doubts … are removed by reference to the administrative construction.”  \textit{Id.} at 2428, \textit{citing Eaton} at 414-417.

10. \textit{Id.} at 2412. In support of its presumption, the Court acknowledged that resolving regulatory ambiguities entails the exercise of judgment grounded in policy considerations. The Court stated that agencies have a comparative advantage over courts in making policy judgments due to their “unique expertise” often of a scientific or technical nature. Further, the Court stated that its presumption reflected the benefits of uniformity in interpreting genuinely ambiguous regulations (rather than being established through piecemeal decisions issued through litigation). Specifically, the Court stated that “\textit{Auer} deference thus serves to ensure consistency in federal regulatory law, for everyone who needs to know what it requires.” \textit{Id.} at 2413.

11. \textit{Id.} at 2414 (internal citations omitted).

12. \textit{Id.} at 2415.


14. \textit{Id.}

15. \textit{Id.}

16. \textit{Id.} at 2416.

17. \textit{Id.}

18. \textit{Id.}

19. \textit{Id.} This analysis is fact-dependent. By way of example, the Court noted that it considered official staff memoranda published in the Federal Register to set forth the interpretation of an agency, even when the memoranda were not approved by an agency’s head. However, the Court declined to deem statements made during a speech of a mid-level official to constitute the agency’s position on a matter. \textit{Id.}

20. \textit{Id.} at 2417.

21. \textit{Id.} at 2417-2418 (internal citations omitted).

22. \textit{Id.} at 2418.

\textit{Stare decisis} is defined as follows:

(A) Latin term for let the decision stand which refers to precedent. It is a doctrine that requires that judges abide by the prior decisions on the same issues (usually only referring to courts in the same jurisdiction and of equal or higher level.)

(B) To abide or adhere to decided cases. 2. It is a general maxim that when a point has been settled by decision, it forms a precedent which is not afterwards to be departed from. The doctrine of \textit{stare decisis} is not always to be relied upon, for the courts find it necessary to overrule cases which have been hastily decided, or contrary to principle. Many hundreds of such overruled cases may be found in the American and English books of reports. Mr. Greenleaf has made a collection of such cases, to which the reader is referred.

\textit{Black’s Law Dictionary, 2nd Ed., available at} \url{https://dictionary.thelaw.com/stare-decisis/}.


24. \textit{Id.}
25. Id.
26. Id.
27. Id. at 2420, citing 5 U.S.C. §§ 553 (b) and (c).
30. Id. at 2421.
31. Id. (internal citations omitted).
32. Id. at 2422.
33. Id.
34. Id.
35. Id. at 2423.
36. See e.g., Azar v. Allina Health Services, 139 S.Ct. 1804 (2019). Allina Health Services involved a hospital’s suit against the Secretary of the Department of Human services (HHS), alleging that HHS violated the Medicare Act by not engaging in notice and comment rulemaking before changing the Medicare formula for calculating disproportionate share hospital (DSH) payments. The change resulted in a reduction in the hospital’s payments for treating low-income Medicare patients.

The APA does not apply to public benefit programs, like Medicare. However, the Medicare Act includes notice and comment requirements applicable to Medicare policies. The Medicare-specific statute requires the government to provide a notice and comment period for any “rule, requirement, or other statement of policy (other than a national coverage determination), that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities or organizations to furnish or receive services or benefits under [Medicare].” See Allina Health Services at 1809, citing 42 U.S.C. § 1395hh(a) (emphasis added). The issue before the Court was whether HHS’ change in the formula to calculate hospitals’ DSH payments constituted a change in “substantive legal standard.” The Court expressly declined to clarify the distinction between interpretive and substantive rules (“Other questions about the statute’s meaning can await other cases”). Id. at 1814. The Court narrowly held that the phrase “substantive legal standard” could not bear the same construction as the term “substantive rule” in the APA, as the government had argued. The Court did not opine as to whether the appellant’s arguments were correct in every way. The Court found that the “government’s arguments for reversal fail[ed],” and notice and comment was required. Id.
37. See Kisor, 139 S.Ct. at 2416, citing Ford Motor Credit, 444 U.S. at 566-567, n. 9 and n. 10.
38. Id., citing Paralyzed Veterans, 117 F.3d 579 at 587 (D.C. Cir. 1997).
42. For a description of the various auditing bodies and adjudicators, see “HHS Seeks to Improve the Medicare Appeals Process,” by Jessica L. Gustafson, Esq. and Abby Pendleton, Esq., The Health Lawyer, Vol. 29, No. 5, June 2017; see also “What Are

43. Pursuant to Section 1862 of the Social Security Act, Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category).

NCDs are made through an evidence-based process, with opportunities for public participation.

In the absence of an NCD, an item or service may be covered at the discretion of Medicare contractors based on an LCD. LCDs are also made through an evidence-based process, with opportunities for public participation. In fact, LCDs undergo a comment period prior to finalization. See Medicare Program Integrity Manual (CMS Internet-Only Manual 100-08), Chapter 13.

Conversely, LCAs and other contractor articles are defined to include “any bulletin article, website article, educational handout or any other non-LCD document intended for public release that contains coverage/coding statements or medical review related to billing or claims considerations.” See e.g., https://med.noridianmedicare.com/web/jea/policies/coverage-articles. Unlike NCDs and LCDs, there is not opportunity to public participation prior to finalization of such policies.

44. Kisor, 139 S.Ct. at 2426.

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Frameworks for Evaluating Life Care Plans


Introduction

A life care plan, a growing factor in litigation, is an overall service or care plan that provides for goods and services to achieve best outcomes over the life expectancy of a person with a disability resulting from catastrophic injury.

A person for whom life care planning is appropriate has a severe or persistent physical, sensory, or cognitive limitation which limits functional capacities relative to primary aspects of daily living, such as employment, education, personal relations, living arrangements, and recreation, and requires the specialized resources of multiple agencies to maintain community-based or institutional residence. Damages are not limited to physician, hospital, or surgery costs, but also medications, therapies, assistive technology, architectural modifications, supplies and equipment repair and replacement, transportation, supportive care across the continuum of aging, and anything else necessary to promote the health, safety, and well-being for the injured person. The elements of quality and dependability are as important as necessity.

Plaintiff counsels use expert life care planners to research, evaluate, and quantify damages; when preparing for trial, they need to know whether their expert reports will stand up to challenge. Defense counsels use expert life care planners to critique and rebut plaintiff plans; they need to know the grounds on which a plan would be vulnerable. This means that all planners must know what constitutes supportable methodology for plan development, including estimating future costs, to withstand challenges in litigation. This article will describe the required elements of a defensible life care plan.

The Current legal Context for Expert Testimony

The litigation process is intended to lead to the positive resolution of social inequities. In civil tort actions, most often the only “remedy” available is monetary compensation. This increases the importance of an accurate, thorough, and correctly valued life care plan of an injured party submitted to the court as expert testimony to achieve social and economic equity.

The foundation for admission of expert testimony in some states is based on standards set forth in Frye v. United States. These standards generally allowed experts, including rehabilitation, planning, nursing, medicine, economics or vocational experts, to give relevant testimony as long as they had the appropriate qualifications, i.e., “training,” “background,” and “experience.” Jurors, having no information about how an expert drew conclusions, were often left to rely on an expert’s apparent personal credibility or appeal and the expert’s own statements in response to brief qualifying questions from the attorney, which might not have touched on actual relevant experience.
The precedent-setting *Daubert v. Merrell Dow* and *Kumho Tire Co. v. Carmichael* cases at the federal level changed that.

Daubert formally replaced Frye’s “general acceptance” standard with an all-encompassing requirement for scientific validity, thus:

Methods that underlie the expert’s evidence are now examined. If conclusions presented by experts are speculative, based on untested assumptions, subjective belief, or assertions, that testimony is less likely to be admitted.⁵

*Kumho* extended the *Daubert* standard to expert testimony that was not scientific in nature. Justice Breyer, clarifying the *Daubert* gatekeeping function in *Kumho*, said, “Rule 702 [of the Federal Rules of Evidence, pertaining to testimony of expert witnesses] does not distinguish between ‘scientific’ knowledge and ‘technical’ and ‘other specialized’ knowledge, but makes it clear that any such knowledge might be the subject of expert testimony. It is the Rule’s word ‘knowledge’ not the words (like scientific) that modify that word, that establishes a standard of evidentiary reliability.”⁶ Therefore, standards of evidentiary reliability are now equally applied to “scientific knowledge” and “technical and specialized knowledge.” The basis of an expert’s opinion is admissible if:

1. The means employed can and have been tested.

2. Established standards exist that control its use, i.e., error rates are known.

3. It has been subject to peer review and publication, to aid in determining flaws in the methods employed.

This is generally accepted in the technical community. Some states still use *Frye* for expert testimony standards; however, they generally have moved to include requirements for testimony regarding supportive scientific methodology, sometimes colloquially characterized as “Frye-Plus.”

**Excluding Testimony on Methodological Grounds**

The “good grounds” criterion placed a greater emphasis on examinations of an expert’s experience as an acceptable surrogate for scientific proof of reliability. Previously, courts accepted testimony of rehabilitation and other non-physician experts who outlined future services needed, costs, and frequency. Since *Daubert* and *Kumho*, however, the courts rule on whether a testifying expert possesses the experience and underlying licensure necessary to prescribe both medical and non-medical services from backgrounds of medicine, vocational rehabilitation, nursing, and counseling.

Assertions of expertise can be ruled inadmissible when courts conclude that nothing in the non-medical expert’s background would qualify the expert to recommend, for example, specific surgical or medical procedures. This ruling first occurred in *Laura Palmer vs. Ford Motor Company*.⁷ A vocational expert provided opinions on future medical services and care based solely on his (faulty) interpretation of the medical records. The court ruled that he was...
unqualified to offer such opinions, writing that the testimony was insufficient, and that a rehabilitation counselor was not qualified to opine on prognosis or prescribe treatment. Further, the court noted that the recommendations were not supported by available medical and other records. This is important because each individual line item in a life care plan is subject to this scrutiny; any that is found to lack foundation as defined by Rule 702 will be excluded, and the funds provided for any excluded item(s) will be subtracted from the requested damages.

In another case, *Kelly Darbonne Cormier vs. T.H.E. Insurance Company*, significant aspects of future damages were excluded because the court concluded that expert testimony was based on “conjecture and speculation and not supported by the evidence:”

To avoid issues on appeal, a physician’s opinion must be present and held to a “reasonable degree of medical certainty,” that the plaintiff will, more likely than not, need the future medical care in a life care plan, and that further, the cost of every item in the life care plan can be substantiated and is reasonable.

Experts risk having testimony excluded on failure to achieve “good grounds” if they fail to base their conclusions on scientific methods and procedures, rather than on subjective belief, assertion, or unsupported speculation. In cases involving scientific testimony, the expert must substantiate scientific validity.

In *Patti Kinnaman vs. Ford Motor Company*, the plaintiff retained a vocational expert to provide answers to two questions: (1) was the plaintiff substantially limited in the major life activities of working because of tenosynovitis in both wrists and subsequent residual limitations; and (2) were there jobs the plaintiff could have performed if the defendant provided the plaintiff with modified work conditions or equipment? The expert, in part, relied on results obtained from a national computer database, and stated that such reliance was an acceptable method in the field, but admitted no awareness of any literature that supported her methodology. In determining that her testimony was inadmissible, the court concluded that the plaintiff did not meet the burden in establishing the reliability of opinions offered by her expert. The methodology used by the expert was subject to question in four respects: (1) no evidence was offered that the labor market analysis offered had been tested; (2) no evidence was offered that the theory or technique by the expert had been subject to peer review; (3) nothing in the record showed the known or knowable rate of error; and (4) no independent evidence was offered by the expert to substantiate the testimony, although the expert was judged capable to provide this evidence. The expert could not explain the characteristics of the database on which she had relied.

In *Carmelita Elcock vs. Kmart Corporation*, the plaintiff’s vocational expert relied upon a well-known database developed by Vocational Economics, Inc.; the plaintiff’s economist then relied upon that opinion to project an estimate of future lost earnings. The court ruled that despite sufficient evidence of damages, the economic loss portion of the award should be stricken and a new trial granted due to deficiencies in the methods and analytical processes used by both experts. The court opined that combining two widely used and acceptable methods for estimating and establishing vocational disability was subjective, arbitrary, idiosyncratic, illogical, and unreplicable, and, therefore, unreliable. The expert’s testimony also failed a *Daubert* challenge because the methods used conformed to no known standards of vocational
assessment, could not be proven to be used by other experts, and was not referenced in vocational rehabilitation literature.

Further, the Court excluded the forensic economist’s opinion. He presented the plaintiff as 100 percent disabled despite the vocational expert’s report noting only partial disability. The economist inflated the plaintiff’s annual earnings despite evidence to the contrary, another reason to exclude due to inadequate foundation. The court viewed this testimony as empirical assumptions unsupported by the record, depending upon fictional or random data.

The Court also reviewed Rule 703, which excludes testimony when experts unreasonably rely upon speculative data or data not introduced into evidence. The Court additionally referenced Article IV of the Rules of Evidence, Rule 402, in which testimony is admitted if it is “relevant evidence” defined in Rule 401 as “evidence having any tendency” to make “more probable or less probable” the existence “of any fact that is of consequence to the determination of the action.” Under Rule 402, testimony on method reliability “can be deemed relevant only insofar as a jury can usefully apply that methodology to the specific facts of a particular plaintiff’s case.”

Finally, the Court referenced Rule 403, concluding that, since an expert’s imprimatur carries great weight with a lay jury, permitting witnesses to offer opinions unsupported by sufficient factual foundation increases the risk of misleading the jury and confusing the issues.12

Admissibility, Summarized

Damages experts must demonstrate knowledge and understanding of:

- The purpose of long-term planning outside of litigation;
- The client-based and service systems outcomes associated with long-term planning models used outside of litigation for the last 45 years;
- Appropriate methods for investigating and collecting information;
- The critical significance of interdisciplinary collaboration; and
- Attributes of documented and well-researched plan.

Reviewing a Life Care Plan

Professional Standards

Many professional organizations have published methods and frameworks for disability appraisal to meet the demands for standards and court requirements for methodological rigor, including the Case Management Society of America;13 International Association of Life Care Planners;14 American Rehabilitation Economics Association;15 American Association of Legal Nurse Consultants;16 the International Commission on Health Care Certification;17 American Nursing Association;18 and the American Association of Nurse Life Care Planners.19 Private sector entities also have standards frameworks to help their members develop and document professional competence, such as the National Association of Social Work, Standards for Case Management 2000.20 Anyone reviewing a plan will find the relevant standards essential.
**Review Criteria**

Evaluating a life care plan means analyzing its methodological underpinnings. It does not seek to affirm conclusions drawn, but examines the plan’s methods and processes for accuracy and adequacy. Both plaintiff and defense should use this general framework to evaluate plan content:

- Knowledge of and applying professional standards;
- Knowledge of the literature and appropriate theories, standards, and techniques;
- Accepted analytical methods and use of multiple analyses; distinguishing between generally recognized and rarely-accepted methods and procedures; using multiple analytic methods to develop mutually supportive evidence from which to derive conclusions; and identify eccentric facts;
- Reconciling differences; considering conclusions from multiple methods and reconciling alternatives;
- Disclosing and testing analytic assumptions, variables, and conclusions; disclosing analytic assumptions and variables; identifying, justifying, and quantifying the most important ones; testing for reasonableness; and
- Peer review to identify errors in logic, methods, and assumptions.21

Life care planning experts must now show that they understand basic principles and the foundation for long-term planning to obtain access to services and outcomes. Courts can only evaluate testimony by comparing it to standard frameworks and adherence to scientific merit. Therefore, professional organization standards and quality assurance guidelines provide testifying experts with self-evaluation criteria:

- An agreed-upon framework explaining the essential constituents of long-term planning;
- Methods of specifying outcomes; and
- Evidence indicating adherence to scientific methods of inquiry during plan development.22

**Reviewing Life Care Planning Decisions**

Conclusions and recommendations in a long-term plan spring from the planner’s decisions about how to collect, interpret, and write about a disabled person’s medical, educational, vocational and technological wants and needs.

An opposing planner, either plaintiff or defense, cannot reconstruct exactly how another acted to develop a plan and its conclusions, but is able to infer the planner’s reasoning based on evidence in the plan itself. If this “evidence” includes untested assumptions, conjecture, suppositions, or assertions so vague that a court cannot determine the planner’s reasoning, a report risks exclusion.23

Opposing experts can expect to be asked to form opinions on an expert’s methods regarding the science, or lack of it, in the report, by answering the following:

1. What are the planner’s assumptions about the injured person?
2. How did the planner attempt to refute or confirm any assumptions?

3. Were the planner’s opinions about needs valid? If not, why not?

4. Did the planner rely on subjective or unreliable data collection and planning methods? If not, what was omitted?

5. Was the planner’s work comprehensive? If not, what were the consequences?

6. Did the planner use good methods and processes as a reasonable foundation for opinions?

7. Did the planner accurately represent the person’s needs?

8. Did planning deficiencies undercut the planner’s ability to form valid and reliable conclusions about the needs of the person for whom the plan was designed?

9. Are calculations accurate? If not, what is the cumulative effect of an inaccurate calculation over life expectancy?24

**Target Populations**

Disability is not one-dimensional. Plans must reflect that individuals with disabilities have unique functional levels of independence or adjustment on a continuum ranging from chronic need for assistance or supervision to considerable evidence of and potential for self-help and community independence. Functional areas can be affected by disability, i.e., speech, hearing, mobility, cognition, and vision; the extent to which individuals can advocate on their own behalf may vary. Environmental and agency service opportunities are not universally available. Highly specialized services, such as assistive technology or architectural modifications for access, can promote independence by producing speech, facilitating mobility, enhancing hearing, or compensating for low or no vision. A court can exclude a life care plan for failing to individualize to the person’s unique needs; this is most often done when the planner’s methodology is shown not to be based on an individual assessment, as in Elcock, above.

**Chronic Disability and Lifetime Supports**

A proper life care plan evaluation must determine how well a planner has accounted for barriers and constraints. Someone with severe or enduring disabilities needs an organized system of supportive resources to support continued independence and residence in the community. Therefore, the life care planner must comprehensively identify and examine all life needs. Sometimes the planner’s specialty or personal preferences do not predispose to comprehensive assessment. A resulting plan can miss recognizing needs during the life care planning process—and they remain unrecognized. Needs cannot be fully met with plans developed on an insufficient knowledge base.

The service structure of most service agencies can compound an end-user’s problems. When only narrow planning is offered by a community agency, "add-ons" to direct services are typically time-limited, highly focused, and organized around a specific area of expertise. This
presents a particular constraint to someone with significant and multiple disabilities who needs a wide range of rehabilitation and medical services. The average person is likely largely unfamiliar with these. Often, individuals with disabilities and family members must cross boundaries, service requirements, time frames, and policies of many types of agencies, dealing with many providers.

It is not unusual for a person with significant disability to require five to six separate types of medical evaluations and monitoring; two to three types of specialty therapies or intervention; assistance in entering and exiting a residence or provider office; architectural modifications for safe home, transportation, and employment access; a daily medication regimen; daily needs for catheterization by another person; administration of a daily bowel program by still another; and assistance to dress, eat, bathe, and transfer -- the most basic and personal activities of daily living.

The prescient planner must know when shortcomings in resource availability are likely to occur and build in safeguards to ensure that service delivery focuses on the individual’s needs. Consider common characteristics of most persons with chronic disability. They:

1. Have had or will have sustained contact with medical and rehabilitative care.


3. Have diminished capacity to work in regular employment and/or will require adaptations to return to employment.

4. Have difficulty completing activities of daily living.

5. Rarely seek out and enjoy leisure time activities due to the restrictiveness with which these activities are organized.

6. Have relations with others that may be strained by what others perceive as extreme dependency.


9. Frequently lack skills and abilities needed to seek help and will require long-term guidance to advocate for their own needs (e.g., from the National Institute of Mental Health; Office of Health and Human Services; Department of Education; Division of Aging; National Council on Developmental Disabilities).

10. Cannot capably identify all of the resources they need or when they will need them. They also lack the knowledge to identify the potential risks, dangers or negative outcomes of resources used in the past or recommended for them.
11. Lack information about what services they need as a function of their disability, where to locate and secure needed medical, surgical, technological, and clinical services and resources.

12. Will frequently terminate services prematurely or have interactions that result in conflict with providers due to lack of information on purpose, use and outcome of needed services.

13. Lack the ability to knowledgeably direct their own care when performed by another.

Much outcome research completed between 1975 and 2000 demonstrated gains in access to service, increased tenure in community-based settings, reductions in emergency hospitalizations, and gains in quality of life when a person’s needs were met using strategies consistently linking them to services they need. These classic findings have held true with the passage of time.

The life care plan should be able to assist the individual to:

1. Locate sources for additional services;

2. Identify when additional services are needed;

3. Secure resources as they are required;

4. Retain resources for as long as is beneficial.

Finally, without strategies for implementation, a plan has no integrity and will fail after litigation has concluded. Without attention to barriers, a plan can have little true reliability, validity, relevance and consistency. This failure will reveal a key deficit in how an expert planner identifies, individualizes, and interprets information about the person.

Plans should reflect the real-life conditions that will exist long after litigation is over. Realistic life care planning requires identifiable processes that will connect individuals and family members to the full spectrum of services needed.

**Fails in Life Care Plans**

Planners often find themselves between the Scylla of externally imposed time constraints and the Charybdis of requirements for extensive plan development. The following inevitably occur:

1. Planning processes are often arbitrary.

2. Life care plans and service recommendations are developed in isolation with little foundation.

3. There is no collaboration with service providers, reviewing important medical or therapeutic information or prior service records to show how the person has responded to services in the past and will likely do in the future.
4. The planner truncated or skipped home visits and face-to-face contact with providers and others with useful first-hand information.

5. There is incomplete or absent evidence-based research to evaluate potential consumer risks from service components.

6. There were few efforts to require medical specialists to justify the resources they have recommended.

7. The planner fails to challenge service recommendations made by others; they only meet technical requisites required for foundation.

8. There is no effort to determine if a physician or other provider possessed the training and experience required to knowledgeably recommend the service being promoted; customer perspectives and future safety are ignored.

9. National databases with information regarding probability for employment, educational success, or the prevalence of potential medical complications aren’t consulted.

10. Information on local services and resources and costs is inadequate or inaccurate.

These failures result in a life care plan that contains little information on previous successes and failures, basic safety considerations, and necessary problem-solving supports and services.

The life care planner should assist the individual and family to learn more about all resources and supports they will need and how to get them. Planning processes which provide only for cursory or haphazard collection of information about consumer and family members’ needs, values, and preferences betray this intent, as do resources prescribed which fail to be evidence-based.

Life care plans must emphasize both consumer-based and provider-based outcomes to assure that all service needs are identified, all factors affecting access to services are addressed, and all factors that will constrain service continuation are a component of plan resources. Otherwise, the plan is demonstrably insufficient, inadequate and incomplete, having ignored some services and commodities needed by the consumer.
### Attributes of Defensible Life Care Plans

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<tr>
<th>Attributes</th>
<th>Evidence</th>
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<tbody>
<tr>
<td><strong>Comprehensive</strong></td>
<td>Report documents:</td>
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<td>- Review of all prior services and treatment</td>
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<td>- Completed clinical interviews with family members and current treating team</td>
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<td></td>
<td>- Evaluated equipment, residential, leisure, employment, and technology needs</td>
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<td>- Evaluated performance of activities of daily living</td>
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<td><strong>Individualized</strong></td>
<td>Report:</td>
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<td>- Reflects specific, unique obstacles, circumstances and needs</td>
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<td>- Shows evidence of extensive research into details of the individual’s life</td>
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<td>- Is rich in consumer-, family-, provider-, and community-based information relating solely to this person</td>
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<td><strong>Collaborative</strong></td>
<td>Documents:</td>
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<td>- Include evidence of collaboration with service providers, including background and training</td>
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<td>- Address multidisciplinary perspectives, skills, and expertise</td>
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<td>- Include multidisciplinary team’s assessment of client strengths, problems, service needs, and future complications</td>
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<td>- Promote decreased subjectivity</td>
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<tr>
<td><strong>Reproducible/Transparent</strong></td>
<td>Data collection, planner methods, and plan formation are defined, clear, logical and reproducible</td>
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<td><strong>Expert</strong></td>
<td>Conclusions are generalizable, not idiosyncratic to the planner</td>
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<td>Process is standardized and consistent</td>
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<td><strong>Knowledgeable</strong></td>
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<td>- Has generalized and specialized knowledge in disciplines and subject areas re the disability and the client’s needs and preferences</td>
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<td>- Provides evidence of ongoing continuing education in the field</td>
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<td>- Includes architecture, characteristics, needs, complications, and outcomes associated with different disabilities, disability rights, economics, law, medicine, nursing, social work, specialized therapies, technology, and social policy</td>
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Includes evidence of careful research in primary and secondary databases, relevant literature reviews, and appropriate professional guidelines for care

**Outcome-Based Report:**
- Recommends resource(s) to overcome identified deficiencies in consumer and existing resource network
- Sets specific objectives for service providers and the individual
- Defines strategies for continual service access
- Contains time frames for plan re-evaluation

**Factual/Evidence-Based Report:**
- Is true and grounded
- Contains historical information, observations, and conclusions
- Is based on most current and recent data, long-term functional needs, services and costs
- Conforms to recommendations by treating providers
- Documents that resources have a logical relationship to identified problems
- Includes peer-reviewed research on service/outcomes, potential benefits/risks negative side-effects

**Conclusion**

Life care plans are an increasingly important aspect of personal injury cases, but to be upheld in court they must meet various criteria and be appropriately structured to be admissible. Plaintiff and defense counsel should be aware of these criteria when deciding on a plan’s validity and vulnerability to challenge.

12. Note also FRE Rule 803, which pertains to exceptions to the hearsay rule. Opposing counsel may challenge life care planner assessment and analysis as being based on hearsay, e.g., medical records and not personal interviews with treating team members. However, Rule 803 makes specific exception to the hearsay rule for business records ordinarily kept in the ordinary course of business, e.g., contemporary medical records made and maintained by a physician office, clinic, hospital, or other healthcare facility.

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