

**ABBOZZ TA' LIĠI**  
**msejjah**

*ATT li jirregola min hu intitolat għal, u l-kwalità ta', s-servizzi tas-saħħa f'Malta, li jikkonsolida u jirrifirma l-istrutturi tal-Gvern u l-entitajiet responsabbli għas-saħħa u li jipprovi għad-drittijiet tal-pazjenti.*

IL-PRESIDENT bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqgħa f'dan il-Parlament, u bl-awtorità tal-istess, hareġ b'liġi dan li ġej:-

TAQSIM TAL-ATT

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## TAQSIMA I

## Dispożizzjonijiet Ġenerali

Titolu fil-qosor  
u bidu fis-seħh.

**1.** It-titolu fil-qosor ta' dan l-Att hu l-Att tal-2013 dwar is-Saħha.

(2) Dan l-Att għandu jidhol fis-seħh fid-data li l-Ministru jistabbilixxi b'avviz fil-Gazzetta, u dati differenti jistgħu jiġu stabbiliti għal dispożizzjonijiet differenti ta' dan l-Att.

Tifsir.

**2.** F'dan l-Att sakemm ir-rabta tal-kliem ma teħtieġx xort'oħra -

"Kumitat Konsultattiv" tfisser il-Kumitat Konsultattiv dwar il-Benefiċċji tas-Saħha stabbilit bl-artikolu 23;

"Kunsill" tfisser il-Kunsill tas-Saħha stabbilit bl-artikolu 17;

"Ministru" tfisser il-Ministru responsabbli għas-Saħha, u "Ministeru" għandha tiftiehem skont hekk;

"pazjent" tfisser persuna li qed tirċievi jew irċeviet, attenzjoni, kura jew trattament mediku, kemm f'ambjent ta' kura tas-saħha jew xort'oħra;

"persuna assicurata" tfisser kull persuna inkluża fil-lista stabbilita fl-artikolu 25;

Kap. 460.

"Stat Membru" tfisser Stat firmatarju tat-Trattat kif definit bl-Att dwar l-Unjoni Ewropea.

Skop.

**3.** L-għan ewlieni ta' dan l-Att huwa li jistabbilixxi u jassigura sistema tas-saħha mibnija fuq il-prinċipji ta' aċċessibilità, kwalità u sostenibilità billi jirregola min hu intitolat għal, u l-kwalità ta', is-servizzi tas-saħha f'Malta, li jikkonsolida u jirrifirma l-istrutturi u l-entitajiet tal-Gvern responsabbli għas-saħha, u li jipprovdi għad-drittijiet tal-pazjenti.

## TAQSIMA II

## Direttorat għall-Politika tas-Saħha

Direttorat għall-  
Politika tas-  
Saħha.

**4.** (1) Għandu jiġi stabbilit Direttorat għall-Politika tas-Saħha li l-missjoni tiegħu għandha tkun, b'mod ġenerali sabiex jaġixxi bħala l-konsulent ewlieni tal-Ministru dwar il-kwistjonijiet kollha relatati mal-politika tas-saħha tal-Gvern, u b'mod partikolari li jagħti pariri lill-Ministru dwar l-iżvilupp ta' politika u l-kordinazzjoni ta' pjani strateġiċi, dwar it-tfassil u l-implimentazzjoni ta' pjanijiet ta'

azzjoni, u dwar l-evalwazzjoni tar-rizultati sabiex ikunu assigurati s-sostenibbiltà tas-saħha pubblika u tas-servizzi tas-saħha.

(2) Il-Kap ta' dan id-Direttorat għandu jkun Direttur Ġenerali li għandu jkun ukoll, *ex officio*, l-Uffiċjal Mediku Ewlieni tal-Gvern.

5. Id-Direttorat għall-Politika tas-Saħha għandu, b'mod generali, jeżerċita dawk il-funzjonijiet u jaqdi dawk id-dmirijiet u responsabbiltajiet li johorġu mill-liġi, u b'mod partikolari, dawk il-funzjonijiet u dmirijiet li l-Ministru jista', minn żmien għal żmien, jistabbilixxi b'regolamenti.

Funzjonijiet u dmirijiet tad-Direttorat.

### TAQSIMA III

#### Direttorat għas-Servizzi tas-Saħha

6. (1) Għandu jiġi stabbilit Direttorat għas-Servizzi tas-Saħha li l-missjoni tiegħu għandha tkun li jassigura l-operat u l-għoti ta' servizz tas-saħha effettiv u effiċjenti, b'emfazi fuq sistemi ta' tmexxija kliniċi u korporattivi, fuq l-għoti tas-servizz u fuq l-evalwazzjoni kontinwa tal-kwalità, f'qafas stabbilit ta' decentralizzazzjoni u awtonomija kkontrollati u li jinvolvi s-sehem tal-persuni li jagħmlu użu mill-istess servizz.

Direttorat għas-Servizzi tas-Saħha.

(2) Il-Kap ta' dan id-Direttorat għandu jkun Direttur Ġenerali.

7. Id-Direttorat għas-Servizzi tas-Saħha għandu, b'mod generali, jeżerċita dawk il-funzjonijiet u jaqdi dawk id-dmirijiet u responsabbiltajiet li johorġu mill-liġi, u b'mod partikolari, dawk il-funzjonijiet u dmirijiet li l-Ministru jista', minn żmien għal żmien, jistabbilixxi b'regolamenti.

Funzjonijiet u dmirijiet tad-Direttorat.

### TAQSIMA IV

#### Direttorat għar-Regolamentazzjoni tas-Saħha

8. (1) Għandu jiġi stabbilit Direttorat għar-Regolamentazzjoni tas-Saħha li l-missjoni tiegħu għandha tkun li jhars is-saħha pubblika, johroġ licenzi, jissorvelja u jispezzjona l-għoti tas-servizzi tas-saħha bil-ħsieb li tkun assigurata l-kwalità u s-sigurtà tagħhom, li jirrakkomanda l-*standards* li għandhom jintlaħqu minn dawk li joffru servizzi tas-saħha u li jagħti pariri lill-Ministru dwar kwistjonijiet li jikkonċernaw is-saħha pubblika.

Direttorat għar-Regolamentazzjoni tas-Saħha.

(2) Il-Kap ta' dan id-Direttorat għandu jkun Direttur Ġenerali li għandu jkun ukoll, *ex officio*, is-Supritendent tas-Saħha Pubblika.

9. Id-Direttorat għar-Regolamentazzjoni tas-Saħha għandu, b'mod generali, jeżerċita dawk il-funzjonijiet u jaqdi dawk id-

Funzjonijiet u dmirijiet tad-Direttorat.

dmirijiet u responsabbiltajiet li joħorġu mill-liġi, u b' mod partikolari, dawk il-funzjonijiet u dmirijiet li l-Ministru jista', minn żmien għal żmien, jistabbilixxi b' regolamenti.

## TAQSIMA V

### Disposizzjonijiet komuni għad-Direttorati kollha

Hatra ta' Diretturi Ġenerali.

**10.** Id-Diretturi Ġenerali jinhatru mill-Prim Ministru wara sejha pubblika għal perjodu ta' tliet snin li jista' jiġi mġedded għal perjodu jew perjodi ulterjuri skont il-każ, taht dawk il-pattijiet, kondizzjonijiet, funzjonijiet u dmirijiet kif stabbilit fl-ittri rispettivi tal-ħatra.

Rappreżentanza legali.

**11.** Ir-rappreżentanza legali u ġuridika tad-Direttorati għandha tkun vestita fid-Diretturi Ġenerali rispettivi, jew f'xi persuna jew persuni oħra mahtura sabiex jaġixxu f'isimhom.

Id-Diretturi Ġenerali jkunu responsabbli għall-uffiċjali, eċċ.

**12.** Bla ħsara għad-disposizzjonijiet ta' dan l-Att, it-tmexxija eżekuttiva, l-amministrazzjoni, u l-kontroll amministrattiv tal-uffiċjali u l-impjegati tad-Direttorati għandhom ikunu r-responsabbiltà tad-Diretturi Ġenerali.

Qadi ta' funzjonijiet permezz ta' terzi.

**13.** Bla ħsara għad-disposizzjonijiet ta' dan l-Att, il-funzjonijiet tad-Direttorati, jew xi waħda minnhom, tista' tkun eżerċitata permezz ta' persuna jew kuntrattur awtorizzat wara li jkun intlaħaq ftehim f'dan is-sens:

Iżda ebda ftehim simili ma jista' jintlaħaq ma' terzi persuni sakemm:

(a) il-qadi ta' dik il-funzjoni jew funzjonijiet permezz ta' terzi jkun ta' benefiċċju għad-Direttorat; u

(b) l-istima tan-nefqa sabiex isir il-qadi ta' dik il-funzjoni jew funzjonijiet permezz ta' terzi ma tkunx teċċedi dik is-somma stabbilita, minn żmien għal żmien, mill-Ministru jew mis-Segretarju Permanenti, u r-raġuni speċifika għal tali ftehim tkun approvata mill-Ministru wara li jikkonsulta l-Ministru responsabbli mill-finanzi; u

(ċ) tkun ħarġet sejha pubblika għal dak il-għan.

Skambju ta' informazzjoni bejn id-Direttorati.

**14.** (1) Kull Direttorat jista' jitlob, jiġbor u jivverifika kull informazzjoni, *data* u statistika, skont kif ikun meħtieġ għall-qadi tal-funzjonijiet tiegħu.

(2) Direttorat għandu jkollu aċċess għal kull informazzjoni li jista' jkollhom Direttorati oħrajn, jew entitajiet oħra stabbiliti bi, jew

taħt dan l-Att, u għandu d-dritt jitlob u jikseb kull tagħrif li jinħtieg għall-qadi tal-funzjonijiet tiegħu minn pazjenti, qraba, persunal u professjonisti, u mingħand dawk kollha li jipprovdu servizzi tas-saħħa, kemm pubbliċi u privati, u dan it-tagħrif għandu jingħatalhu fi żmien raġonevoli mid-data tat-talba.

(3) Kull Direttorat għandu jkollu aċċess għal statistika u tagħrif iehor ta' natura ekonomika u soċjali kif meħtieg biex ikun jista' jwettaq il-funzjonijiet tiegħu skont dan l-Att.

**15.** Id-Direttorati għandhom, bla hsara għall-funzjonijiet tagħhom, jirrispettaw id-diversità tal-entitajiet, tas-servizzi u tal-programmi tas-saħħa tagħhom, u jiddjalogaw u jikkollaboraw ma' entitajiet, istituzzjonijiet u aġenziji oħra, kemm pubbliċi u privati, lokali u barranin, dwar politika, inizjattivi u proġetti sabiex jiżguraw li s-sistema kollha fil-pajjiż topera b'mod effettiv.

Rispett għad-diversità ta' istituzzjonijiet tas-Saħħa.

**16.** (1) Għandu jiġi stabbilit Bord, li jkun magħruf bħala l-Bord dwar il-Politika u Strateġija fis-Saħħa, presjedut mill-Ministru, biex jiddiskuti u jevalwa l-politika, l-istrateġija u d-direzzjoni u l-iżviluppi fil-qasam tas-saħħa u jissorvelja u jsegwi l-implimentazzjoni tal-politika u tal-istrateġija tas-saħħa adottata mill-Gvern.

Bord dwar il-Politika u Strateġija fis-Saħħa.

(2) Il-Bord għandu jkun kompost kif previst fl-Iskeda A, u l-Ministru jista' b'regolamenti jemenda l-imsemmija Skeda, u jipprovdi għal kull materja oħra jew proċedura li jidhirlu meħtieg għall-aħjar twettiq tal-funzjonijiet tal-Bord.

## TAQSIMA VI

### Kunsill tas-Saħħa

**17.** (1) Għandu jiġi stabbilit Kunsill tas-Saħħa.

Twaqqif u kompożizzjoni tal-Kunsill tas-Saħħa.

(2) Il-Kunsill għandu jkun kompost kif previst fl-Iskeda B, u l-Ministru jista' b'regolamenti jemenda l-imsemmija Skeda, u jipprovdi għal kull materja oħra jew proċedura li jidhirlu meħtieg għall-aħjar twettiq tal-funzjonijiet tal-Kunsill.

**18.** (1) Hu dmir tal-Kunsill tas-Saħħa li jagħti, meta msejjaħ mill-Ministru, il-parir tiegħu fuq hwejjeġ li jaffettwaw dak kollu li għandu x'jaqşam mas-saħħa f'Malta.

Dmirijiet tal-Kunsill.

(2) Bla hsara għall-generalità ta' dak hawn fuq imsemmi, b'mod partikolari hu d-dmir tal-Kunsill li jagħti l-parir tiegħu fuq dak kollu li l-liġi tipprovdi li dwaru għandu jkun mitlub il-parir tal-Kunsill.

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Setgħat tal-Kunsill.

**19.** (1) Il-Kunsill għadnu jkollu s-setgħa li jahtar sotto-kumitati u li jdahhal fihom membri li mhumiex membri tal-imsemmi Kunsill meta jkun qed jiddiskuti materji speċifiċi fuq l-agenda tiegħu.

(2) Il-Kunsill tas-Saħħa jista' wkoll jirrakkomanda dawk il-miżuri, inkjesti jew investigazzjonijiet xjentifiċi li, fil-fehma tiegħu, huma utili fl-interess tas-saħħa pubblika.

Laqgħat tal-Kunsill u *quorum*.

**20.** Il-Kunsill ma jista' jittratta ebda materja jekk ma jkunx hemm preżenti mill-anqas hames membri:

Izda, jekk il-Kunsill jiġi msejjaħ biex jikkunsidra xi kwistjoni li fuqha l-parir tiegħu jkun meħtieġ b'mod urgenti mill-Gvern, il-Kunsill jista' jiddeċidi bil-maġġoranza tal-voti ta' dawk il-membri preżenti.

Setgħa biex il-Ministru jagħmel regolamenti.

**21.** Bla ħsara għas-setgħat tal-Ministru li jagħmel regolamenti taħt l-artikolu 31 biex jagħti seħħ lil kull dispożizzjoni ta' dan l-Att, il-Ministru jista' jagħmel, ibiddel jew iħassar regolamenti dwar it-tmexxija xierqa tal-affarijiet tal-Kunsill.

## TAQSIMA VII

## Benefiċċji tas-Saħħa u min hu intitolat għalihom

Benefiċċji tas-saħħa.

**22.** Il-Ministru għandu, wara li jikkunsidra l-parir tal-Kumitat Konsultattiv dwar il-Benefiċċji tas-Saħħa imwaqqaf bl-artikolu 23, jistabbilixxi dawk il-benefiċċji tas-saħħa li għandhom ikunu provduti direttament jew indirettament mis-sistema pubblika tas-servizzi tas-saħħa.

Kumitat Konsultattiv dwar il-Benefiċċji tas-Saħħa.

**23.** (1) Għandu jkun stabbilit Kumitat Konsultattiv dwar il-Benefiċċji tas-Saħħa.

(2) Il-Kumitat Konsultattiv dwar il-Benefiċċji tas-Saħħa jista' jwaqqaf sotto-kumitati sabiex jittrattaw kategoriji ta' benefiċċji differenti u speċifiċi kif jidhirlu xieraq. Bla ħsara għall-ġeneralità ta' dak imsemmi hawn fuq, il-Kumitat Konsultattiv dwar Lista Formularja tal-Gvern stabbilit bir-Regolamenti dwar Prodotti Mediċinali Disponibbli fis-Servizzi tas-Saħħa tal-Gvern għandu jitqies bħala wieħed minn dawk is-sotto-kumitati.

L.S. 458.31

(3) Il-Kumitat Konsultattiv għandu jkun kompost kif previst fl-Iskeda Ċ, u l-Ministru jista' b'regolamenti jemenda l-imsemmija Skeda, u jipprovdi għal kull materja oħra jew proċedura li jidhirlu meħtieġ għall-aħjar twettiq tal-funzjonijiet tal-Kumitat Konsultattiv.

(4) Il-Kumitat Konsultattiv għandu jiltaqa' kemm il-darba jkun meħtieġ u għandu jirregola l-proċeduri tiegħu:

Iżda f'kazijiet ta' trattament urgenti u vitali, l-Uffiċjal Mediku Ewlieni tal-Gvern jista' jawtorizza l-ghoti ta' tali benefiċċju tas-saħħa u minnufih fl-ewwel opportunità possibbli jagħti rendikont ta' dan lill-Ministru u lill-Kumitat Konsultattiv.

**24.** (1) Il-Kumitat Konsultattiv għandu jirrakkomanda l-benefiċċji tas-saħħa li għandhom ikunu provduti direttament jew indirettament mis-sistema pubblika tal-kura tas-saħħa u għandu jżomm lista li tkun aċċessibbli għall-pubbliku u aġġornata b'mod regolari, ta' dawn il-benefiċċji.

Setgħat tal-Kumitat.

(2) Waqt li jkun ihejji din il-lista, il-Kumitat Konsultattiv għandu jkun gwidat b'dan li ġej:

- (a) evidenza internazzjonali;
- (b) kunsiderazzjonijiet dwar it-teknoloġija fis-saħħa;
- (ċ) konsultazzjoni mal-partijiet interessati;
- (d) il-kapaċità fis-sistema tas-saħħa pubblika;
- (e) kunsiderazzjonijiet soċjali u epidemjoloġiċi;
- (f) kemm jiswew il-benefiċċji u kemm huma sostenibbli.

**25.** (1) Bla ħsara għal kull dispożizzjoni oħra fil-liġi, persuna assicurata biss tista' tikkwalifika għall-benefiċċji tas-saħħa b'xejn li huma provduti minn, jew għan-nom ta', is-sistema pubblika tas-saħħa.

Min hu intitolat għall-benefiċċji tas-saħħa.

(2) Għall-finijiet ta' dan l-Att, persuna assicurata tfisser:

(a) ċittadin ta' Stat Membru jew taż-Żona Ekonomika Ewropea, jew ċittadin Svizzeru, jew persuna bi status ta' resident li joqgħod għal żmien twil skond ir-Regolamenti dwar Status ta' Residenti li joqogħdu għal żmien Twil (Ċittadini ta' Pajjiżi Terzi), li r-residenza primarja tiegħu tkun f'Malta u li huwa:

L.S. 217.05

(i) kopert b'mod attiv b'assigurazzjoni soċjali skond l-Att dwar is-Sigurtà Soċjali; jew

Kap. 318.

(ii) meqjus li huwa kopert għall-fini ta' saħħa skond l-Att dwar is-Sigurtà Soċjali, irrISPETTIVAMENT mill-istatus tal-kontribuzzjonijiet tas-sigurtà soċjali; iżda jeskludi persuni li inkella jkunu meqjusa hekk assicurati permezz tal-Konvenzjoni Ewropea dwar l-Assistenza

Kap. 318.

Soċjali u Medika u l-Protokoll għaliha; jew

(iii) fil-pussess ta' assigurazzjoni tas-saħħa maħruġa mill-awtorità kompetenti ta' Stat Membru ieħor skond it-termini tar-Regolamenti tal-Kommunità fis-seħħ dwar l-applikazzjoni ta' skemi ta' sigurtà soċjali; jew

(b) ċittadin ta' pajjiż barrani li għandu ftehim reċiproku ma' Malta dwar il-kura tas-saħħa, dwar dik il-kura u fejqan li għalihom dak iċ-ċittadin ikun intitolat skond id-disposizzjonijiet ta' dak il-ftehim jew kull haġa li turi li jkun sar ftehim wara l-ewwel ftehim; jew

Kap. 420.

(ċ) persuna koperta bl-Att dwar ir-Rifugjati jew b'regolamenti li saru tahtu, iżda biss fir-rigward ta' kura u trattament li għalih dawn il-persuni jkunu intitolati skont it-termini tar-regolamenti, *policies* amministrattivi jew ftehim ieħor li jkun sar wara; jew

(d) dipendenti tal-persuni msemmija fil-paragrafi (a) sa (ċ).

(2) Il-Ministru jista', minn żmien għal żmien, permezz ta' regolamenti taht dan l-Att, jistabbilixxi illi xi benefiċċji tas-saħħa jkunu ristretti għal xi kategoriji partikolari ta' persuni assigurati.

Tariffi għal kura fis-sistema pubblika tas-saħħa.

**26.** (1) Għandu jiġi stabbilit Reġistru, li jinżamm mis-Segretarju Permanenti fil-Ministeru tas-Saħħa, li fih jinkludi il-benefiċċji, servizzi, interventi, u trattamenti kollha provduti mis-sistema pubblika tas-saħħa, u l-ispiza u, jew it-tariffi ma' kull tali benefiċċju, servizz, intervent u trattament. Dan ir-Registru għandu jkun aġġornat kull sena, jew qabel, skont kif jistabbilixxi l-Ministru minn żmien għal żmien.

(2) Dawn it-tariffi u, jew in-nefġiet, għandhom ikunu aċċesibbli għall-pubbliku.

(3) Bla ħsara għal ebda liġi jew rogolamenti oħra, dawn it-tariffi u, jew in-nefġiet, għandhom jiġu meqjusa bħala l-għola rimbors possibbli fil-każ li persuna tagħżel xi forma ta' kura tas-saħħa transkonfini taht xi forma ta' ftehim li Malta tista' tkun parti minnu, irrispettivament mit-tariffi u, jew nefġiet attwali li persuna tkun hallset għal tali kura tas-saħħa transkonfini.

(4) Kull persuna li ma titqiesx persuna assigurata skont dan l-Att għandha tħallas it-tariffi u, jew in-nefġiet kollha għall-benefiċċji, servizzi, interventi, u trattamenti skont kif jirriżultaw mir-registru stabbilit taht is-subartikolu (1).



(5) Bla ħsara għas-subartikolu (4), jew għal kull liġi jew regolament ieħor, il-Ministru jista' japprova li t-tariffa jew in-nefqa, kollha kemm hi jew parti minnha, li hija dovuta minn xi persuna, li ma tkunx persuna assigurata, f'kazijiet eċċezzjonali u, jew għal raġunijiet umanitarji, tista' tiġi rrinunzjata.

27. Bla ħsara għal ebda liġi jew regolamenti oħra fis-seħħ li jitttrattaw il-protezzjoni tal-konsumatur, dawk kollha li jipprovdu servizzi tal-kura tas-saħħa, kemm dawk pubbliċi meta l-pazjent jew klijent ma jkunx persuna assigurata skond dan l-Att, u dawk privati fil-kazijiet kollha, huma obbligati li japplikaw l-istess skali ta' tariffi għal servizzi offruti lill-pazjenti f'sitwazzjonijiet mediċi komparabbli, indipendentement mill-pajjiż li jkunu ġejjin minnu.

Tariffi għal kura tas-saħħa privata.

## TAQSIMA VIII

### Drittijiet u Sigurtà tal-Pazjenti

28. Huwa d-dritt ta' kull pazjent illi:

Drittijiet tal-Pazjenti.

(a) jirċievi kura tas-saħħa skond id-dispożizzjonijiet ta' dan l-Att;

(b) jirċievi informazzjoni dwar l-istat ta' saħħtu u dwar is-servizzi tas-saħħa u trattamenti li jista' jkollu aċċess għalihom;

(ċ) jiġi mogħti informazzjoni ċara minn qabel dwar l-għażliet ta' trattament li jista' jkollu aċċess għalihom u li jkun involut fid-diskussjonijiet u d-deċiżjonijiet dwar it-trattament li ser jingħata;

(d) jkollu aċċess għall-informazzjoni medika dwaru skont l-Att dwar il-Protezzjoni u l-Privatezza tad-*Data*, sakemm dan ma jkunx ta' detriment għall-benesseri tiegħu; Kap. 440.

(e) jkollu d-*data* medika tiegħu proċessata skont l-Att dwar il-Protezzjoni u l-Privatezza tad-*Data*; Kap. 440.

(f) jirrifjuta kwalunkwe trattament offrut lilu, sakemm tali rifjut ikun akkumpanjat minn firma tal-istess pazjent;

(g) jkun eżaminat u mogħti t-trattament mingħajr dewmien żejjed jew bla bżonn;

(h) jippreżenta lment dwar is-servizz li jkun irċieva u li jkun infurmat fi żmien raġjonevoli bir-riżultat tal-investigazzjoni dwar l-istess ilment;

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(i) jappella minn kull deċiżjoni meħuda taħt dan l-Att quddiem it-Tribunal ta' Revizjoni Amministrattiva imwaqqaf bl-Att dwar il-Ġustizzja Amministrattiva u kull regolament magħmul taħtu.

Kap. 490.

Responsabbiltà tal-pazjenti.

**29.** Bla ħsara għal ebda disposizzjoni taħt dan l-Att, jew xi ligi oħra, filwaqt li dawk li jipprovdu s-servizzi tas-saħħa huma mistennija li jipprovdu servizz bażat fuq ir-rispett lejn id-dinjità umana, dawk li jirċievu s-servizz għandhom jagħmlu użu minnu b'mod responsabbli filwaqt li juru r-rispett xieraq lejn il-professjonisti, lejn il-ħaddiema u lejn il-proprietà.

Charter tad-Drittijiet u r-Responsabbiltajiet tal-Pazjenti.

**30.** (1) Il-Ministru għandu, fi żmien sentejn mid-dhul fis-seħħ ta' din it-Taqsima ta' dan l-Att, jippubblika dokument li għandu jkun imsejjaħ iċ-*Charter* tad-Drittijiet u r-Responsabbiltajiet tal-Pazjenti.

(2) Dan iċ-*Charter* għandu jistabbilixxi sommarju tad-drittijiet u r-responsabbiltajiet tal-pazjenti u persuni oħra fis-seħħ fil-mument tal-pubblikazzjoni.

(3) Dan iċ-*Charter* għandu jkun aġġornat b'mod regolari sabiex jirrifletti x-xejriet u l-materji tal-mument.

## TAQSIMA IX

### Disposizzjonijiet oħra

Setgħat tal-Ministru li jagħmel regolamenti.

**31.** Il-Ministru jista', bla ħsara għad-disposizzjonijiet ta' dan l-Att, jagħmel regolamenti biex jagħti seħħ lil kull disposizzjoni ta' dan l-Att, jew biex jirregola jew xort'oħra jipprovdi dwar kull haġa għar-rigward tal-funzjonijiet u l-attivitajiet li jaffettwaw il-kura tas-saħħa skont dan l-Att, u jista' b'mod partikolari, imma mingħajr preġudizzju għall-generalità ta' dak hawn qabel imsemmi, jagħmel regolamenti għal kull għan minn dawn li ġejjin:

(a) sabiex jirregola kull haġa li għandha x'taqsam ma', jew li hi inċidentali għat-twettiq tal-funzjonijiet jew għat-ħaddim u l-amministrazzjoni ta' entitajiet tal-kura tas-saħħa;

(b) biex jippreskrivi dak it-tagħrif, rapporti u reżokonti li għandhom jintbagħtu lill-Ministru jew lid-Diretturi Ġenerali mill-Principali u, jew mill-Kapijiet Eżekuttivi, u minn dawk l-uffiċjali u persuni l-oħra li għandhom x'jaqsmu mal-kura tas-saħħa skont mal-Ministru jidhirlu meħtieġ li jitlob, u b'dak il-mod, f'dik il-forma, f'dak iż-żmien, u fuq dawk is-sugġetti li hu jista' jispeċifika fir-regolamenti;

(ċ) biex jistabbilixxi kull dritt u, jew hlas li jistgħu ikollhom jingabru minn jew taht dan l-Att, jew għal xi servizz mogħti konformi mad-disposizzjonijiet ta' dan l-Att;

(d) biex jipprovdi dwar kull formola jew proċedura li jistgħu jkunu meħtieġa jew spedjenti u li dwarhom ma jkun hemm ebda proċedura speċifika f'dan l-Att;

(e) biex jistabbilixxi regoli li bihom il-Gvern jista' jirratifika u jagħti seħħ lil kull konvenzjoni internazzjonali li tirrigwarda s-saħħa u li tkun diġà ratifikata mill-Gvern ta' Malta; jew biex ikun hemm konformità ma' kull obbligu internazzjonali tal-Gvern ta' Malta jew mad-Direttivi tal-Unjoni Ewropea dwar xi materja jew qasam li għandu x'jaqsam mas-saħħa;

(f) biex jistabbilixxi l-funzjonijiet u d-dmirijiet tad-direttorati u d-dipartimenti stabbiliti bi, jew taht, dan l-Att;

(g) sabiex jassigura l-għoti tas-servizzi tas-saħħa fi proċess shiħ u kontinwu matul il-ħajja, billi jistabbilixxi dawk l-entitajiet tas-saħħa b'mod li jkun meħtieġ minn żmien għal żmien fil-Gżejjer Maltin u, biex jistabbilixxi, meta ma jkunx xort'oħra provdut f'dan l-Att, jew f'xi Att ieħor, statuti u regoli li jirregolaw il-missjoni, skop, funzjonijiet, setgħat u dmirijiet, il-kontabilità finanzjarja jew xort'oħra, u kull proċedura oħra li għandhom ilkoll jiġu segwiti, mwettqa u osservati minn xi entità hekk imwaqqfa b'dan l-Att jew tahtu;

(h) biex jistabbilixxi, meta ma jkunx xort'oħra provdut f'dan l-Att, jew f'xi Att ieħor, statuti u regoli li jirregolaw il-missjoni, skop, funzjonijiet, setgħat u dmirijiet, il-kontabilità finanzjarja jew xort'oħra, u kull proċedura oħra li għandhom ilkoll jiġu segwiti, mwettqa u osservati minn xi Kunsill, Kumitat jew Bord imwaqqfin b'dan l-Att jew tahtu;

(i) biex, bla ħsara wkoll għad-disposizzjonijiet ta' kull liġi oħra, jagħti lil persuna li tħoss ruħha aggravata minn xi deċiżjoni ta' xi entità, xi korp jew organizzazzjoni mwaqqfa taht dan l-Att, mezz u proċeduri biex jew twassal l-ilmenti u l-aggravju tagħha dwar, jew tikkontesta jew tappella minn, dik id-deċiżjoni quddiem it-Tribunal ta' Revizjoni Amministrattiva imwaqqaf bl-Att dwar il-Ġustizzja Amministrattiva, u biex Kap. 490. tikseb sodisfazzjon jekk tingħata raġun;

(j) biex jistabbilixxi kull haġa li għandha jew li tista' tiġi stabbilita taht dan l-Att u biex jipprovdi dwar kull haġa oħra

kif jidhirlu xieraq;

(k) biex jistabbilixxi l-pieni għal kull kontravvenzjoni jew ksur ta' kull disposizzjoni ta' kull regolament magħmul taht dan l-Att, jew għal nuqqas ta' tharis ta' xi dispożizzjoni bħal dik jew ta' xi htiega magħmula tahtha:

Izda regolamenti magħmulin taht dan l-artikolu jistgħu jiddisponu b'mod differenti għal skopijiet jew ċirkostanzi differenti, għal klassijiet jew tipi ta' entitajiet differenti, u għal klassijiet ta' pazjenti differenti;

(l) biex jistabbilixxi l-qafas nazzjonali dwar il-politika tas-saħha għal dawk li joffru servizzi tas-saħha, kemm pubbliċi kif wkoll privati, u jkun id-dmir ta' dawk kollha li joffru tali servizzi li jimplimentaw din il-politika skont il-potenzjal u l-htigiet differenti tal-pazjenti li jattendu għandhom;

(m) biex jistabbilixxi dawk l-eċċezzjonijiet possibbli għal kull disposizzjoni f'kull liġi, fl-aħjar interess tas-saħha f'Malta.

Thassir u  
riserva.  
Kap. 94.

**32.** (1) B'effett mid-dhul fis-seħh ta' dan l-Att, id-dispożizzjonijiet tal-Ordinanza dwar l-Organizzazzjoni tad-Dipartiment tas-Saħha għandhom jiġu mħassra. Sabiex ikun evitat kull dubbju, partijiet minn dik l-Ordinanza jistgħu jkunu mħassra f'dati differenti skont id-dati tad-dhul fis-seħh tal-partijiet jew artikoli li jikkorrispondu f'dan l-Att.

(2) Kull regolament jew ordni magħmulin taht id-dispożizzjonijiet tal-Ordinanza revokata u li jkunu għadhom fis-seħh fil-bidu fis-seħh ta' dan l-Att, jew xi parti jew artikolu rilevanti, għandhom, sakemm ma jiġix provdut b'dan l-Att jew bis-saħha tiegħu, jibqgħu fis-seħh u jkollhom effett bħallikieku magħmulin taht dan l-Att.

(3) Kull liċenza, permess jew awtorizzazzjoni oħra mogħtija taht xi dispożizzjoni ta' dik l-Ordinanza għandhom jibqgħu fis-seħh bħallikieku dawn kienu liċenzi, permessi jew awtorizzazzjonijiet oħra mogħtija bl-awtorità ta' dan l-Att.

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## SKEDA A

[Artikolu 16(2)]

Il-Bord dwar il-Politika u Strateġija fis-Saħha għandu jkun kompost kif ġej:

- (a) il-Ministru, bħala President;
- (b) is-Segretarju Permanent fil-Ministeru, bħala Viċi-President;
- (ċ) it-tliet Direttur Ġeneral tad-Direttorati mwaqqfa taħt l-Att;
- (d) il-kontrollur finanzjarju fil-Ministeru, u fin-nuqqas tiegħu, l-oghla uffiċjal responsabbli mill-finanzi tal-Ministeru;
- (e) konsulent tal-Ministru;
- (f) kull uffiċjal ieħor li l-Ministru jidhirlu, minn żmien għal żmien, xieraq li jappunta fuq dan il-Bord; u
- (g) uffiċjal maħtur mill-Ministru biex jaġixxi ta' Segretarju.

## SKEDA B

[Artikolu 17(2)]

(1) Il-Kunsill tas-Saħha għandu jkun kompost kif ġej:

- (a) il-Ministru, bħala President;
- (b) is-Segretarju Permanent fil-Ministeru, bħala Viċi-President;
- (ċ) l-Avukat Ġenerali jew rappreżentant tiegħu;
- (d) l-Uffiċjal Mediku Ewlieni tal-Gvern;
- (e) persuna li tirrapreżenta l-professjonisti fil-kura tas-saħha;
- (f) persuna li tirrapreżenta s-Saħha Pubblika;
- (g) persuna li tirrapreżenta lil dawk li jipprovdu servizzi tas-saħha privati;
- (h) persuna nominata mill-assoċjazzjonijiet li jirrapreżentaw il-pazjenti;

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(i) kull uffiċjal ieħor li l-Ministru jidhirlu, minn żmien għal żmien, xieraq li jappunta fuq dan il-Bord; u

(j) uffiċjal maħtur mill-Ministru biex jaġixxi ta' segretarju.

(2) Il-membri msemmin fil-paragrafu (1)(e), (f), (g), (h), (i) u (j) ikunu nominati mill-Ministru għal dak iż-żmien li l-Ministru, minn żmien għal żmien, jiddeċidi.

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## SKEDA Ċ

[Artikolu 23(3)]

(1) Il-Kumitat Konsultattiv dwar il-Benefiċċji tas-Saħħa għandu jkun kompost kif ġej:

(a) is-Segretarju Permanent fil-Ministeru, bħala President;

(b) id-Direttur Ġenerali għas-Servizzi tas-Saħħa bħala Viċi-President;

(ċ) il-*Clinical Chairperson* fid-Dipartiment tal-Mediċina fil-Ministeru;

(d) il-*Clinical Chairperson* fid-Dipartiment tal-Kirurgija fil-Ministeru;

(e) spiżjar;

(f) persuna li għandha l-*warrant* biex tipprattika ta' avukat f'Malta bħala rappreżentant tal-Ministeru;

(g) rappreżentant tal-Ministru responsabbli għall-Finanzi;

(h) rappreżentant tad-Dipartiment responsabbli mill-Protezzjoni tal-Konsumatur;

(i) kull uffiċjal ieħor li l-Ministru jidhirlu, minn żmien għal żmien, xieraq li jappunta fuq dan il-Bord; u

(j) uffiċjal maħtur mill-Ministru biex jaġixxi ta' segretarju.

(2) Il-membri msemmin fil-paragrafu (1)(e), (f), (g), (h), (i) u (j) ikunu nominati mill-Ministru għal dak iż-żmien li l-Ministru, minn żmien għal żmien, jiddeċidi.

### **Ghanijiet u Raġunijiet**

L-Ghanijiet u r-Raġunijiet ta' dan l-Abbozz ta' Liġi huma sabiex jipprovdi, minflok l-Ordinanza dwar l-Organizzazzjoni tad-Dipartiment tas-Saħħa, liġiu aġġornata dwar it-tmexxija u l-amministrazzjoni tad-dipartiment involut fl-għoti ta' servizzi relatati mas-saħħa pubblika, f'konformità mal-esiġenzi tal-htigijiet ta' illum.

L-Abbozz ta' Liġi jimmira wkoll biex jirregola min hu intitolat għal, u l-kwalità ta', servizzi tas-saħħa f'Malta, u sabiex jipprovdi għad-drittijiet tal-pazjenti.

**A BILL**  
**entitled**

*AN ACT to regulate the entitlement to, and the quality of, healthcare services in Malta, to consolidate and reform the Government structures and entities responsible for Health and to provide for the rights of patients.*

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same, as follows:-

ARRANGEMENT OF ACT

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## PART I

## General Provisions

1. The short title of this Act is the Health Act, 2013. Short title and commencement.
- (2) The provisions of this Act shall come into force on such date as the Minister may establish by notice in the Gazette, and different dates may be established for different provisions of this Act.
2. In this Act, unless the context otherwise requires - Interpretation.
- "Advisory Committee" means the Advisory Committee on Healthcare Benefits established by article 23;
- "Council" means the Council of Health established under article 17;
- "insured person" means a person included in the list established by article 25;
- "Member State" means a State party to the Treaty as defined by the European Union Act; Cap. 460
- "Minister" means the Minister responsible for Health, and "Ministry" shall be construed accordingly;
- "patient" means a person who is receiving, or has received, medical attention, care, or treatment, whether in a healthcare setting or otherwise.
3. This Act intends to establish and ensure a health system based on the principles of accessibility, quality and sustainability by regulating the entitlement to, and the quality of, healthcare services in Malta, consolidating and reforming the Government structures and entities responsible for health and by providing for the rights of patients. Scope.

## PART II

## Directorate for Policy in Health

4. (1) There shall be established a Directorate for Policy in Health whose mission shall be, in general, to act as the chief adviser to the Minister on all matters related to the Government's health policies and particularly to advise the Minister on the development of policy and co-ordination of strategic plans, on the design and implementation of action plans, and on the evaluation of outcomes in order to contribute to the sustainability of public health and health Directorate for Policy in Health.

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care services.

(2) The Head of this Directorate shall be a Director General who shall also be, *ex officio*, the Chief Medical Officer to Government.

Functions and duties of the Directorate.

5. The Directorate for Policy in Health shall in general exercise those functions and fulfil all the duties and responsibilities emanating from law, and in particular, those functions and duties which the Minister may, from time to time, establish by regulations.

### PART III

#### Directorate for Healthcare Services

Directorate for Health Services.

6. (1) There shall be established a Directorate for Healthcare Services whose mission shall be to ensure the effective and efficient operation and delivery of healthcare services with an emphasis on clinical and corporate governance, service delivery and quality review within an established framework of controlled decentralization and autonomy involving user participation.

(2) The Head of this Directorate shall be a Director General.

Functions of the Directorate.

7. The Directorate for Healthcare Services shall in general exercise those functions and fulfil all the duties and responsibilities emanating from law, and in particular, those functions and duties which the Minister may, from time to time, establish by regulations.

### PART IV

#### Directorate for Health Regulation

Directorate for Health Regulation.

8. (1) There shall be established a Directorate for Health Regulation whose mission shall be to safeguard public health, licence, monitor and inspect the provision of healthcare services in order to ensure their quality and safety, and to recommend the standards to be met by healthcare providers and advice the Minister on matters relating to public health.

(2) The Head of this Directorate shall be a Director General, who shall also be, *ex officio*, the Superintendant of Public Health.

Functions of the Directorate.

9. The Directorate for Health Regulation shall in general exercise those functions and fulfil all the duties and responsibilities emanating from law, and in particular, those functions and duties which the Minister may, from time to time, establish by regulations.

## PART V

## Provisions Common for all Directorates

**10.** The Directors General shall be appointed by the Prime Minister after a call for applications for a period of three years which may be renewed for a further period or periods, as the case may be, under such terms, conditions, functions and responsibilities as may be stated in the respective letter of appointment.

Appointment of Directors General.

**11.** The legal and juridical representation of the Directorates shall be vested in the respective Director General, or in any other person appointed and acting on his behalf.

Juridical representation.

**12.** Without prejudice to the provisions of this Act, the executive management, the administration and the administrative control of the officers and employees of the Directorates shall be the responsibility of the Directors General.

Directors General to be responsible for officers, etc.

**13.** Without prejudice to the provisions of this Act, any function of a Directorate may be exercised through an authorised person or contractor after an agreement to that effect has been reached:

Exercise of functions through third parties.

Provided that no such agreement with third parties shall be entered into unless:

(a) the exercise of that particular function or functions through an authorised person or contractor is for the benefit of the Directorate; and

(b) the estimated amount for the exercise of that particular function or functions does not exceed that sum established, from time to time, by the Minister or the Permanent Secretary, and the special reason for such an agreement has been approved by the Minister after consultation with the Minister responsible for finance; and

(c) a call for tenders has been issued for such purpose.

**14.** (1) Every Directorate may request, collect and verify any information, data and statistics, as may be required for the performance of its functions.

Exchange of information between the Directorates.

(2) A Directorate shall have access to all information which another Directorate or other entity, established by or under this Act, may possess, and is entitled to request and obtain all data it may require from patients, relatives, personnel and professionals, and from public and private healthcare providers, and such data shall be given

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to it within a reasonable time from the date of request.

(3) Every Directorate shall have access to other statistics and data of an economic and social nature as required in order that it may perform its functions according to this Act.

Respect for the diversity of health institutions.

**15.** Without prejudice, and subject to, their functions, the Directorates shall respect the diversity of healthcare entities, services and programmes, and dialogue and collaborate with other entities, institutions and agencies, both public and private, local and foreign, about policies, initiatives and projects in order to ensure that the whole system operates effectively within the country.

Health Policy and Strategy Board.

**16.** (1) There shall be established a Board to be known as the Health Policy and Strategy Board, presided by the Minister, to discuss and evaluate the policy, strategy developments and direction in the health sector and to monitor and follow the implementation of the health policy and strategy adopted by the Government.

(2) The Board shall be composed as provided for in Schedule A, and the Minister may by regulations amend the said Schedule, and provide for any other matter or procedure he may deem necessary for the better implementation of the functions of the Board.

## PART VI

### Council of Health

Establishment and composition of Council of Health.

**17.** (1) There shall be established a Council of Health.

(2) The Council shall be composed as provided for in Schedule B, and the Minister may by regulations amend the said Schedule, and provide for any other matter or procedure he may deem necessary for the better implementation of the functions of the Council.

Duties of the Council of Health.

**18.** (1) It shall be the duty of the Council to, whenever so requested, advise Government on any matter affecting all matters related to health in Malta.

(2) Without prejudice to the generality of the above, it shall be the duty of the Council, in particular, to advise on any matter with regards to which the law provides that the advice of the Council shall be sought.

Powers of the Council.

**19.** (1) The Council shall have the power to appoint sub-committees and to co-opt thereon members who are not members of the said Council when discussing specific items on its agenda.

(2) The Council shall also have the power to recommend any such measures, enquiries or scientific investigations as, in its opinion, are useful in the interests of the public health.

**20.** It shall not be lawful for the Council to transact any business unless there are at least five of its members present:

Meetings of the Council and quorum.

Provided that, if the Council is convened to consider any matter upon which its advice is urgently required by the Government, the Council may decide by a majority of the members present.

**21.** Without prejudice to the powers of the Minister under article 31 to make regulations to give effect to any of the provisions of this Act, the Minister may make, vary or revoke regulations for the proper conduct of the business of the Council.

Power of the Minister to make regulations.

## PART VII

### Healthcare Benefits and Entitlement

**22.** The Minister shall establish the healthcare benefits that are to be provided directly or indirectly by the public healthcare system, after considering the advice of the Advisory Committee on Healthcare Benefits established in article 23.

Healthcare benefits.

**23.** (1) There shall be established an Advisory Committee on Healthcare Benefits.

Advisory Committee on Healthcare Benefits.

(2) The Advisory Committee on Healthcare Benefits may set up sub-committees to deal with different and specific categories of benefits as it may deem necessary. Without prejudice to the generality of the foregoing, the Government Formulary List Advisory Committee established by the Availability of Medicinal Products within the Government Health Services Regulations shall be deemed to be one of the aforementioned sub-committees.

S.L. 458.31

(3) The Advisory Committee shall be composed as provided for in Schedule C, and the Minister may by regulations amend the said Schedule, and provide for any other matter or procedure he may deem necessary for the better implementation of the functions of the Advisory Committee.

(4) The Advisory Committee shall meet as often as necessary and shall regulate its own procedures:

Provided that in the case of urgent vitally necessary treatment, the Chief Medical Officer may authorise the provision of such healthcare benefits and duly report to the Minister and the

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Advisory Committee at the first available opportunity.

Powers of the  
Committee.

**24.** (1) It shall be the duty of the Committee to recommend the healthcare benefits to be provided directly or indirectly by the public healthcare system and to maintain a publicly accessible list of such benefits regularly updated.

(2) In formulating its advice, the Committee shall be guided by the following:

- (a) international evidence;
- (b) health technology assessments;
- (c) consultation with relevant stakeholders;
- (d) capacity within the public health system;
- (e) social and epidemiological considerations;
- (f) affordability and sustainability.

Entitlement to  
free healthcare  
benefits.

**25.** (1) Without prejudice to any other provision of any other law, only an insured person may qualify for free healthcare benefits provided by, or on behalf of, the public healthcare system.

(2) For the purpose of this Act, an insured person means:

(a) a national of a Member State or of the European Economic Area, or a Swiss citizen, or a long term resident in terms of the Status of Long-Term Residents (Third Country Nationals) Regulations, whose primary residence is in Malta and who is:

S.L. 217.05

Cap. 318

(i) actively covered by social insurance in terms of the Social Security Act; or

Cap. 318

(ii) deemed to be covered for healthcare in terms of the Social Security Act irrespective of their social security contribution status, but excluding persons who would otherwise only be deemed to be so insured by virtue of the European Convention on Social and Medical Assistance and Protocol thereto; or

(iii) in possession of a health insurance cover by the competent authority of another Member State in terms of the Community Regulations on the application of social security schemes in force; or

(b) a citizen of a country which has a reciprocal healthcare agreement in force with Malta, in respect of such care and treatment to which such citizen would be entitled under the terms of such agreement or any understanding or agreed minutes subsequent thereto; or

(c) a person covered by the Refugees Act or any regulations made thereunder, but only in respect of such care and treatment to which such persons would be entitled under the terms of regulations, administrative policies or agreements subsequent thereto; or Cap. 420

(d) dependants of persons mentioned in paragraphs (a) to (c).

(2) The Minister may, from time to time, determine through regulations made under this Act that certain healthcare benefits may be restricted to certain categories of insured persons.

**26.** (1) There shall be established a Register, to be kept by the Permanent Secretary of the Ministry for Health, which shall include all the benefits, services, interventions and treatments provided by the public healthcare system, and the cost and, or fees corresponding to each such benefit, service, intervention and treatment. This register shall be updated on an annual basis, or before, as the Minister may from time to time determine. Public healthcare fees.

(2) The fees and, or costs, referred to in sub-article (1) shall be made publicly available.

(3) Without prejudice to any other law or regulations, the established fees and, or costs, shall be construed as the maximum reimbursement possible should a person opt for any form of cross-border healthcare under any form of agreement which Malta may be a party to, irrespective of the actual fees and, or cost incurred in pursuance of such cross-border healthcare.

(4) Any person, not being an insured person as defined under this Act, shall be subjected to pay the full fees and, or costs for benefits, services, interventions or treatments as they result from the register established in sub-article (1).

(5) Without prejudice to sub-article (4) or to any other law or regulation, the Minister may approve for the partial, or full, waiver of fees and, or costs due by any person, not being an insured person, in exceptional circumstances and, or on humanitarian grounds.

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Healthcare fees  
levied by  
private  
healthcare.

**27.** Without prejudice to any other law or regulations relating to consumer protection in force at any time, all healthcare providers, both public providers where the patient or customer is not an insured person, and private providers in all instances, shall be obliged to apply the same scale of fees for the services offered to patients in comparable medical situations, irrelevant of the country of which they are nationals.

## PART VIII

## Patients' Rights and Safety

Patients rights.

**28.** It shall be the right of every patient:

(a) to receive healthcare in accordance with the provisions of this Act;

(b) to receive information concerning the state of his health and the health services and treatments available;

(c) to be provided in advance with clear information on the treatment options available and to be involved in discussions and decisions about the treatment to be given;

Cap. 440.

(d) to access his medical records in accordance with the Data Protection Act, provided this is not to the detriment of his overall wellbeing;

Cap. 440.

(e) to have his medical data processed in conformity with the Data Protection Act;

(f) to refuse treatment that is offered to him, provided such refusal is endorsed by his signature;

(g) to be seen and treated without excessive or undue delay;

(h) to file a complaint about services received and be informed of the outcome of the investigation of his complaint in a timely manner;

Cap. 490.

(i) to appeal in respect of any decision taken under this Act to the Administrative Review Tribunal in accordance with the provisions of the Administrative Justice Act and any applicable regulations made thereunder.

Patients'  
responsibilities.

**29.** Without prejudice to anything provided in this Act and, or any other law, whilst health care providers are expected to provide services based on the respect for human dignity, users are expected to



make use of the services available in a responsible manner and to show respect to professionals, employees and also for the property.

**30.** (1) The Minister shall, within two years of the coming into force of this Part, publish a document to be known as the Charter of Patient Rights and Responsibilities.

Charter of  
Patients' Rights  
and  
Responsibilities.

(2) The Charter shall set out a summary of the rights and responsibilities of patients and other relevant persons as existing at the time of publication.

(3) The Charter shall be updated on a regular basis to reflect contemporary trends and issues.

## PART IX

### Miscellaneous

**31.** The Minister may, subject to the provisions of this Act, make regulations to give effect to any provisions of this Act or to regulate or otherwise provide about anything in respect of the functions and the activities which affect the provision of healthcare, and may in particular, but without prejudice to the generality of the aforesaid, make regulations for any of the following purposes:

Powers of the  
Minister.

(a) to regulate any matter connected with, or incidental to, the implementation of the functions, operation and administration of all healthcare entities;

(b) to prescribe such data, reports and statements of accounts which have to be sent to the Minister and to the Directors General by the Principals and, or the Chief Executive Officers, and such other officers and persons relating to healthcare as the Minister may deem necessary to request, and in such manner, form, time and on such subjects as he may specify in the regulations;

(c) to establish any fee and, or payment which may be due by, or under this Act, or for any service given in compliance with the provisions of this Act;

(d) to provide about any form or procedure which may be required or expedient, and about which there would be no specific procedure in this Act;

(e) to establish rules by means of which the Government may ratify and give effect to international conventions relating to health and which have already been

ratified by the Government of Malta; or in order to achieve compliance with any international obligation pertaining to the Government of Malta or with European Union Directives on any matter or area concerning health;

(f) to establish the functions and duties of the directorates and departments established by, or through this Act;

(g) in order to ensure the provision of health services in a full and continuous process throughout life, to establish those healthcare entities in such manner as it may from time to time appear to be necessary in the Maltese Islands and, unless otherwise provided in this Act or in any other law, to establish also statutes and rules to regulate the mission, scope, functions, powers and duties, financial accountability or otherwise, and any other procedure which has to be followed, performed or observed by any entity so established by or under this Act;

(h) to establish, unless otherwise provided in this Act or in any other law, statutes and rules to regulate the mission, scope, functions, powers and duties, financial accountability or otherwise, and any other procedure which has to be followed, performed or observed by any Council, Committee or Board established by or under this Act;

(i) to afford, subject also to the provisions of any other law, to a person aggrieved by the decision of any entity, body or organisation established by or under this Act, means and procedures either to lodge his complaints and aggravation about a decision or to contest or appeal from such a decision to the Administrative Review Tribunal in accordance with the provisions of the Administrative Justice Act and any applicable regulations made thereunder, and to be satisfied if that aggravation is upheld;

(j) to establish anything which is due to be, or may be established under this Act, and to provide on any other matter as may be deemed to be appropriate;

(k) to establish the fines for any contravention or breach of any provision of any regulation made under this Act, or for non-compliance with any provision or any requirement imposed under such provision:

Provided that any regulations made under this paragraph may provide differently for different aims or circumstances, for different classes or types of entities, and for

different classes of patients;

(l) to establish the framework of the national health policy for public and private healthcare providers, and it shall be the duty of all such providers to implement this policy according to the potential and the various needs of patients attending thereat;

(m) to establish, in the paramount interest of health in Malta, any possible exceptions to any provision contained in any law.

**32.** (1) With effect from the coming into force of this Act, the provisions of the Department of Health (Constitution) Ordinance shall be repealed. For the avoidance of doubt, parts of that Ordinance may be repealed at different dates on the coming into force of a corresponding Part or Article of this Act.

Repeal and  
saving.  
Cap. 94.

(2) Any regulations or orders made under the provisions of the said Ordinance and still in force on the commencement of this Act, or the relevant Part or article, shall, until provision is made by or in virtue of this act, continue to remain in force and have effect as if made under this Act.

(3) Any licence, permission or other authorisation granted under any provision of the aforesaid Ordinance shall continue to have effect as if it were a licence, permission or other authorisation granted under the authority of this Act.

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## SCHEDULE A

[Article 16(2)]

The Health Policy and Strategy Board shall be composed as follows:

- (a) the Minister, as Chairman;
- (b) the Permanent Secretary in the Ministry, as Deputy Chairman;
- (c) the three Directors General established under this Act, *ex officio*;
- (d) the financial controller of the Ministry, and in his absence, the highest ranking officer responsible for the financial administration of the Ministry;
- (e) a Minister's consultant;
- (f) any other officer who the Minister may deem, from time to time, fit to appoint on this Board; and
- (g) an officer appointed by the Minister to act as secretary.

## SCHEDULE B

[Article 17(2)]

- (1) The Council of Health shall be composed as follows:
- (a) the Minister, as Chairman;
  - (b) the Permanent Secretary in the Ministry, as Deputy Chairman;
  - (c) the Attorney General or his representative;
  - (d) the Chief Medical Officer to Government;
  - (e) a person representing the healthcare professionals;
  - (f) a person representing public health;
  - (g) a person representing private healthcare providers;
  - (h) a person nominated by associations representing the patients;
  - (i) any other officer who the Minister may deem, from time to time,

fit to appoint on this Board; and

(j) an officer appointed by the Minister to act as secretary.

(2) The members referred to in paragraph (1)(e), (f), (g), (h), (i) and (j) shall be appointed by the Minister for such term as the Minister shall, from time to time, decide.

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## SCHEDULE C

### [Article 23(3)]

(1) The Advisory Committee on Healthcare Benefits shall be composed as follows:

(a) the Permanent Secretary in the Ministry, as Chairman;

(b) the Director General Healthcare Services, as Deputy Chairman;

(c) the Clinical Chairperson of the Department of Medicine in the Ministry;

(d) the Clinical Chairperson of the Department of Surgery in the Ministry;

(e) a pharmacist;

(f) a person who has the warrant to practice as advocate in Malta representing the Ministry;

(g) a representative of the Minister responsible for Finance;

(h) a representative of the Consumer Protection Department;

(i) any other officer who the Minister may deem, from time to time, fit to appoint on this Board; and

(j) an officer appointed by the Minister to act as secretary.

(2) The members referred to in paragraph (1)(e), (f), (g), (h), (i) and (j) shall be appointed by the Minister for such term as the Minister shall, from time to time, decide.

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### Objects and Reasons

The Objects and Reasons of this Bill are to provide, in lieu of the Department of Health (Constitution) Ordinance, for an updated law on the running and administration of the department involved in the provision of services connected with public health, in line with the exigencies of today's requirements.

The Bill also aims to regulate the entitlement to, and the quality of, healthcare services in Malta, and to provide for the rights of patients.

