

1 **Policy:** **Patient Safety – The Prevention, Recognition, and**
 2 **Management of Adverse Outcomes**

3
 4 **Date of Implementation** **February 18, 2003**

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 6 **Product:** **Specialty**
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 9 To protect the health and safety of members, American Specialty Health – Specialty (ASH)
 10 has identified quality of care strategies for making practitioners aware of the need to
 11 implement office-based methods to reduce clinical errors and improve patient safety. These
 12 strategies include encouraging practitioners to adopt evidence-based health care
 13 approaches to patient care, maintain their clinical skills at or above broadly accepted
 14 professional standards of care, and follow applicable care management guidelines. ASH
 15 monitors practitioners in their delivery of care and then compares them to other network
 16 practitioners via ASH clinical and administrative criteria set forth through the Clinical
 17 Performance System. Practitioner performance is a helpful indicator during the
 18 recredentialing process.
 19

20 It is important to note that all forms of healthcare service carry some potential risk of harm.
 21 Implementing basic risk management procedures that prevent, identify, and manage actual
 22 or alleged adverse outcomes can help practitioners minimize the risk of harm or injury to
 23 the member.
 24

25 ASH has identified the following goals in improving member safety:

- 26 • Identify types of adverse outcomes;
- 27 • Educate practitioners regarding patient safety standards;
- 28 • Decrease the incidence of adverse events through the identification and
 29 management of preventable events and risk factors;
- 30 • Facilitate the appropriate reporting of adverse outcomes;
- 31 • Evaluate clinical diagnostic and therapeutic procedures applicable to the specialty
 32 services represented by ASH against professionally recognized standards of
 33 practice, current scientific evidence, and consensus of appropriate experts for
 34 safety, plausibility, efficacy and/or diagnostic utility, and evidence-based practices
 35 [see the *Evidence Based Health Information Evaluation / Technology Assessment*
 36 (*QM 32 – ALL*) and *Evidence Selection and Evaluation (QM 33 – ALL)* policies for
 37 additional information];
- 38 • Identify and act in the event of a medical emergency [see the *Emergency*
 39 *Communication Triage (MBR 2 – ALL)* policy]; and
- 40 • Support or participate in studies to improve patient safety-related clinical outcomes.

1 **Patient Safety Defined**

2 ASH accepts the National Patient Safety Foundation’s definition of patient safety as:
 3 *“The avoidance, prevention, and amelioration of adverse outcomes or injury stemming*
 4 *from the processes of health care.”*

5
 6 ASH also accepts the Institute of Medicine Aims for the 21st Century published in their
 7 text, *Crossing the Quality Chasm* (2001). Page 5 of this report states:

8
 9 *“The committee proposes six aims for improvement to address key dimensions in which*
 10 *today’s health care system functions at far lower levels than it can and should. Health Care*
 11 *should be:*

12 *Safe – avoiding injuries to patients from the care that is intended to help them.*

13 *Effective – providing services based on scientific knowledge to all who could*
 14 *benefit, and refraining from providing treatment/services to those not likely*
 15 *to benefit (avoiding under-utilization and over-utilization, respectively).*

16 *Patient Centered – providing care that is respectful of and responsive to individual*
 17 *patient preferences, needs, and values and ensuring that patient values guide*
 18 *all medical/clinical decisions.*

19 *Timely – reducing wait times and sometimes harmful delays for both those who*
 20 *receive and those who give care.*

21 *Efficient – avoiding waste, including waste of equipment, supplies, ideas, and*
 22 *energy.*

23 *Equitable – providing care that does not vary in quality because of patient*
 24 *characteristics such as gender, geographic location, or socioeconomic*
 25 *status.”*

26
 27 Patient safety, which is one of many domains of health care quality concerns, is the subject
 28 matter of this document. Two other domains of quality concerns are:

- 29 • Practices that are consistent with current clinical or scientific knowledge and with
 30 best practices; and
- 31 • The ability to meet client/customer/member-specific values and expectations.

32
 33 ASH’s clients, customers, and members place great significance on the outcome measure
 34 of *patient satisfaction*, including satisfaction with the clinical outcome. Patient safety is a
 35 driving force behind patient satisfaction.

36
 37 ASH recognizes that patient safety has three primary components:

- 38 • Risk factor assessment (Prevention)
- 39 • Recognizing adverse outcomes (Identification)
- 40 • Management of adverse outcomes (Amelioration)

1 **Risk Factor Assessment (Prevention)**

2 A thoughtful and attentive patient evaluation, which includes special attention to general
3 risk factors and risks associated with the type of intervention considered is used to identify
4 patients at risk. Knowledge of basic risk assessment procedures minimizes the liability
5 risks inherent in the practitioner’s practice. The following should be considered as part of
6 the clinical evaluation:

7 8 **Assessment of Red Flags**

9 The 'red flag' approach is utilized broadly in patient care. At any time the patient is under
10 care, the practitioner is responsible for seeking and recognizing signs and symptoms that
11 require additional diagnostics, treatment/service(s), and/or referral. This ongoing process
12 is necessary to discover potential serious underlying conditions that may either need urgent
13 attention or an alteration in the treatment approach. Red flags can present themselves at
14 several points during the patient encounter and can appear in many different forms.

15
16 Due to the rarity of actual red flag diagnoses in clinical practice, it is emphasized that the
17 practitioner does not need to perform expensive or invasive diagnostic procedures (e.g., x-
18 ray, imaging, laboratory studies) in the absence of suspicious clinical characteristics. As an
19 example, there is no need to screen the patient for red flag conditions by taking x-rays or
20 other imaging studies if the initial presentation is consistent with mechanical
21 musculoskeletal pain without red flags.

22
23 Important red flags and events as well as the points during the clinical encounter at which
24 they are likely to appear include:

25 26 **Health History:**

- 27 • Personal or family history of cancer;
- 28 • Current or recent urinary tract, respiratory tract, or other infection;
- 29 • Anticoagulant therapy or blood clotting disorder;
- 30 • Metabolic bone disorder (Osteopenia and osteoporosis);
- 31 • Unintended weight loss;
- 32 • Significant trauma sufficient to cause fracture or internal injury;
- 33 • Trauma with skin penetration
- 34 • Immunosuppression (e.g. AIDS/HIV/ARC);
- 35 • Intravenous drug abuse, alcoholism;
- 36 • Prolonged corticosteroid use;
- 37 • Previous adverse reaction to substances or other treatment modalities;
- 38 • Use of substances or treatment which may contraindicate proposed services; and/or
- 39 • Uncontrolled health condition (diabetes, hypertension, asthma, etc.).

Present Complaint:

- Writhing or cramping pain;
- Precipitation by significant trauma;
- Pain worse at night or not relieved by any position;
- Suspicion of vascular/cerebrovascular compromise;
- Symptoms indicative of progressive neurological disorder;
- Unexplained dizziness or hearing loss;
- Complaint inconsistent with reported mechanism of injury and/or evaluation findings; and/or
- Signs of Psychological distress.

Physical Examination/Assessment:

- Fever, chills, or sweats of unknown origin;
- Neurologic deficit (special senses, peripheral sensory, motor, language, cognitive);
- Positive vascular screening tests (carotid stenosis, vertebrobasilar insufficiency, abdominal aortic aneurysm, etc.);
- Surface lesions or infections in area to be treated;
- Widespread or multiple contusions;
- Abnormal vital signs;
- Signs of allergic reaction;
- Signs of Abuse/Neglect;
- Signs of psychological distress;
- Unexplained severe tenderness or pain;
- Inability to reproduce symptoms of musculoskeletal diagnosis or complaints;
- Uncontrolled hypertension;
- Signs of nutritional deficiency.

Pattern of Signs/Symptoms Not Consistent with Benign Disorder:

- Chest tightness, difficulty breathing, chest pain;
- Headache of morbid proportion;
- Rapidly progressive neurological deficit;
- Significant, unexplained extremity weakness or clumsiness;
- Change in bladder or bowel function;
- New or worsening numbness or paresthesia;
- Saddle anesthesia;
- New or recent bilateral radiculopathy.

1 Lack of Response to Appropriate Care:

- 2 • History of consultation/care from a series of practitioners or a variety of health
3 care approaches without resolving the patient’s complaint;
4 • Unsatisfactory clinical progress, especially when compared to apparently similar
5 cases or natural progression of the condition; and/or
6 • Signs and symptoms that do not fit the normal pattern and are not resolving.

7
8 ***Assessment of Yellow Flag(s)***

9 Yellow flags are adverse prognostic indicators with a psychosocial predominance
10 associated with chronic pain and disability. Yellow flags signal the potential need for more
11 intensive and complex treatment and/or earlier specialist referral.

12
13 When yellow flags are present, clinicians need to be vigilant for deviations from the normal
14 course of illness and recovery. Examples of yellow flags include depressive symptoms,
15 injuries still in litigation, signs, and symptoms not consistent with pain severity, and
16 behaviors incongruent with underlying anatomic and physiologic principles.

17
18 **Error Prevention**

19 Another important aspect of safety and prevention of adverse events is error prevention.
20 To prevent errors, a clear understanding and acceptance of the causes of clinical errors and
21 unsafe practices is necessary along with an active management approach to ensure the
22 potential for errors is eliminated from the clinical interaction. Some causes of clinical errors
23 include:

- 24 • Prescription of an incorrect/inappropriate treatment/service or modality for the
25 patient’s health status or condition.
26 • Recommendation of an ingested or topical product (e.g., supplement or balm)
27 having an ingredient to which the patient has had a prior adverse reaction.
28 • Diagnostic errors leading to the application of an incorrect/inappropriate therapy
29 such as failure to implement a needed diagnostic test that would more clearly define
30 the patient’s condition, misinterpretation of diagnostic results and tests, and failure
31 to act appropriately on abnormal examination or test results.
32 • Therapeutic/diagnostic equipment failure.
33 • Misunderstanding or misinterpretation of clinical information provided to the
34 treating practitioner by a third party clinician.
35 • Inadequate medical records that do not clearly identify information necessary to
36 avoid injury or adverse outcome by the clinician at a future date or a third party
37 using the medical record to render treatment/services in the absence of the author.
38 (Paraphrased from the Agency for Healthcare Research and Quality; Publication
39 Number 00-PO37 Feb 25, 2000)

1 Diagnostic and therapeutic adverse outcomes can be minimized by avoiding experimental,
 2 untested, or quasi-scientific diagnostic and therapeutic procedures. Some keys to reducing
 3 adverse events include:

- 4 • Always take into account any contraindications to the intended use of the
 5 treatment/service.
- 6 • Inform patients of the risks, consequences, or side effects that may arise from
 7 diagnostic or therapeutic procedures.
- 8 • Patient selection for appropriate use of treatments/services and therapeutic
 9 modalities is important. Take into consideration patient tolerances,
 10 contraindications, and risk of side effects before applying any treatment/service.

11 **Recognizing Adverse Outcomes (Identification)**

12 Clinical errors are defined as failure of a planned action to be completed as intended (errors
 13 of execution) or the use of an incorrect/inappropriate plan to achieve an aim (errors of
 14 planning).
 15

- 16 • Errors of execution (e.g., commission of direct injury to the patient; can also include
 17 omission of a step or procedure that leads to unexpected injury to the patient).
 18

19 *Slips or Lapses* occur when the action conducted was not what was intended. It is
 20 an error of execution. A slip is observable and a lapse is not (i.e., a slip of the hand
 21 and a lapse of memory).
 22

- 23 • Errors of planning (e.g., missed diagnosis, inappropriate application of
 24 treatment/service, or incorrect/inappropriate treatment/service selection).
 25 *Mistakes* In a mistake the action proceeds as planned but fails to achieve its
 26 intended outcome because the planned action was incorrect/inappropriate.
 27

28 *Slip versus Mistake* A slip might be involved when the practitioner chooses an
 29 appropriate modality but sets the dial to 10 when the intention was to set the dial to
 30 1.0. A mistake, on the other hand, might be involved when selecting the
 31 incorrect/inappropriate modality (e.g., hot pack) because the diagnosis is
 32 incorrect/inappropriate (e.g., missed the diagnosis of septic arthritis).
 33

- 34 • Slips, lapses, and mistakes in patient care are serious errors and can potentially
 35 result in harming patients. Adverse outcomes do not always imply actual injury
 36 and may not be a direct result of the treatment. Even when there is no injury to the
 37 patient resulting from the error, it may cause the patient to experience concern,
 38 which may result in the reporting of a complaint.
 39

40
 41 A self-limiting treatment/service-induced discomfort that is non-injurious but does cause
 42 the patient to experience concern may result in the reporting of a complaint. This

1 discomfort can be considered to be within the range of normal reactions to manipulation,
 2 physiotherapy, acupuncture, massage, or other appropriately prescribed care by the
 3 practitioner. Beyond reassurance, no intervention is likely to be medically necessary.
 4

5 **Risk Management (Amelioration)**

6 A willingness to acknowledge the reality of an adverse outcome along with quick action to
 7 assist the patient is essential to patient safety. Knowledge and use of basic risk management
 8 procedures for managing actual or alleged adverse outcomes can help health care
 9 practitioners minimize harm or injury to patients. Open and honest dialogue with patients
 10 is encouraged.
 11

12 In the unfortunate occurrence of an adverse event, it is important to properly evaluate the
 13 situation, communicate with the patient in a factual manner without assessing blame, select
 14 a means to remedy the situation, monitor the outcome of the event, and document these
 15 and other relevant event(s) in the medical record.
 16

17 If the practitioner concludes that the injury is negligible, reassurance and self-care
 18 instructions are all that are likely to be medically necessary. However, when an injury is
 19 significant, the practitioner should render a diagnosis, ensure delivery of necessary
 20 urgent/emergency care, and/or make necessary referrals.
 21

22 If an adverse outcome is reported, ASH investigates and evaluates the issues and may seek
 23 recommendations from the Practice Review Committee (PRC) in order to determine what
 24 action may be appropriate.
 25

26 When professional misconduct or injury is suspected, ASH performs an investigation to
 27 assess for:

- 28 • Adequate documentation;
- 29 • Appropriate monitoring, timely recognition, and treatment/service;
- 30 • Appropriate plans for follow-up, implement work-up; and
- 31 • Referral in a timely manner, if needed.
 32

33 Proper risk management strategies maximize patient safety. These strategies include
 34 implementing an evidence-based health care approach; accurate, timely practitioner/patient
 35 communication, and maintaining best practice clinical skills and knowledge.
 36

37 **Adverse Event Clinical Indicators**

38 Adverse Event Clinical Indicators are utilized to:

- 39 • Identify adverse events and protect the health and safety of ASH members.
- 40 • Decrease the incidence of adverse events through the identification of preventable
 41 events.

- 1 • Facilitate the appropriate reporting of adverse outcomes that may result in
- 2 Corrective Action Plans (CAP).
- 3 • Evaluate practitioner performance during the recredentialing process (in addition
- 4 to the evaluation process that occurs at the time of the event).
- 5 • Assist with the development of studies to improve clinical outcomes.