111TH CONGRESS 2D SESSION

H. R. 4662

To amend title XVIII of the Social Security Act to improve the diagnosis and treatment of lymphedema under the Medicare Program and to reduce costs under such program related to the treatment of complications of lymphedema, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

February 23, 2010

Mr. Kissell introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend title XVIII of the Social Security Act to improve the diagnosis and treatment of lymphedema under the Medicare Program and to reduce costs under such program related to the treatment of complications of lymphedema, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- This Act may be cited as the "Lymphedema Diag-
- 5 nosis and Treatment Cost Saving Act of 2010".

1	SEC. 2. COVERAGE OF LYMPHEDEMA DIAGNOSIS AND
2	TREATMENT SERVICES UNDER MEDICARE.
3	(a) Coverage of Services.—Section 1861 of the
4	Social Security Act (42 U.S.C. 1395x) is amended—
5	(1) in subsection $(s)(2)$ —
6	(A) in subparagraph (DD), by striking
7	"and" at the end;
8	(B) in subparagraph (EE), by adding
9	"and" at the end; and
10	(C) by adding at the end the following new
11	subparagraph:
12	"(FF) lymphedema compression treatment
13	items (as described in subsection (iii)) and
14	lymphedema diagnosis and treatment services
15	(as described in subsection (hhh)) if such serv-
16	ices are prescribed by and reviewed by a treat-
17	ing physician and performed by such physician
18	or—
19	"(i) a physical therapist or an occupa-
20	tional therapist who meets the quality re-
21	quirements of subsection (hhh)(2)(C);
22	"(ii) a qualified professional, such as
23	a physician, nurse practitioner, clinical
24	nurse specialist, chiropractor, or physi-
25	cian's assistant who is licensed or certified
26	by the State in which the services are per-

1	formed to perform therapy services and
2	who meets the quality requirements of
3	(hhh)(2)(C); or
4	"(iii) a qualified person, such as a
5	physical therapist assistant, occupational
6	therapy assistant, licensed massage thera-
7	pist, licensed practical nurse, or licensed
8	home health practitioner who meets the
9	quality requirements of (hhh)(2)(C) pro-
10	viding such services are rendered under the
11	direct supervision of a physical therapist or
12	occupational therapist qualified in
13	lymphedema treatment and management
14	who meets the quality requirements of
15	(hhh)(2)(C)."; and
16	(2) by adding at the end the following new sub-
17	sections:
18	"(hhh) Lymphedema Diagnosis and Treatment
19	Services.—(1) The term 'lymphedema diagnosis and
20	treatment services' means, with respect to an individual
21	and consistent with paragraph (3), differential diagnosis
22	and treatment of lymphedema (regardless of cause) ac-
23	cording to the current standard of lymphedema diagnosis
24	and treatment described in paragraph (2)(A) by, or under
25	the direction of, a health care professional that is a cer-

- 1 tified provider as described in paragraph (2)(B) in an out-
- 2 patient setting and that meets the quality standards de-
- 3 scribed in paragraph (2)(C), but only if the physician who
- 4 is managing the individual's lymphedema certifies that
- 5 such services are needed under a comprehensive plan of
- 6 care related to the individual's diagnosed lymphedema.
- 7 "(2) For purposes of paragraph (1):
- "(A) The current standard of lymphedema di-8 9 agnosis and treatment described in this subpara-10 graph is such standard as defined by the American 11 Cancer Society and the International Society of 12 Lymphology and called 'complex decongestive ther-13 apy', a multi-modal therapy comprising manual 14 lymph drainage, compression therapy, exercise, and 15 skin care. Such standard consists of the initial phase 16 of treatment which is performed by qualified health 17 care professionals on an outpatient basis (Phase 1 18 treatment) and the continuing maintenance phase 19 (Phase 2 treatment) which is performed in a home 20 setting by the patient, patient's family, or patient's 21 aide after receiving instruction described in para-
 - "(B) A qualified provider is a physician or lymphedema therapist knowledgeable of the diagnosis and current medical standard of treatment of

graph (5).

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2 ignated by the Secretary, that, in addition to pro-3 viding lymphedema outpatient self-management

lymphedema, or any other individual or entity des-

- 4 training services (as defined in paragraph
- 5 (3)(C)(iii)), provides other items or services for
- 6 which payment may be made under this title.
 - "(C)(i) Subject to clause (ii), the quality standards described in this subparagraph are quality standards established by the Secretary equivalent to the practice standards established by the Lymphology Association of North America.
 - "(ii) In applying this subsection during the 3-year period beginning on the date of the enactment of this subsection, a therapist who has completed at least 135 hours of lymphedema treatment training and is certified by the training school is deemed to have met the requirement of clause (i), and may practice under a certified provider within a plan of care developed by the certified provider; regardless of whether the therapist meets the experience standards established by the Lymphology Association of North America.
 - "(D) The term 'lymphedema diagnosis' means the differential diagnosis of the source of the patient's edema and the identification of the specific

etiology in order to develop the lymphedema treatment plan. Such term shall include diagnostic tools
such as the lymphoscintigraphic functional test or
other test the Secretary determines to be efficatious
to directly observe lymphatic system function may be
indicated if medical history or tests to rule out other
causes are not adequate to provide a clear positive
diagnosis of lymphedema.

9 "(3) COVERAGE.—With respect to lymphedema diag-10 nosis and treatment services coverage under this part, the 11 following shall apply:

"(A) MANUAL LYMPH DRAINAGE.—

"(i) Lymphedema diagnosis and treatment services coverage under this part shall include an initial course of manual lymph drainage as part of complete decongestive therapy (Phase 1) when medically required by the qualified provider described in paragraph (2)(B).

"(ii) The schedule and number of manual lymph drainage treatment sessions shall be determined by the treating physician or lymphedema therapist as required by medical necessity, and not the limits governing rehabilitation therapy described in section 1833(g).

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1	"(B) Compression binding systems, gar-
2	MENTS AND DEVICES.—
3	"(i) For purposes of this part, the mate-
4	rials and aids used in lymphedema compression
5	therapy—
6	"(I) while physically resembling items
7	in other benefit categories such as surgical
8	dressings, durable medical equipment,
9	splints and braces, orthotics and pros-
10	thetics described in subsections $(s)(5)$,
11	(s)(6), and $(s)(9)$, do not serve the same
12	medical function as such items in such
13	other categories and have significantly dif-
14	ferent therapeutic characteristics and uses;
15	and
16	"(II) are specified in subsection (iii)
17	as a separate benefit category.
18	"(ii) Such coverage shall include any com-
19	pression garments, binding systems and devices
20	described in subsection (iii) deemed by the pa-
21	tient's qualified caregiver to be medically nec-
22	essary as part of the treatment of lymphedema.
23	"(iii) Such coverage shall include replace-
24	ments when required to maintain their medi-
25	cally required compressive function or to accom-

1	modate changes in the patient's dimensions or
2	medical condition.
3	"(C) Lymphedema self-management train-
4	ING.—
5	"(i) In general.—
6	"(I) The initial course of treatment
7	(phase 1) described in paragraph (2)(A),
8	with respect to such services, shall include
9	training of the patient and an aide or fam-
10	ily member as required to perform self-
11	treatment in a home setting, including any
12	of the following home treatment modalities
13	which are determined by the qualified pro-
14	vider to be medically required and are a
15	part of the continuing maintenance phase
16	(phase 2) home treatment plan described
17	in paragraph (2)(A):
18	"(aa) Self-manual lymph drain-
19	age (simple lymph drainage).
20	"(bb) Compression bandaging.
21	"(ce) Donning and care of com-
22	pression garments.
23	"(dd) Performance of an appro-
24	priate decongestive exercise program.

1	"(ee) Use of specialized manually
2	adjustable compression devices, don-
3	ning aids, and other required ancillary
4	equipment; and if medically indicated.
5	"(ff) Use of sequential gradient
6	compression pneumatic pump.
7	"(II) As part of such treatment, pa-
8	tient training shall include instruction on
9	periodic self-measurements, skin care, indi-
10	cations of infection, and the steps to be
11	taken if infection occurs.
12	"(III) The term 'lymphedema out-
13	patient self-management training services'
14	means educational and training services
15	furnished to an individual diagnosed with
16	lymphedema by a certified provider (as de-
17	scribed in paragraph (2)(B)) in an out-
18	patient setting but only if the physician
19	who is managing the individual's
20	lymphedema condition certifies that such
21	services are needed under a comprehensive
22	plan of care related to the individual's
23	lymphedema condition.
24	"(ii) Consultation with organizations
25	IN ESTABLISHING PAYMENT AMOUNTS FOR

1 SERVICES PROVIDED BY PHYSICIANS.—In es-2 tablishing payment amounts under section 1848 3 physicians' services for consisting of 4 lymphedema outpatient self-management train-5 ing services, the Secretary shall consult with 6 appropriate organizations, including such orga-7 nizations representing individuals or Medicare 8 beneficiaries with lymphedema, in determining 9 the relative value for such services under sec-10 tion 1848(c)(2).

- "(D) MEASUREMENTS TO DEFINE TREATMENT EFFICACY.—Periodic measurements shall be made to enable evaluation of the efficacy of the treatment plan and patient adherence, to modify the treatment plan or to determine the need for follow-up courses of treatment.
- "(E) Follow-up treatment.—Such coverage shall provide for follow-up treatments whenever medically required to periodically validate home techniques, to monitor progress against the written treatment plan, and to modify the treatment plan as required.
- "(F) Denial.—No individual other than a licensed physician or certified lymphedema therapist competent to evaluate the specific clinical issues in-

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1	volved in the care requested, may deny or modify re-
2	quests for authorization of health care services or
3	materials described in subsection (iii) pursuant to
4	this subsection.
5	"(G) Prohibition of additional treat-
6	MENT FEES.—No additional fees or deductibles may
7	be assessed, with respect to such treatment, for com-
8	pliance with this title other than assessed for similar
9	medical services.
10	"(iii) Lymphedema Compression Treatment
11	ITEMS.—
12	"(1) Definition.—The term 'lymphedema
13	compression treatment item' means compression
14	therapy materials and supplies used daily in the
15	medical treatment of lymphedema upon prescription
16	of the treating physician or the rapist, including—
17	"(A) compression binding systems com-
18	prising, as medically required, short-stretch and
19	medium-stretch compression bandages; cotton
20	synthetic, or foam padding; gauze or elastic fin-
21	ger and toe bandages; foam pads; and tubular
22	bandages;
23	"(B) compression garments and compression
24	sion pads for compression treatment of

1	lymphedematous arms, legs, torso, face and
2	neck, breast and chest, abdomen, and genitalia;
3	"(C) manually-adjustable compression
4	sleeves and padded directional flow sleeves for
5	use on upper and lower limbs;
6	"(D) orthotic shoes; and
7	"(E) donning aids, bandage rollers, and
8	other specialized items used with the items de-
9	scribed in subparagraphs (A) through (D).
10	"(2) Special requirement on lymphedema
11	PUMPS.—Such term shall include a pneumatic pump
12	for the treatment of lymphedema only if the treating
13	physician or therapist's prescription for such pump
14	is accompanied by a certificate of medical necessity
15	which specifies as a minimum—
16	"(A) the differential diagnosis of
17	lymphedema and any related co-conditions such
18	as venous insufficiency, peripheral arterial dis-
19	ease, lipedema, morbid obesity, myxedema, and
20	any other condition which may be significant in
21	the selection of a type, specification, and usage
22	of the pump; and
23	"(B) the physician's or therapist's judge-
24	ment of the type and specifications of the pump
25	based on the patient's medical necessity."

1	(b) Payment.—
2	(1) Lymphedema outpatient self-manage-
3	MENT TRAINING SERVICES INCLUDED AS PHYSI-
4	CIANS' SERVICES.—Section 1861(s)(2)(S) of such
5	Act $(42 \text{ U.S.C. } 1395x(s)(2)(S))$ is amended by in-
6	serting "and lymphedema outpatient self-manage-
7	ment training services under subsection
8	(hhh)(3)(C)" after "subsection (qq) ".
9	(2) Lymphedema compression treatment
10	ITEMS.—
11	(A) In General.—Section 1833(a) of
12	such Act (42 U.S.C. 1395l(a)) is amended—
13	(i) in paragraph (8), by striking at
14	the end "and";
15	(ii) in paragraph (9), by striking at
16	the end the period and inserting a semi-
17	colon; and
18	(iii) by adding at the end the fol-
19	lowing new paragraph:
20	"(10) in the case of lymphedema compression
21	treatment items described in section 1861(iii), the
22	amount determined under section 1834(n); and".
23	(B) Payment Determined.—Section
24	1834 of such Act (42 U.S.C. 1395m) is amend-

1	ed by adding at the end the following new sub-
2	section:
3	"(n) Payment for Lymphedema Compression
4	TREATMENT ITEMS.—
5	"(1) General rule for payment.—
6	"(A) IN GENERAL.—With respect to a
7	lymphedema compression treatment item de-
8	scribed in section 1861(iii) for which payment
9	is determined under this subsection, subject to
10	subparagraph (D), payment shall be made in an
11	amount equal to 80 percent of the payment
12	basis described in subparagraph (B).
13	"(B) Payment Basis.—The payment
14	basis described in this subparagraph, with re-
15	spect to a lymphedema compression treatment
16	item described in section 1861(iii), is the actual
17	charge for the item.
18	"(C) EXCLUSIVE PAYMENT RULE FOR
19	HOME HEALTH AGENCIES.—This subsection
20	shall constitute the exclusive provision of this
21	title for payment for lymphedema compression
22	treatment items described in section 1861(iii)
23	under this part or under part A to a home
24	health agency.
25	"(D) Exceptions.—

1	"(i) Subparagraph (B) shall not apply
2	to an item furnished by a public home
3	health agency (or by another home health
4	agency which demonstrates to the satisfac-
5	tion of the Secretary that a significant por-
6	tion of its patients are low income) free of
7	charge or at nominal charges to the public.
8	"(ii) Subparagraph (B) shall not
9	apply to items that are furnished as an in-
10	cident to a physician's professional service.
11	"(2) Special payment rules.—
12	"(A) Allowable items.—To be eligible
13	for payment under this subsection, an item de-
14	scribed in section 1861(iii) must—
15	"(i) be ordered by a qualified physi-
16	cian or lymphedema therapist for treat-
17	ment of diagnosed lymphedema;
18	"(ii) primarily and customarily be
19	used to serve a medical purpose;
20	"(iii) generally not be useful to a per-
21	son in the absence of an illness or injury;
22	and
23	"(iv) be appropriate for use in the
24	home.

1	"(B) ALLOWABLE QUANTITIES.—In the
2	case it is determined by the qualified physician
3	or qualified lymphedema therapist involved that
4	compression therapy demands daily compression
5	as part of lymphedema treatment according to
6	section 1861(hhh)(1), then payment may be
7	made in accordance with this subsection for the
8	following quantities—
9	"(i) in the case of compression bind-
10	ing systems described in section
11	1861(iii)(1)(A), 2 sets for each affected
12	body part;
13	"(ii) in the case of compression gar-
14	ments described in section 1861(iii)(1)(B),
15	2 garments for each affected body part;
16	"(iii) in the case of compression de-
17	vices described in section 1861(iii)(1)(C), 1
18	each for each affected body part; and
19	"(iv) in the case of compression ther-
20	apy aids described in section
21	1861(iii)(1)(D), as determined by the
22	qualified physician or qualified
23	lymphedema therapist.
24	"(C) Allowable use.—Payment may be
25	made under this subsection for a lymphedema

1	compression treatment item described in section
2	1861(iii) only if such item—
3	"(i) is prescribed by a certified pro-
4	vider as defined in section
5	1861(hhh)(2)(B);
6	"(ii) is used as part of a lymphedema
7	treatment plan described in section
8	1861(hhh)(1);
9	"(iii) is used by a patient who has
10	been instructed in lymphedema self-man-
11	agement described in section
12	1861(hhh)(5); and
13	"(iv) is used to treat a diagnosed con-
14	dition of chronic lymphedema.
15	"(D) COMPRESSION RANGE.—The
16	lymphedema compression treatment items for
17	which payment may be made under this section
18	must provide a compression no less than
19	30mmHg and no greater than 60mmHg.
20	"(E) QUALIFIED FITTERS.—The
21	lymphedema compression treatment items for
22	which payment may be made under this section
23	must be measured and fitted by a qualified fit-
24	ter who is an individual who—

1 "(i) is a qualified lymphedema thera-2 pist, as defined in section 1834(o)(2), who 3 meets the quality standards of section 4 1861(hhh)(2)(C);

"(ii) in the case of a State that provides for the licensing of orthotists and prosthetists, is licensed in orthotics or prosthetics by the State in which the item is supplied;

"(iii) in the case of a State that does not provide for the licensing of orthotists and prosthetists, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics, and is certified by the American Board for Certification inOrthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that the Secretary determines, in consultation with appropriate experts in orthotics and prosthetics, has training and education standards that are necessary to provide such prosthetics and orthotics; or

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1	"(iv) is certified by the qualified man-
2	ufacturer of the item to be qualified to fit
3	the particular garment or device.
4	"(F) Requirements for suppliers of
5	COMPRESSION THERAPY ITEMS.—A supplier of
6	the lymphedema compression treatment items
7	described in this subsection must meet the re-
8	quirements of section 1834(j) in order to re-
9	ceive payment under this subsection.
10	"(3) Replacement of compression therapy
11	ITEMS.—
12	"(A) In general.—Payment shall be
13	made under this subsection, with respect to an
14	individual, for the replacement of compression
15	bindings, compression garments, or compression
16	devices if an ordering physician determines that
17	the provision of a replacement item, or repair of
18	such an item, is necessary because of any of the
19	following:
20	"(i) A change in the physiological or
21	medical condition of the individual.
22	"(ii) A loss of required compression of
23	the item that is not restorable by washing
24	and drying.

1	"(iii) An irreparable change in the
2	condition of the device, or in a part of the
3	device.
4	"(B) Length of Reasonable useful
5	LIFETIME.—The reasonable useful lifetime of a
6	lymphedema compression treatment item de-
7	scribed in section 1861(iii) shall be as follows,
8	except that, if the Secretary determines that, on
9	the basis of prior experience in making pay-
10	ments for such an item under this title, such
11	lifetimes are no longer appropriate with respect
12	to a particular item, the Secretary shall estab-
13	lish an alternative reasonable lifetime for such
14	item:
15	"(i) Compression binding kit.—In
16	the case of compression binding systems
17	described in section 1861(iii)(1)(A), the
18	greater of 6 months or per manufacturer's
19	warrantee.
20	"(ii) Compression garments.—In
21	the case of compression garments de-
22	scribed in section 1861(iii)(1)(B), the
23	greater of 4 months or per manufacturer's
24	warrantee.

1	"(iii) Compression devices.—In the
2	case of compression devices described in
3	section 1861(iii)(1)(C), the greater of 3
4	years or per manufacturer's warrantee.
5	"(iv) AIDS.—In the case of compres-
6	sion therapy aids described in section
7	1861(iii)(1)(D), as required to maintain
8	functional usefulness.".
9	(C) Supplier requirements.—Section
10	1834(j)(5) of such Act $(42 U.S.C. 1395m(j)(5))$
11	is amended—
12	(i) in subparagraph (E), by striking
13	at the end "and";
14	(ii) in subparagraph (F), by striking
15	at the end the period an inserting "; and";
16	and
17	(iii) by adding at the end the fol-
18	lowing new subparagraph:
19	"(G) lymphedema compression treatment
20	items (as described in section 1861(iii)).".
21	(3) Lymphedema diagnosis and treatment
22	SERVICES.—
23	(A) In general.—Section 1833(a) of
24	such Act, as amended by paragraph (2)(A), is

1	further amended by adding at the end the fol-
2	lowing new paragraph:
3	"(11) with respect to lymphedema diagnosis
4	and treatment services (as defined in subsection
5	(hhh)(1))—
6	"(A) furnished by a qualified physical ther-
7	apist or qualified occupational therapist, as de-
8	fined in section 1834(o)(2)(A), the amounts de-
9	scribed in section 1834(k); or
10	"(B) furnished by a lymphedema therapist,
11	as defined by 1834(o)(2)(B), under direction of
12	a qualified physical therapist or qualified occu-
13	pational therapist, the amounts described in
14	section 1834(o).".
15	(B) Payment method.—Section 1834 of
16	such Act, as amended by paragraph (2)(B), is
17	further amended by adding at the end the fol-
18	lowing new subsection:
19	"(o) Payment for Outpatient Lymphedema Di-
20	AGNOSIS AND TREATMENT SERVICES.—
21	"(1) In general.—For purposes of section
22	1833(a)(11)(B), in the case of lymphedema diag-
23	nosis and treatment services described in section
24	1861(hhh) for which payment is determined under
25	this subsection and that are performed by a quali-

1	fied lymphedema therapist (as defined in paragraph
2	(2)) under the direction of a qualified physician
3	therapist or qualified occupational therapist, the
4	payment basis shall be 80 percent of the lesser of—
5	"(A) the actual charge for the service; or
6	"(B) the applicable fee schedule amount
7	(as defined in paragraph (3)) for the services.
8	"(2) Qualified therapists.—For purposes of
9	this subsection:
10	"(A) IN GENERAL.—The term 'qualified',
11	with respect to a physical therapist, occupa-
12	tional therapist, or lymphedema therapist,
13	means that the physical therapist, occupational
14	therapist, or lymphedema therapist meets the
15	quality requirements described in section
16	1861(hhh)(2)(C).
17	"(B) Lymphedema therapist.—The
18	term 'lymphedema therapist' means any of the
19	following individuals so long as such individual
20	is legally authorized to practice by the State in
21	which the lymphedema diagnosis and treatment
22	service involved is performed and meets the
23	quality requirements described in subparagraph
24	(A):

1	"(i) A registered nurse, nurse practi-
2	tioner, family nurse practitioner or clinical
3	nurse specialist (as described in section
4	1861(aa)(5)).
5	"(ii) A doctor of medicine or doctor of
6	osteopathy (as described in section
7	1861(r)(1).
8	"(iii) A physician assistant (as de-
9	scribed in section 1861(aa)(5)).
10	"(iv) A chiropractor.
11	"(v) A licensed massage therapist.
12	"(vi) A licensed home health practi-
13	tioner.
14	"(3) APPLICABLE FEE SCHEDULE AMOUNT.—
15	In this subsection, the term 'applicable fee schedule
16	amount' means, with respect to services furnished in
17	a year, the amount determined under the fee sched-
18	ule established under section 1848 for such services
19	furnished during the year or, if there is no such fee
20	schedule established for such services, the amount
21	determined under the fee schedule established for
22	such comparable services as the Secretary specifies.
23	"(4) Uniform coding.—For claims for serv-
24	ices for which the amount of payment is determined
25	under this subsection, the claim shall include a code

- 1 (or codes) under a uniform coding system specified 2 by the Secretary that identifies the services fur-3 nished.
- 4 "(5) Restraint on billing.—The provisions 5 of of subparagraphs (A)and (B)section 6 1842(b)(18) shall apply to lymphedema diagnosis 7 and treatment services for which payment is made 8 under this subsection in the same manner as they 9 apply to services provided by a practitioner described 10 in section 1842(b)(18)(C), except that in applying 11 such subparagraphs the practitioner described shall 12 be any practitioner described in paragraph (2)(B).".
- 13 (C) EXCLUSION FROM CERTAIN THERAPY
 14 SERVICES.—Section 1833(g)(4) of such Act (42
 15 U.S.C. 1395l(g)(4)) is amended by inserting
 16 "or to expenses incurred with respect to
 17 lymphedema diagnosis and treatment services
 18 (as defined in subsection (hhh)(1))" before the
 19 period at the end.
- 20 (c) EFFECTIVE DATE.—The amendments made by 21 this section shall apply to items and services furnished on 22 or after the date that is 90 days from the date of the 23 enactment of this Act.