Report to the State of Iowa General Assembly

HF 322 EPILEPSY TREATMENT AND EDUCATION TASK FORCE

REPORT AND RECOMENDATIONS

Final Report - January 23, 2013

Foreword

I am pleased to present this report from the Iowa Epilepsy Treatment and Education Task Force. It is a summary of the work that the nine member task force completed between November 15, 2011 and November 13, 2012.

It was a pleasure serving with such a diverse and respected group of stakeholders and while task force members had strong opinions, we worked together to build consensus and develop recommendations that will improve healthcare outcomes for epilepsy patients and caregivers throughout Iowa.

This report is required to be submitted to the Iowa General Assembly and Governor by December 31, 2012. We will also be hosting a public meeting to share with legislators the task force's summary and recommendations on Tuesday, January 15th, 2013 from 3:00 PM – 5:00 PM in the Lucas Building in Room 320.

Sincerely,

Dale Todd
Chairman
Iowa Epilepsy Treatment and Education Task Force

Epilepsy Treatment and Education Task Force Members

In accordance with the legislation in HF 322, the task force membership consists of the following members, appointed by the specified organizations:

- Three patients or patient representatives appointed by the Epilepsy Foundation of Iowa
- Three physicians appointed by the Iowa Medical Society and the Iowa Osteopathic Medical Association
- Three pharmacists appointed by the Iowa Pharmacy Association in collaboration with the Iowa Retail Federation.

Member	Representing	Nominated By
Brett Barker, PharmD Nevada, IA	Pharmacists	Iowa Pharmacy Association & Retail Federation
Dr. David Friedgood, DO Des Moines, IA	Physicians	Iowa Medical Society & Iowa Osteopathic Medical Association
Dr. Todd Janus, PhD, MD Des Moines, IA	Physicians	Iowa Medical Society & Iowa Osteopathic Medical Association
Kevin Harris, Des Moines, IA	Patient Representative	The Epilepsy Foundation of North Central Illinois, Iowa and Nebraska
Chasity Mease, PharmD (Vice-Chair) West Des Moines, IA	Pharmacists	Iowa Pharmacy Association & Retail Federation
Dr. David Moore, MD, Ames, IA	Physicians	Iowa Medical Society & Iowa Osteopathic Medical Association
Ames, IA Dr. Geoff Wall, PharmD, FCCP, BCPS, CGP Johnston, IA	Pharmacists	Iowa Pharmacy Association & Retail Federation

Dale Todd, Chair, Cedar Rapids, IA	Patients/Patient Representatives	The Epilepsy Foundation of North Central Illinois, Iowa and Nebraska
Kristin L. Wells, Cedar Falls, IA	Patients/Patient Representatives	The Epilepsy Foundation of North Central Illinois, Iowa and Nebraska

Staff support was provided by Roxanne Cogil and Vic Verni of the Iowa Epilepsy Foundation, Jill Myers Geadelmann, Bureau Chief, Bureau of Chronic Disease Prevention and Management, Iowa Department of Public Health and Melissa Ellis, Executive Officer, Division of Health Promotion and Chronic Disease Prevention, Iowa Department of Public Health.

Background

Epilepsy is the fourth most common neurological disorder in the U.S. after migraine, stroke, and Alzheimer's disease. Its prevalence is greater than autism spectrum disorder, cerebral palsy, multiple sclerosis and Parkinson's disease combined. One in 10 adults will have a seizure sometime during their life and more than 30,000 Iowans have epilepsy.[1]

The initial impetus for the creation of the task force was to assess and research the impact on people with epilepsy when their medication or generic equivalent of their anti-seizure medication was switched. This is the legislation as it relates to the creation of the Task Force:

House File 322 AN ACT RELATING TO THE CREATION OF A TASK FORCE CONCERNING DRUG PRODUCT SELECTION RELATIVE TO ANTIEPILEPTIC DRUGS FOR THE TREATMENT OF EPILEPTIC SEIZURES AND INCLUDING EFFECTIVE DATE PROVISIONS. BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA: Section 1. EPILEPSY TREATMENT AND EDUCATION TASK FORCE. 1. a.

[1] Institute for Medicine for the National Academies, 2012. "Epilepsy Across the Spectrum: Promoting Health and Understanding."

Within sixty days of the effective date of this Act, a task force consisting of patients, physicians, and pharmacists shall be formed to provide education and House File 322, p. 2 information and to assess the impact on people with epilepsy of generically equivalent drug product selection of antiepileptic drugs for the treatment of epileptic seizures. The department of public health shall provide administrative support to the task force. b. The membership of the task force shall consist of the following members, appointed by the specified organization: (1) Three patients or patient representatives appointed by the epilepsy foundation of Iowa. (2) Three physicians appointed by the Iowa medical society and the Iowa osteopathic medical association. (3) Three pharmacists appointed by the Iowa pharmacy association in collaboration with the Iowa retail federation. 2. a. A subcommittee of the task force, equally representative of patients, physicians, and pharmacists, shall work with the epilepsy foundation of Iowa and other appropriate entities to develop education and information materials on epilepsy treatment and medication selection. b. The materials shall be developed and distributed in a manner that informs the perspectives of patients, physicians, pharmacists, and insurers. 3. The department of public health, in consultation with the epilepsy foundation of Iowa, shall administer any funds appropriated or received for the purposes of the task force. The funds shall be distributed through a grant to the epilepsy foundation of Iowa for the development and distribution of education and information materials as specified in this section. 4. It is the intent of the general assembly that the only changes made in the law regarding drug product selection of antiepileptic drugs for the treatment of epileptic seizures for the duration of the task force shall be those necessary to comply with changes by the United States food and drug administration regarding interchangeability standards for the use of substitution for such drugs. 5. The task force shall submit a report of its activities, findings, and any recommendations to the general assembly by January 1, 2013. The task force shall be dissolved on that date.

Historically, this has been a very contentious issue within the medical community, among epilepsy advocates, pharmacists and within the pharmaceutical and insurance industries.

Past efforts in Iowa to create and pass legislation regulating the “switching of medications for epilepsy patients without the consent of their doctors,” has met stiff opposition from members of the pharmacy community. The creation of the Task Force has been a welcome attempt by the legislature to bring both sides of the issue together to research, discuss and work on recommendations in a productive and collaborative manner.

The committee met a total of 8 times with the charge of submitting a final report to the Legislature by January 1, 2013.

Activities

It was important to the committee in the early meetings that any recommendations to the legislature should be based **on fact, not just anecdotal evidence**. It was felt by some that much of the past discussion on the topic of generic medications, patient switching and patient safety was made on emotions and not driven by data or research. This being the case, the committee believed that it would be helpful as a first step to attempt to gauge the extent of the problem in Iowa by getting input from Iowa Neurologists and those doctors that specialize in treating patients with epilepsy - epileptologists.

Survey of Iowa Neurologists and Epileptologists

Since no hard data had been compiled to date in Iowa that analyzed the prevalence of medication switching and the related patient safety and health issues, a subcommittee of the Task Force led by Dr. Geoff Wall, Professor of Clinical Sciences at Drake University College of Pharmacy and Health Sciences was formed to develop a relatively simple survey that was e-mailed to neurologists and epileptologists throughout Iowa. Ninety surveys were e-mailed to neurologists and 21 were returned. Below is a copy of the survey and its results:

Dear Iowa Neurologist,

As you know there are currently 17 drugs approved by the FDA for treatments of epilepsy. As many of these drugs' branded patent lives has either expired or will expire in the next several years significant questions has arisen about the appropriate switching of patients with epilepsy to different manufacturers formulations of the same anti-convulsant drug.1-3The State of Iowa has commissioned an Epilepsy Task Force to provide guidance on the subject of manufacturer switching of anti-epileptic drugs (AEDs) and its relevance to the citizens of Iowa. To help assess the scope of the problem (if it exists) the Task Force has developed a brief survey to query Iowa neurologists on your experiences on manufacturer changes by the pharmacy.4-5 The Task Force

would appreciate you sharing your experience and expertise by completing this brief survey on an important subject for Iowa patients with epilepsy.

1. MacDonald JT. Breakthrough seizure following substitution of Depakene capsules (Abbott) with a generic product. Neurology. 1987;37:1885.
2. Anon. Assessment: generic substitution for antiepileptic medication. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 1990;40:1641-3.
3. Roach ES. The Cost of Gullibility. Arch Neurol 2009;66:1418-50.
4. Berg MJ, et al. Generic substitution in the treatment of epilepsy: Patient and physician perceptions. Epilep Behav 2008;13:693.
5. Kramer G, et al. Experience with Generic Drugs in Epilepsy Patients: An Electronic Survey of Members of the German, Austrian and Swiss Branches of the ILAE. Epilepsia 2007;48:609-11

1. The switching of anti-epileptic drugs (AEDs) between different manufacturers leads to adverse outcomes such as side effects or break through seizures.

#	Answer	Response	%
1	I strongly agree with this statement	11	55%
2	I somewhat agree with this statement	7	35%
3	I neither agree nor disagree with this statement	1	5%
4	I somewhat disagree with this statement	1	5%
5	I strongly disagree with this statement	0	0%
	Total	20	100%

2. I personally have had patients with loss of seizure control when their AED was changed to another manufacturer.

#	Answer	Response	%
1	Yes	18	90%
2	No	1	5%
3	Not Sure	1	5%
	Total	20	100%

3. If you answered YES to the previous question, please help us quantify the degree of this problem by answering the following: If you consider all the patients with epilepsy you care for that have received different manufacturers' AEDs, what is your best estimation of the case frequency of break through seizures?

#	Answer	Response	%
1	Very Rarely	1	6%
2	Rarely	5	28%
3	More often than rarely, but uncommonly	10	56%
4	Commonly	2	11%
5	Very Commonly	0	0%
	Total	18	100%

4. I will write Dispense As Written (DAW) when I am concerned about the changing of AED manufacturers in my patients with epilepsy.

#	Answer	Response	%
1	I strongly agree with this statement	15	75%
2	I somewhat agree with this statement	4	20%
3	I neither agree nor disagree with this statement	1	5%
4	I somewhat disagree with this statement	0	0%
5	I strongly disagree with this statement	0	0%
	Total	20	100%

5. When I have written "DAW" for AED prescriptions, Pharmacists have still dispensed a non-branded (generic brand) AED to the patient without contacting me first.

#	Answer	Response	%
1	Yes	13	65%
2	No	3	15%
3	Not Sure	4	20%
	Total	20	100%

6. If you said YES to the previous question, please help us quantify the degree of this problem by answering the following: If you consider all the patients with epilepsy you care for, what is your best estimation of the frequency of cases that you have written a "DAW" AED prescription, but have had a non-branded (generic brand) AED dispensed to the patient without contacting you first?

#	Answer	Response	%
1	Very Rarely	1	8%
2	Rarely	2	15%
3	More often than rarely, but uncommonly	5	38%
4	Commonly	4	31%
5	Very Commonly	1	8%
	Total	13	100%

7. Third party payers such as prescription benefit management companies are the biggest barrier to my using branded AEDs in my patients with epilepsy.

#	Answer	Response	%
1	I strongly agree with this statement	8	40%
2	I somewhat agree with this statement	8	40%
3	I neither agree nor disagree with this statement	3	15%
4	I somewhat disagree with this statement	1	5%
5	I strongly disagree with this statement	0	0%
	Total	20	100%

8. To facilitate communication with the pharmacist, I would be willing to write (or, if able, to communicate via electronic prescription) the indication for the AED (e.g. “for epilepsy”) on the prescription.

#	Answer	Response	%
1	I strongly agree with this statement	12	60%
2	I somewhat agree with this statement	6	30%
3	I neither agree nor disagree with this statement	0	0%
4	I somewhat disagree with this statement	1	5%
5	I strongly disagree with this statement	1	5%
	Total	20	100%

9. Overall, the costs of AEDs and the patients' inability to afford them poses a BIGGER problem to loss of seizure control than switching of manufacturers' AEDs.

#	Answer	Response	%
1	I strongly agree with this statement	4	20%
2	I somewhat agree with this statement	8	40%
3	I neither agree nor disagree with this statement	6	30%
4	I somewhat disagree with this statement	2	10%
5	I strongly disagree with this statement	0	0%
	Total	20	100%

Summary of survey data:

When asked to describe the survey results Dr. Geoff Wall said that "although the survey results were not a statistical scientific study and a relatively small sample size, the committee felt that the results suggested to the medical community that there was a perception among neurologists that a real problem exists when switching medications among manufacturer's and that a real possibility of harm to those with epilepsy exists."

Task Force member Kevin Harris, father of a child with epilepsy said "with 90% of responding Epileptologists & Neurologists indicating that they have had patients lose seizure control due to a switch; the results from the survey support reports from patients and caregivers indicating that anti-epileptic drugs (AED) switching between manufacturers is a serious problem."

Education

Attempting to gain an assessment of the degree of medication switching among epilepsy patients and their providers is an important goal; however the committee felt strongly that providing education about this issue to practitioners, pharmacists and patients was a significant component of the legislative intent for the task force.

The group felt that completion of this charge would have the most immediate and enduring impact on those patients with epilepsy in Iowa. Until more concrete clinical data can be attained from scientifically approved studies like the FDA Equigen Study[2] that is in the process of recruiting patients, we believe that the Task Force, medical community and additional stakeholders should proceed on the assumption that a percentage of patients with epilepsy are susceptible to adverse events if changes in their anti-epileptic drug formulation occurs. Thus the problem in these patients is that these medications may be substituted without knowledge or authorization of the practitioner and often without knowledge and consent of the patient.

It was suggested at this point by Dr. Todd Janus and Dr. Geoff Wall that the committee should channel much of its energy and discussion to working with and attempting to educate some of the relevant regulatory boards (Medicine, Pharmacy, Insurance, etc.) to provide education of this potential problem and work toward **professional and system-based solutions** to address the following areas:

A) Patients, Practitioners and Pharmacists need to be educated in the potential serious adverse consequences of substitution of different anti-epileptic drug formulations.

B) Patients, Practitioners and Pharmacists need to be involved in systems –based changes that allow for the dispensing pharmacist to verify to the practitioner and notify the patient of any deviation from the prescribed anti-epileptic drug formulation.

[2] U.S. National Institutes of Health, Equivalence Among Antiepileptic Drug Generic and Brand Products in People With Epilepsy: Single-Dose 6-Period Replicate Design (EQUIGEN Single-Dose Study)

C) Patients, Practitioners and Pharmacists need to be educated on the published data concerning the risk of potentially life threatening seizure(s) should different anti-epileptic drug formulations be substituted in patients at risk.

D) Patients, Practitioners and Pharmacists need to be educated in the state and federal requirements concerning prescribers writing Dispense as Written (DAW) instructions to the dispensing pharmacist.

E) Patients, Practitioners and Pharmacists need to be involved in systems –based changes that allow for the dispensing pharmacist to dispense the same formulation of anti-epileptic drugs to at risk patients for as long as practicable.

F) Patients, Practitioners and Pharmacists need to be educated in the requirements of Mail-order pharmacies in dispensing requirements and work to attain system-based changes similar to local pharmacies as listed above.

G) Pharmacy Benefit Managers and third party payers-should be educated on the published data concerning the risk of potentially life threatening seizure(s) should different anti-epileptic drug formulations be substituted in patients at risk and work on an approach that does not overtly penalize the patients they cover who may need brand-name anti-epileptic drugs.

Outreach Material and Additional Training

A subcommittee of the Task Force was formed to provide "educational material and information to people with epilepsy, pharmacists and physicians on the issue of the problems that patients may encounter when switching between different formulations of generic medications." Chasity Mease (a pharmacist) and Kevin Harris (parent of a child with epilepsy) developed marketing materials to be shared with the epilepsy community. With input from the medical community, National Epilepsy Foundation and Iowa Pharmacists, the sub-committee developed a TEAM flyer (Together Everyone Achieves no More Seizures) that was used for outreach and continuing education (Attachment 1). More than 19,000

flyers were printed for current and future activities and will continue to be distributed at upcoming health fairs, in-services, support groups meetings and educational conferences.

In conjunction with Iowa Pharmacy Association's Annual Meeting, a patient safety CEU class was developed that provided educational credits and support to pharmacists on the topic of switching of generic medications. In this class the "best practices" of notifying the patient and provider when a manufacturer change may need to be made was discussed and encouraged. To date thirty-seven pharmacists have completed the epilepsy "continuing education class," as of 12/27/12 and 127 have registered for the activity as of 12/27/12.

Meeting materials and educational outreach material was also made available to the public on the Iowa Department of Public Health's "Epilepsy Treatment and Patient Safety" website.

Board of Pharmacy

It soon became quite evident in our discussions that an important stakeholder, the Iowa Board of Pharmacy, was missing from our deliberations, especially since the Board is responsible for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and precursor substances throughout the State. So an invitation was extended to Terry Witkowski, Executive Officer of the board, to attend the August meeting of the Task Force.

At this meeting, the Task Force learned a great deal about the membership of the board, how often it meets, how it operates and what it regulates and licenses. In regards to issues with generic medications we learned several things:

1. That a very small number of complaints (4 out of 800) have to do with epilepsy medications. Informal inquiries are not logged; only when they become formal complaints do they get logged as such.
2. The board has no authority over insurance companies.
3. Compliance officers have little authority over out of state pharmacies.

4. Most patients and Doctors are not familiar with the Iowa Board of Pharmacy complaint process or complaint procedures.
5. There appears to be confusion regarding the definition of DAW (dispense as written).
6. While the issue has been discussed by the Board of Pharmacy of the potential problems epilepsy patients may face when switched between different manufacturer generic anticonvulsants, it was strongly felt by members of the Task Force that more education on the issue should occur with Pharmacy Board staff.

A letter was drafted by the Task Force and mailed on November 11, 2012, addressing the concerns of the committee and making recommendations to the Iowa Board of Pharmacy (Attachment 2). On January 8, 2013 we received a reply to our letter from Lloyd Jessen, Executive Director of the Iowa Board of Pharmacy (Attachment 4). The letter was reassuring to us and demonstrated that the staff and members of the Board of Pharmacy were taking our concerns seriously and had already began to implement appropriate actions to remedy the issue we had brought to their attention. Specifically:

1. Compliance monitors are now fully aware that all inquiries that may qualify as a complaint must be routed through the Board office so that they may be appropriately processed and reviewed for appropriate action, as well as to monitor trends.
2. While the board lacks the necessary statutory authority to discipline nonresident pharmacies for violations of Iowa's drug product selection/generic substitution law, they have acknowledged that they need new legislation to remedy this situation. Lacking this authority still does not prevent them from being able to discipline out of state pharmacies for other violations including dispensing errors. Mr. Jessen anticipates that the Board will take many more formal disciplinary actions against non-resident pharmacies in 2013.
3. The Board agrees with our belief that more education on the issue of generic medications is of the utmost importance. To that end new educational efforts are being directed to Iowa pharmacists and Board

compliance officers and staff. Brochures and social media have recently been utilized and the March 2013 issue of the Board Quarterly Newsletter will include an article on drug product selection/generic substitution and will promote the TEAM approach as a "best practice," for Iowa pharmacists and patients.

Most importantly the board looks forward to working with the epilepsy to help ensure improved health outcomes for those with epilepsy in Iowa. This is a welcome dialog that should continue.

Insurance Industry

As an important stakeholder in the discussion of the challenges posed by the switching of generic medications among epilepsy patients, the task force believed it was important to interview representatives of the insurance industry to get their input and insight on the issue.

At the November 13, 2012 meeting, Matt Hosford, Pharmacy Director for Wellmark Blue Cross and Blue Shield of Iowa, spoke about Wellmark's efforts to improve outcomes for people with epilepsy and BCBS's policy regarding the use of generic medications for people with epilepsy. Director Hosford informed the committee that Wellmark's formulary is driven by practicing physicians. Their "Pharmacy and Therapeutics" committee reviews all new drugs. Their goal is to manage outcomes in the best interest of their organization and the patient. Outcomes are important to them and as the largest medical insurance company in Iowa they understand the inconvenience caused to people with epilepsy when they are forced to deal with medication access issues.

It should be noted here that Task Force members were very appreciative of the fact that Wellmark updated their policies several years ago to more accurately reflect the concerns of patients with epilepsy and their physicians when it has been determined that the best outcome for the patient is to stay on their name brand medication. This is especially critical for the medically fragile or complex

patients with epilepsy. Wellmark has determined that the cost benefit analysis to all parties' long-term results in approved health outcomes.

While it was noted that Wellmark appears to understand the challenges that epilepsy patients and their doctors face, the concern still exists from Task Force members that numerous other insurance companies do not understand the full implications of the challenges with generic anti-convulsants which create additional barriers for epilepsy patients. Outreach and education efforts need to continue with these industry stakeholders in a more focused and precise manner in the near future.

Iowa Medicaid

As one of the largest purchasers of anti-seizure medications in Iowa, Iowa Medicaid is also a significant stakeholder in the discussions about the role of generics and anti-seizure medications. Many of the task force members believed that more outreach should be devoted to this organization in an attempt to help them understand the cost savings involved when patients are well controlled on their appropriate medication.

Several issues were brought up in our discussion of Iowa Medicaid that were tangential to the discussion of generic medications, but are still relevant to the discussion of patient safety and access to medication that committee members discussed.

Iowa Medicaid rules state that while "prior authorization", is required for preferred drugs as specified on the Iowa Medicaid Preferred Drug list, payment for these medications "will be only authorized when there is documentation of previous trial and therapy failure with the non-preferred agent, unless evidence is provided that the use of these agents would be medically contraindicated". The committee noted that this can at times pose as a barrier to timely medication access for patients and efforts should be made to improve and streamline the system that is currently in place. The definition of failure should be more

compassionate to the patient and they should not be forced to fail a medication(s) when the physician believes that there are name brand medications in the market place that would be effective.

Iowa Neurologists also believe that the list of medications currently available on Iowa Medicaid Preferred medications list excludes at least four name brand anticonvulsants that have been proven quite successful in the treatment of epilepsy patients. Banzel, Vimpat, Onfi and Potiga are all members of relatively new antiseizure medications classes that are used as add-on therapies for complicated patients, which there are no generic substitutions. These products are relatively not used that much, but would go a long way towards helping patients gain better seizure control. We should be finding ways to improve access to these medications instead of limiting it.

Overcoming the problems and barriers that epilepsy patients and their physicians face in securing the appropriate medication adds time and costs to the burden of those living with epilepsy. Breaking down these barriers is a noble goal that all parties should be interested in, particularly if it can help decrease costs to the system and improve patient's healthcare outcomes.

Legislation

On several occasions the Task Force discussed past efforts to pass legislation. While some states have already passed legislation limiting the switching of generic medications without physician and patient notification (Attachment 3), it was the consensus of the group that at this time the issue was still not fully understood by members of the legislature; the issue is a complicated one that in the past there was not much scientific data to support either side of the issue and at this time attempting to pass legislation similar to past efforts might not be a good use of time and energy when short time fixes should be tried first. Past efforts appeared to be broad and punitive towards pharmacists.
Epilepsy advocates believe that patient safety should be paramount and are supportive of the pharmacists concerns. This is why it will be important to insure

that all stakeholders are supportive of future legislative efforts prior and when moving forward in the future.

A proposal to help clarify some the “dispense as written,” language was agreed upon by the group. Task Force member Brett Barker a pharmacist said that “The proposed legislation takes a step forward by clarifying language of DAW rules allowing patients and prescribers to continue to have ultimate control over the substitution of medications. The legislation utilizes an existing mechanism familiar to both pharmacists and physicians that specifically targets this subsection of patients without overburdening Iowa pharmacies with onerous regulation.”

As a group we will be supporting the recommendations listed below.

Recommendations – Moving Forward and Working Together

1. Insurance companies play a substantive role in assisting or hindering the ability of patients and physicians to secure the appropriate medication. The Task Force believes that this is an area that needs more education outreach and investigation. Using the Wellmark Blue Cross and Blue Shield of Iowa model for epilepsy patient management, the Task Force might be able to highlight best practices that improve healthcare outcomes for epilepsy patients who use other insurance company models. Not enough time was devoted to outreach efforts to other insurance companies in the short window of time that the task force had to operate in.
2. As part of the statewide task force on epilepsy treatment and education, the Task Force agrees to legislative language that a) provides authority to the Board of Pharmacy for oversight of non-resident pharmacies related to the drug product selection law, b) prohibits drug product selection for generic medications when a specific manufacturer’s product is prescribed and the diagnosis of epilepsy is written on the prescription, c) requires third party payers to cover the cost difference, and d) allows the pharmacist to provide an emergency supply of a substitutable equivalent of a specific generic manufacturer's product in the event the pharmacy is out of the

prescribed medication. It will still require the pharmacist to alert the patient and prescribing physician of the substitution but allows a 72-hour window to resolve the shortage. This should help clear up some of the confusion with the DAW (dispense as written) language.

3. With upcoming changes in insurance plans because of the Affordable Care Act, the potential for Medicaid expansion and the creation of State Healthcare Insurance Exchanges, the members of the task force believe it is important that Health insurance address the needs of individuals with chronic conditions and disabilities like epilepsy in order to achieve the goal of providing meaningful coverage. The spectrum of epilepsy is a complex and severe disorder, unique from many other chronic medical conditions. Due to diversity in patient demographics and seizure types/severity, the management of epilepsy patients is often complex and requires an individualized approach based on etiology as well as co morbidities, concomitant medications, and patient preference. People with epilepsy must have access to:

    •Specialist care and a robust physician network that will serve patients in the plan's coverage network, without arbitrary barriers (visit limitations or burdensome prior authorization requirements) to needed specialty care. Physician directed care and epilepsy treatment innovations.

    •A robust prescription drug formulary that allows patients to maintain access to antiepilepsy drugs (AEDs) without bureaucracy such as "fail first" or prior authorization procedures.

    •Nondiscriminatory practices that protect access with clear coverage and appeal rights.

4. Practitioners and pharmacists need to be educated on the published data concerning the risk of potentially life threatening seizure(s) should different anti-epileptic drug formulations be substituted in patients at risk. And educational outreach efforts need to be continued in a broader

collaborative effort between all other Iowa legislative boards and commissions to develop and enhance the current system of medication dispensing so that pharmacists continue to dispense the same formulation of anti-epileptic drugs to at – risk patients for as long as practical.

5. The role of patient education and responsibility needs to be stressed. Epilepsy patients and their caregivers need to be actively engaged, fully aware and accept a certain level of responsibility for knowing and understanding their medication. The epilepsy community will work to continue educate patients to learn to know and understand their medications, dosage and potential serious adverse consequences of substitution of different anti-epileptic drug formulations.

6. Outreach efforts should be expanded to include and educate Iowa family physicians on product selection/generic medication potential risks. In Iowa, a shortage of neurologist mean that many patients must wait weeks and sometimes months to get an appointment, this is particular the case for pediatric neurologists and epileptologists. Compounding this challenge is the fact that because of Iowa's rural nature many epilepsy patients are treated by their primary care physician. This means that quite often the family physician is the primary point of contact and care for epilepsy patients.

7. The issue of differences in the bio-equivalency of anticonvulsant medications and the potential risks to epilepsy patients is becoming more fully realized by those in the physicians, pharmacists and those in epilepsy community. This is why Task Force members believe that it is important to keep the original legislative intent of the Task Force intact and continue with educational outreach and other collaborative efforts that can help the State of Iowa improve healthcare outcomes for people with epilepsy.

Executive Summary

Unlike other diseases, the dangers faced by epilepsy patients when their medication is received at a dose that is not effective can be catastrophic. This is the underlying principle that has unified Task Force members in their discussions and work throughout our meetings.

While not a specific goal of HF 322, the creation of the Task Force has led to a productive dialog and new partnerships between physicians, patient advocates, pharmacists and other stakeholders in the epilepsy community.

As more scientific research continues on the patient safety issues associated with generic medications, efforts to increase awareness among patients, physicians and pharmacists about the risks posed by the generic switching of anti-consultants should expand to include insurance company stakeholders and other healthcare representatives involved in improving a patient's healthcare outcomes.

The Task Force has made progress in Iowa accomplishing this goal, but more work continues to remain.

Attachments

Attachment 1 – Flyer produced by Education Task Force
Attachment 2 - Letter to Iowa Board of Pharmacy from Task Force
Attachment 3 – State By State comparisons provided by National Epilepsy Foundation
Attachment 4 – Letter from Iowa Board of Pharmacy

Footnotes

1. Institute for Medicine for the National Academies, 2012. "Epilepsy Across the Spectrum: Promoting Health and Understanding."

2. U.S. National Institutes of Health, Equivalence Among Antiepileptic Drug Generic and Brand Products in People With Epilepsy: Single-Dose 6-Period Replicate Design (EQUIGEN Single-Dose Study)